

PLOVDIV UNIVERSITY „PAISII HILENDARSKI“

DEPARTMENT OF PUBLIC LAW

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ABSTRACT

for the award of the educational and scientific degree "Doctor"

Field of Higher Education 3. Social, Economic and Legal Studies

Professional Field: 3.6 Law

SUPERVISOR:

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PLOVDIV 2021

The dissertation was discussed and directed for public defense by the Department of Public Law at the Faculty of Law of the University of Plovdiv "Paisii Hilendarski" - Plovdiv on 19.02.2021.

The doctoral student is enrolled in part-time study at the Department of Public Law at the Faculty of Law of the University of Plovdiv "Paisii Hilendarski" - Plovdiv on February 6, 2019.

The research on the dissertation work was carried out in the Faculty of Law of the University of Plovdiv "Paisii Hilendarski" - Plovdiv.

The defence of the dissertation will take place on 22.06.2021 before a scientific jury appointed by order of the Rector of Plovdiv University "Paisii Hilendarski" - Plovdiv.

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Introduction

This dissertation examines for the first time the public law aspects of patient safety in Bulgaria. The study is new and covers the health care system in our country, aiming to draw conclusions about the state and the norms governing our health care, compared to similar norms in EU countries and non-EU countries, including the United States.

In the field of healthcare, patient safety is a global priority today. The topic has been of interest during the various stages of development of medicine. Many studies have been done and various results have been provided on the topic, involving academics, politicians, health professionals, various organizations and others. Millennia ago, Hippocrates was aware of the potential for injury resulting from the benevolent actions of healers, and since then "*primum non nocere*" has become a central tenet of modern medicine.

The present dissertation is structured in three chapters. The first chapter provides a detailed historical overview of patient safety and traces the development through the various historical transitions to the present day. The analysis of different countries aims to compare foreign experience with that of Bulgaria in order to offer a safe health environment for all patients. The topic of major global initiatives to improve patient safety is addressed and some international sources for the protection of patients' rights are discussed. The second chapter pays attention to patient safety in Bulgaria, the adopted programs for improving the health of the nation, the health control bodies and the legal ways to protect the rights of the patient. Chapter three addresses a very important and delicate issue of quality and culture in healthcare, because we believe they are an integral part of patient safety. The issue of errors and adverse medical events and the responsibility of the doctor under Bulgarian law is considered.

Chapter One

Patient safety in the world - the definite and historical overview

§ 1. Historical overview of patient safety

As far as it is known, the first legal regulation of medical error and the issue of patient safety in writing was made by Hammurabi - King of Mesopotamia. The king, who attached great importance to legislative activity, embarked on it at the very beginning of his reign, and in 1750 BC the Laws of Hammurabi were created. The laws are conditionally divided by researchers into 282 original articles. In its part about medical error, some rules look like this - in surgery, if the patient dies and the reason is the doctor and if the patient is blinded by medical fault, the punishment is to cut off the doctor's fingers¹.

Patient safety and "Do no harm" have always been of interest throughout history. And although this expression is most often associated with Hippocrates, English and American literature in 1847, and in particular Wortington Hooker presents that a similar expression was made by Galen - "In the first place does not hurt" (ancient Roman physician, surgeon, and philosopher, in ancient Greek known as Galenos)². The historical development of patient safety cannot fail to mention Hungary-born Dr. Ignas Semelweiss (History of hand washing), who discovered that microorganisms can be transmitted from patient to patient and healthcare professionals must take measures to limit them.

For patient safety Joint Commission International - JCI was founded in 1951, which works to ensure quality and safety in health services, but this has taken its place in the health system since 1960s). Ernest Codman focused on the subject in 1955, laying the first foundation for patient safety, and through its reports Institute of Medicine in America (IOM) conducted research and studies on patient safety and they have made a very significant contribution to the development of patient safety. around the world.

Patient safety has continued to evolve over the years, with the United States having the largest literature share in the 1900s and 2000s. The years (1854-2003) testify to the growing importance of patient safety in the world.

¹ <https://istorianasveta.eu/>

² Ilan R. and Fowler R.(2005) Evolution of Health Services Research for Critical Care Brief History of Patient Safety Culture and Science.Journal of Critical Care 20:2-5, available at <https://www.scribd.com/document/467169230/Brief-history-of-patient-safety-culture-and-science>

There are many definitions of patient safety globally. Although they are different, they are united by the idea of safe medical care and safety for patients when they are treated. There is still no single definition that is perceived as the only one.

We offer a definition of patient safety:

"Patient safety is a system of rules and actions that must be followed by all employees in the health system in the provision of health care throughout the treatment and diagnostic process, guaranteeing the right to an informed choice and not allowing harm to the patient."

Summary of the survey of twelve countries: Austria, England, Belgium, the Netherlands, Turkey, Italy, Sweden, Switzerland, Denmark, Germany, USA. If we have to summarize briefly the measures taken by the countries we studied, the following conclusion can be drawn about the actions they have taken to improve patient safety:

in all countries analyzed, the focus on patient safety has not shifted over the years;

- established laws related to patient safety;
- regulations;
- strategies;
- systems for reporting adverse medical events;
- emphasis on research and reports;
- electronic reporting platforms;
- hospital ombudsmen;
- mandatory and voluntary reporting;
- patient safety person;
- established agencies that collect and process data from reported adverse medical events;
- guaranteed anonymity in reporting;
- reporting is encouraged (by doctors, patients, relatives, non-medical staff, etc.);

- free reporting, etc.

Participants in the patient safety process

It is a mistake to think that only patients are involved in patient safety. This process is not one-sided, but a set and interaction between doctors, patients, medical institutions and not to exclude non-medical staff. Although the role is different for each of them, they are together in the process of reducing adverse medical events. However, the European Commission's technical report identifies other key players, both nationally and internationally, in activities related to improving and ensuring patient safety³.

§ 2. Main initiatives in the international plan for improvement of patient safety - the World Health Organization and patient safety

- The World Health Organization, abbreviated WHO, is one of the largest medical institutions, ranking next to the Red Cross and the World Medical Association. It was created to limit all diseases that can cause an epidemic, as well as to improve overall health.⁴

- The creation of the Global Alliance for Patient Safety is a significant step in the fight to improve health safety in all Member States. The Alliance's main objective is to facilitate the development of patient safety policy and practice in the Member States. This can be achieved through a number of key functions and other short-term initiatives identified by the Alliance in an annual work program⁵.

- AHRQ (US Agency for Quality Research) has established centers of excellence for patient safety research and also participates in research capacity building by forming networks of clinicians and researchers to develop research strategies and specific research proposals.⁶

- Resolutions and patient safety declarations of the World Health Assembly, the WHO Executive Board and the WHO Regional Committees.⁷

³ See more Radeva, N. Study of factors influencing patient safety in intensive care of acute pancreatitis, dissertation for awarding the educational and scientific degree "Doctor"

⁴ <https://www.who.int/patientsafety/about/en/>

⁵ <https://www.who.int/patientsafety/worldalliance/alliance/en/>

⁶ <https://www.who.int/patientsafety/worldalliance/alliance/en/index3.html>

⁷ <https://www.who.int/patientsafety/policies/resolutions/en/>

- SIMPATIE is a project to improve patient safety in Europe, which has developed an overview of patient safety actions and tools.⁸
- International Alliance of Patients 'Organizations (IAPO).⁹
- Joint Commission International (JCI) is one of the world's leading non-profit organizations for patient safety.¹⁰
- The European Patient Safety Network (EUNetPaS) project was funded and supported by the European Commission under the Public Health Program in 2007.¹¹
- Global summits on patient safety

§ 3. International sources for protection of patients' rights

Having made a historical overview and analysis of the participants and the steps for patient safety worldwide, we will focus on one of the important international sources for the protection of patients' rights. Bulgaria has ratified the following international and regional European acts in the field of health insurance and patients' rights: the Universal Declaration of Human Rights, a UN document; The International Covenant on Economic, Social and Cultural Rights - ratified on September 21, 1970, in force since January 3, 1976; International Covenant on Civil and Political Rights; European Social Charter - in force for Bulgaria from 01.08.2000.

The declarations and Recommendations of the World Medical Association (WMA) and the World Health Organization (WHO) regulating patients' rights are: European Convention for the Protection of Human Rights and Fundamental Freedoms 1950, International Covenant on Civil and Political Rights 1966, European Hospital Patient Rights Charter 1979.

Other international instruments governing medical law are - Declaration on Human Organ Transplantation (WMA 1987), Declaration on Euthanasia (WMA 1987), Recommendation on the Legal Protection of Persons Suffering from Mental Disorders in Treatment by coercion (CoE Committee of Ministers 1983),

⁸ <https://docplayer.net/6389198-A-patient-safety-vocabulary.html>

⁹ <https://www.iapo.org.uk/strategy>

¹⁰ <https://www.worldhospitalsearch.org/the-value-of-jci-accreditation/who-is-joint-commission-international/>

¹¹ <https://www.eunetpas.eu/>

Declaration on the Human Rights and Personal Freedom of Physicians (WMA 1985), Opinion on Trade in Viable Organs (WMA 1985), Oslo Declaration - Opinion on Therapeutic Abortion (SMA 1983), Opinion on in vitro fertilization and embryo transplantation (WMA 1987).

We will also focus on modern codes of ethics. In 1948, the World Medical Association adopted the Geneva Declaration, which proclaimed the dedication of the physician to the humanitarian goals of medicine. A year later, the WHO adopted the "International Code of Medical Ethics", which affirms the general and specific obligations of physicians to patients and colleagues.¹²

¹² Adopted at the 2nd General Assembly of the SMA in Geneva, September 1948.

CHAPTER TWO

Analysis of the health system and patient safety in Bulgaria

§ 1. The health system in Bulgaria and current programs for improving the health of the nation

The health system in Bulgaria is traditionally highly centralized. The main responsible participants at the national level are the National Assembly, the Council of Ministers (CoM) and the Ministry of Health (MoH), the National Health Insurance Fund (NHIF) and the professional organisations of doctors and dentists. The Ministry of Health is responsible for the overall organization and functioning of the health care system (for health legislation, coordination and management of many subordinate institutions, for the planning and regulation of health care providers and for the financing of specific types of health services).¹³

The health insurance system with compulsory and voluntary health insurance was established through the Health Insurance Act of 1998. Social (compulsory) health insurance (HIA) is provided by the only National Health Insurance Fund (NHIF).

Programs to improve the health of the nation

For each country, the positive development of the health system is of particular importance for its overall vision, and this process affects the entire nation. Achieving patient safety in treatment is the complex interaction between doctors, patients, modern technologies that strive for better results from ongoing treatments to provide a safer health environment. It is the state that can regulate and create measures to achieve better health care and satisfaction. European countries are a sufficient example from which lessons can be learned and a truly European and quality healthcare can be offered so to meet the needs of Bulgarian patients. That is why we will list the most important steps that have been taken in Bulgaria in recent years for the overall improvement of citizens' health, the established programs and strategies, review of legislation and regulatory authorities. Some of the most important actions are:

- The National Plan of the Republic of Bulgaria for Readiness in Case of Influenza Epidemics includes all necessary actions and responsibilities of the various institutions in each of the phases of a possible pandemic¹⁴

¹³ https://www.researchgate.net/publication/334203713_Blgaria_Analiz_na_zdravnata_sistema_2018

¹⁴ <http://www.strategy.bg/StrategicDocuments/View.aspx?lang=bg-BG&Id=366>

- The Health Objectives Concept 2020¹⁵ encourages each country in the European Region to participate in the implementation of the European goals and to set its own national goals and objectives related to the health of its citizens. In 2012, all 53 Member States of the WHO European Region adopted a new Common Policy Framework - Health 2020
- Published draft of the National Health Strategy 2021-2030¹⁶ - Six priorities for the development of the health sector have been formulated: focus on strengthening the public health system, improving the quality, efficiency and control of medical activities; development of an effective drug policy; development of e-health; the future of human resources; ensuring the financial sustainability of the health system
- Policy priorities of the Ministry of Health¹⁷ (MoH) for the period 2014-2022. All programs to improve the health of the nation are published on the official website of the MoH
- The National Health Card¹⁸ determines and plans on a territorial basis the needs of the population for affordable outpatient and inpatient medical care and implements the national health policy
- National Program Bulgaria 2030¹⁹ - The National Development Program BULGARIA 2030 is a framework strategic document of the highest order in the hierarchy of national program documents, determining the vision and general objectives of development policies in all sectors of government, including their territorial dimensions

We propose to take the following measures to improve the health policy, which will guarantee at the same time to all citizens / patients quality and safe treatment:

¹⁵ <https://www.mh.government.bg/bg/politiki/strategii-i-kontseptsii/koncepcii/koncepciya-celi-za-zdrave-2020/>

¹⁶ <http://www.strategy.bg/PublicConsultations/View.aspx?lang=bg-BG&Id=5755>

¹⁷ <https://www.mh.government.bg/bg/politiki/programi/aktualni-programi/>

¹⁸ DECISION № 361 OF MAY 29, 2018 of the Council of Ministers for approval of the National Health Card of the Republic of Bulgaria, pursuant to Art. 34, para. 1 of the Medical Establishments Act

¹⁹ The National Development Program BULGARIA 2030 was adopted by Protocol № 67 of the Council of Ministers of 02.12.2020.

1. An annual review and analysis of data is needed to determine whether the quality of the services offered meets the expectations of patients;
2. To make an annual comparison between small and large settlements;
3. To monitor the number of doctors - how many are needed, where there is a shortage and offer a discussion to solve the problem;
4. To monitor the even distribution of doctors in specialties and where there is a shortage to take the necessary measures;
5. The specialties in medicine that are granted also turn out to be a problem.

Despite the results achieved, a lot of hard work, perseverance and patience is needed regarding the patient safety. Bulgaria has missed a lot of its development compared to other countries. There are no initiatives, no awareness, no clear goals for work in this direction. As part of the EU, Bulgaria should take into account the EU Recommendation, the European Charter of Patients' Rights, learn from foreign experience and create a basis for the development of patient safety in Bulgaria.

Normative regulation of the patient's rights in Bulgaria

The rights of patients and the commitment of the state to provide quality, affordable and timely medical care are contained in various regulations. Written legal instruments include the Constitution of the Republic of Bulgaria, international treaties, laws and by-laws (decrees, ordinances, regulations, instructions and orders).

The Constitution of the Republic of Bulgaria

The Constitution of the Republic of Bulgaria is an act with the highest legal force. It regulates the organization, principles, powers and obligations of state institutions, as well as the rights and obligations of citizens. According to Article 5, paragraph 4 of the Constitution, international treaties ratified by constitutional order, promulgated and entered into force for the Republic of Bulgaria are part of the domestic law of the country. They have an advantage over those norms of domestic law that contradict them.

Laws are the next most normative acts. The executive branch adopts by-laws such as decrees, ordinances, decisions, regulations, instructions and orders.

- Health Act - The Health Act regulates public relations related to the protection of the health of citizens.

- Medical Establishments Act - The Medical Establishments Act, in addition to determining the types of medical establishments in the country and their commercial status, also monitors the activities of medical establishments and the medical and other specialists working in them, as well as whether carries out in compliance with the medical standards for the quality of the provided medical care and ensuring protection of the rights of the patient.

- Law on Medicinal Products in Human Medicine - this law regulates the conditions for the production, import, wholesale and retail of medicinal products, authorization and conduct of clinical trials, monitoring the safety of medicinal products placed on the market, etc. LLPHM guarantees safety in terms of taking and testing drugs.

- Health Insurance Act – This law regulates health insurance in the Republic of Bulgaria and related public relations.

- Transplantation of Organs, Tissues and Cells Act - The purpose of the law is to establish rules for ensuring standards of quality and safety of organs, tissues and cells intended for transplantation in human medicine and to ensure a high level of protection of human health.

- Professional Organizations of Doctors and Dentists Act - According to Art. 1. (1) of the Law on Dental Medicine, this law regulates the structure, organization and activity of the professional organizations of doctors and dentists, the conditions for exercising the medical and dental profession and the responsibility for violation of professional ethics. And point 2 continues that the professional organization of doctors within the meaning of this law is the Bulgarian Medical Union, and of dentists - the Bulgarian Dental Association.

- Professional Organizations of Nurses, Midwives and Associated Medical Specialists Act - this law regulates the structure, organization and activities of professional organizations of nurses, midwives and associated medical professionals, dental technicians and assistant pharmacists, the conditions for exercising their professions and their professional development, as well as for the maintenance of their professional register.

- Professional Organizations of Master Pharmacists Act - this law regulates the structure, organization and activity of the professional organization of master

pharmacists, the conditions for exercising the profession "master pharmacist" and the responsibility for violating the Code of Professional Ethics of master pharmacists and of the rules for good pharmaceutical practice, as reads Art. 1a and Art. 2 continues that the professional organization of master pharmacists within the meaning of this law is the Bulgarian Pharmaceutical Union.

- Control over Narcotic Substances Act - According to Art. 1 This law regulates the organization, powers and tasks of the state bodies exercising control over the production, processing, trade, use, storage, import, export, transit, transportation, transportation and reporting of narcotic substances, as well as on the placing on the market, import and export of precursors.

- Blood, Blood Donation and Blood Transfusion Act - As seen from Art. 1, para 1 of the law, the basic regulation consists in regulation of the public relations, related to the donation, taking, diagnostics, processing, transport, storage, use of blood and blood components and ensuring their quality and safety.

BY-LAWS

Orders

In the field of healthcare there are an extremely large number of bylaws. This is a logical situation due to the need to further develop in detail various problems related to the practice of the medical profession, which cannot be regulated by law²⁰.

For example, in our country there are a number of regulations issued to regulate the rights of patients in health care. Some of the issued regulations are:

- Ordinance №49 of 18.10.2010 on the basic requirements to be met by the structure, activity and internal order of the medical establishments for hospital care and the homes for medical and social care
- Ordinance on the exercise of the right of access to medical care (Effective 02.06.2006, last amended SG No. 29 of 7 April 2017)

Ordinance № 8 of 3 November 2016 on preventive examinations and medical examinations (Effective 01.01.2017, last amended, SG No. 2 of 4 January 2019)

²⁰ Zinovieva, D., Medical Law, Second Revised and Supplementary Edition, Ciela Publishing House, 2016, p. 34, ISBN 978-954-28-2063-5

- Ordinance № 38 of 16.11.2004 on determining the list of diseases for the home treatment of which the national health insurance fund pays for medicines, medical devices and dietary foods for special medical purposes in full or in part. (Effective 01.01.2005 and last amended SG No. 97 of 9 December 2011, supplemented SG No. 15 of 21 February 2012)

Ordinance №39 of 16.11.2004 on prophylactic examinations and medical examinations (last amended and supplemented, SG No. 2 of 8 January 2016).

- Ordinance № 2 of 25.03.2016 on determining the basic package of health activities guaranteed by the NHIF budget

- Ordinance for approval of medical standards

- Ordinance for approval of good medical practices

Medical standards and good medical practices, in addition to legal sources, are the two main measures in recent years, which determine the level and quality of health services offered. In Bulgaria, some of the patients' rights are regulated in several laws and the need to revise the existing ones is absolutely necessary. At the moment, three draft laws related to patients' rights have been drafted and proposed for voting in Bulgaria, they have been officially submitted to the National Assembly, but a single special law on patients' rights has not yet been adopted. All three remained only as an unrealized "Project".

National Framework Agreements for medical and dental activities

NATIONAL FRAMEWORK for medical activities and Article 31, of which guarantee quality and accessibility to medical care, as the parties to the contract perform systematic and planned assessment, monitoring and continuous improvement of the quality of medical services, which ensures equality of access, efficiency and the security of contracted medical services and increasing patient satisfaction.

Similarly, National framework agreement for dental activities, Chapter Three and Art. 4 and 5 of it guarantee the exercise of the rights of health insured persons in accordance with the current legislation in the Republic of Bulgaria, as well as equal rights and access when receiving dental care to health insured persons regardless of their race, nationality, ethnicity, gender, origin, religion,

education, beliefs, political affiliation, personal and social status or property status.²¹

Codes of ethics

There are conflicting opinions about the place, role and importance of codes of ethics in the legal system, but it is not disputed that they are one of the main means of exercising and self-regulation of medical activity.

According to Assoc. Prof. Dr. Petko Lisaev²², the code is a declaration, i.e. there is no force of law or regulation. In his article, Assoc. Prof. Dr. Konstantin Pehlivanov²³ points out that one of the applications of the so-called "soft law" is the adoption by a number of state institutions and professional organizations of the so-called "codes of ethics", "codes of ethics", "codes of conduct" and others. On the one hand, these are non-binding legal acts that do not have the force of legal requirements; on the other hand, however, some are published in the State Gazette, which implies the irrefutable presumption that they are publicly available and known. According to the opinion on the codes of ethics of Assoc. Prof. Dr. Simeon Groysman²⁴, the mixing of different prescriptions makes it difficult to define the codes of ethics as the sources of law. The general characteristics that the author, however, finds in the various codes of ethics are that: they all have a secondary nature.

§2. Health control a guarantee for patient safety

Council of Ministers - According to Art. 3 of the Health Act, the state health policy is managed and implemented by the Council of Ministers. It is the state body that implements the domestic and foreign policy of the country. Has the right of legislative initiative - art. 87, para 1 of the Constitution, and is a major submitter

²¹<https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fbz%2Ebg%3A443%2Fwp%2Dcontent%2Fuploads%2F2020%2F01%2FNRD%5FDD%5F2020%2D2022%2Edoc&wdAccPdf=0>
https://www.patient.bg/index_bg.php

²² See Lisaev, P., *Medical Deontology and Medical Law for Nurses, Midwives and Associates*, ed. Medicine and Physical Education, 2014, pp. 42-43, ISBN 978-954-420-305-4

²³ See Pehlivanov, K., *Codes of Ethics in Bulgarian Law*, p.17, the article is available at <http://web.uni-plovdiv.bg/paunov/Stidia%20Iuris/broi%202%20-%202015/Konstantin%20Pehlivanov.pdf>

²⁴ Groysman, S., *Codes of Ethics as Sources of Law: A General Theoretical View of Legal Regulation through Moral Concepts*, e-edition Challenge the Law, ISSN 1314-7854, accessed at <https://www.challengingthelaw.com/pilosofia/etichnite-kodeksi/#sdfootnote6anc>

of bills. At the proposal of the Minister of Health, the Council of Ministers approves a National Health Strategy, which is adopted by the National Assembly.

Ministry of Health implements the health policy on the territory of the country. By Decree №55 OF MARCH 28, 2019, the Rules of Procedure of the Ministry of Health are adopted, and these rules determine the organization, activity, functions, structure and number of staff of the Ministry of Health.

State Health Control - of the state health control are the Chief State Health Inspector of the Republic of Bulgaria, the regional health inspections and the National Center for Radiobiology and Radiation Protection. The state health control is performed by state health inspectors in the Ministry of Health, the regional health inspectorates and National Center for Radiobiology and Radiation Protection, as the state health inspectors in the Ministry of Health and the regional health inspectorates are civil servants.

Regional health inspections

The state health policy on the territory of the district is implemented and organized by a regional health inspection.

The activity is aimed at fulfilling the following strategic goals:

- Organization and effective implementation of the state health policy on the territory of the respective district.
- Making prevention a mandatory element at all levels.
- Strengthening and increasing the effectiveness of state health control.
- Improving the quality of medical care for the population.

Chief State Inspector

The Chief State Health Inspector is a body of the state health control on the territory of the country. The Chief State Health Inspector is appointed by the Prime Minister on the proposal of the Minister of Health and holds the position of employment.

National Health Insurance Fund and Regional health insurance funds

The main goal of the NHIF is to ensure and guarantee free and equal access of insured persons to medical care - through a certain type, scope and volume of

a package of health activities, as well as free choice of contractor who has a contract with the regional health insurance fund.

The RHIF develops an annual plan, as well as a monthly one for carrying out the inspections, in which the providers of medical care and/ or providers of dental care are indicated, which will be checked after comparison and analysis of the agreed, reported and / or paid activity on the basis of reports by types of activities. RHIF and NHIF.

Executive agencies

Medical Supervision Executive Agency²⁵

The Agency, which is the legal successor of the Medical Audit Executive Agency and the Transplant Executive Agency, carries out: a competent body for management, coordination and control of transplantation in the Republic of Bulgaria in accordance with the Law on Organ, Tissue and Cell Transplantation; inspections in the medical institution of the institution; monitors the observance of patients' rights, accepts complaints / signals from patients; checks on compliance with medical standards and good medical practices, etc.

Suggestions for improving the work of the Executive Agency "Medical Supervision"

1. Motivation of employees related to the importance of the agency and patient safety, awareness of the responsibilities they are charged with.
2. Public system for reporting the results of the performed inspections and penal decrees.
3. Imposition of prescriptions and subsequent control for their observance.
4. Regular analysis and systematization of the information about the final results of the court decisions.
5. Setting clear goals to achieve certain results.
6. Preliminary risk assessment in medical institutions.
7. Territorial deployment of the agency.

²⁵ <https://www.mh.government.bg/bg/ministerstvo/vtorostepenni-razporediteli/izpalnitelna-agentsiya-medicinski-nadzor/>

Supreme Council of Pharmacy

The Supreme Council of Pharmacy discusses and gives opinions on: the main directions and priorities in the field of pharmacy; ethical issues of pharmacy; drafts of normative acts related to pharmacy; scientific priorities in the field of pharmacy; programs for organizing public educational campaigns in the field of medicinal products.

Ethics commissions in healthcare

Ethics Committee for Multicenter Testing

The activity of the commission is related to giving opinions on scientific, medical and ethical aspects for conducting a clinical trial of medical devices, as well as evaluation of documentation for conducting a clinical trial of a medical device.

Transplant Ethics Commission

According to Art. 12 of the Law on Transplants of Tissues and Organs, Tissues and Cells, a specialized National Ethical Commission for Transplantation operates at the Council of Ministers.

The Central Ethical Committee gives opinions on deontological and ethical issues in the field of clinical trials when referred to the Ethics Committees.²⁶

Professional organizations are Bulgarian Medical Union BMA; Bulgarian Dental Association BUA; Bulgarian Pharmaceutical Union.

National Centre for Public Health and Analysis

The National Centre for Public Health and Analysis is a structure of the national health care system and carries out activities for public health protection, health promotion and disease prevention, information provision of health care management²⁷.

Professional organizations - Bulgarian Medical Union; Bulgarian Dental Union ; Bulgarian Pharmaceutical Union.

National Center for Public Health and Analysis

²⁶ <https://www.mh.government.bg/bg/ministerstvo/komisii/komisiya-po-etika/>

²⁷ <https://ncpha.government.bg/bg/>

The National Center for Public Health and Analysis is a structure of the national health care system and carries out activities for public health protection, health promotion and disease prevention, information provision of health care management.²⁸

Patient organizations

Patient organizations are associations of citizens. In the first place, patient organizations protect the rights of patients by participating in the processes of adopting and discussing the various acts that affect patients' rights.

Governor The Administration Act and the Rules of Procedure of the district administrations regulate in the most general way the main functions of the district governor as an executive body and an appointing body. Their specific content and forms of manifestation are established in the general and special laws and by-laws to them by providing specific powers in various areas of public life.

District crisis headquarters

§3. Legal ways to protect the rights of patients in healthcare

Right to appeal in healthcare

A complaint is a means by citizens or patients to signal, express dissatisfaction or against certain actions of a person who has violated the rights and legitimate interests of patients. The right to protection in case of violated rights is the referral to the bodies of state power, which legal possibility is guaranteed by the Constitution.

According to Article 45 of the Constitution of the Republic of Bulgaria, citizens have the right to complaints, proposals and petitions to state bodies. In general, the subject of the signals and complaints submitted by patients is expressed in the following areas: dissatisfaction with the quality of medical care provided; violated patient rights; irregular payments; difficult access to medical care; moral and ethical problems manifested in the course of diagnostic and treatment process; problems related to the health insurance status of patients.

²⁸ <https://ncpha.government.bg/bg/>

Competent authorities for reviewing complaints and alerts from citizens (patients). Referral to public authorities.

A practical way to exercise the right to protection in case of violated rights is to refer to the bodies of state power, which legal possibility is guaranteed by the Constitution. According to Article 45 of the Constitution of the Republic of Bulgaria, citizens have the right to complaints, proposals and petitions to state bodies.

Right to appeal under the Health Act and the Health Insurance Act

The provision of Art. 93 of the Health Act guarantees patients the right to appeal in two aspects. In the first place, patients can file a complaint in case of violations of rights guaranteed by the Health Act. Secondly - the patients, respectively the persons under Art. 93 of the Health Act, may refer to the Regional Health Inspectorate in disputes related to medical care. Complaints have the right to be submitted by compulsorily insured persons under the Health Insurance Act - Article 35, item 6 regulates the right of appeal of compulsorily insured persons in case of violation of the law and the contracts.

A complaint or signal to the Executive Agency for Medical Supervision is submitted when: The person is dissatisfied with the quality of the medical care provided in a certain medical institution, which includes: difficult access; delay in treatment; complications that occurred during the treatment and diagnostic process; misdiagnosis, etc.

Competent authorities to receive and consider complaints and signals are the National Health Insurance Fund and the Regional Health Insurance Fund.

Complaints and signals are considered by health insured persons who believe that they have violated rights related to the use of health services and treatment. Complaints can be from a variety of issues - e.g. additional payment for NHIF activity for which no additional payment is required; payment of a user fee at the attending physician, when the patient is released from such; writing a health book by a dentist (without the use of dental services), etc.

Regional health inspections

According to Art. 93 of the Health Act, the patient, respectively his parent, guardian or trustee, or a person authorized by them has the right to submit complaints and signals to the regional health inspection in case of violation of his rights in disputes related to medical care.

Complaint to (Ministry of Health)

When using health services, the rights and legitimate interests of patients may be affected. By filing a complaint, they have the right to report the violations to the Ministry of Health, as well as the Secretary General and the Inspectorate at the Ministry.

Professional organizations of doctors and dentists can be contacted with a complaint from patients.

The Law on Professional Organizations of Doctors and Dentists regulates the structure, organization and activity of professional organizations of doctors and dentists, the conditions for practicing the medical and dental profession and the responsibility for violating professional ethics.

Chapter three

Quality and culture as a factor for increasing patient safety - the responsibility of the doctor according to Bulgarian law

§ 1. Medical qualitology

It can be said that the problem of the quality of medical care is as old as human history. The Hippocratic oath is a cornerstone for the quality of medical care and today the doctor should serve the patient and the basic rule is not to harm him²⁹.

According to A. Donabedian, one of the founders of medical qualitology, the quality of medical care is defined as the degree of achieving the greatest benefit to human health, without increasing the risk to health, with an optimal balance between benefit and risk. The great importance of "quality" has aroused special interest of the scientific medical community in the early twentieth century, as the

²⁹ Petkova, D. Evidence- and value-based interventions to improve the quality of health care, dissertation for the award of educational and scientific degree "Doctor", p. 6

accumulation of knowledge led to the creation of an independent branch of medical science, which is called medical qualityology.

Medical care as a specialized human activity has three main dimensions: type, quantity and quality, and their combination determines its ability to meet the health needs of people who receive it. The amount of the consumer capacity of medical care can be determined with the help of many measurable parameters, among which the most important are the following: changes in the health status of consumers; the degree of satisfaction and fulfillment of their expectations - efficiency - ie. the price of the obtained health result³⁰.

Selected definitions of quality in healthcare (1980–2018)³¹

For example, Donabedian (1980) in: “Studies in Quality Assessment and Monitoring. The definition of quality and the approaches to its compilation ”- defines:” Quality of care is a type of care that is expected to achieve a maximum inclusive measure of patient well-being, taking into account the balance of expected profits and losses that are present at the process of care in all its parts.

The Medical Institute (IOM) in the United States in 1990 defined the quality of care as “the extent to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

Council of Europe (1997) In: “Development and implementation of quality improvement systems (QIS) in healthcare. Recommendation № R (97) 17 ”gives the following definition,“ Quality of care is the degree to which treatment increases the patient's chances of achieving the desired results and reduces the chances of undesirable results, given the current state of knowledge.

European Commission (2010) in “Quality in healthcare: policy action at EU level. European Council Reflection Paper ”- [Quality care is] healthcare that is effective, safe and responsive to patients' needs and preferences.

The WHO (2018) in the “Handbook on National Policy and Quality Strategy” summarizes that quality health services worldwide should be:

³⁰ https://www.nsoplb.com/uploads/article_documents/kachestvo_doc_ivanov.pdf

³¹ <ps://www.ncbi.nlm.nih.gov/books/NBK549277/>

Effective: providing fact-based health services to those who need them; Safe: avoid harm to the people for whom the care is intended; People-oriented: providing care that meets individual preferences, needs and values.

Quality management in healthcare

Quality management is one of the most discussed issues in both theory and practice of management. One of the most important prerequisites for the emergence of quality systems is the concept of "Total Quality Management", and its creator is William Edward Deming³². Deming was convinced that the poor economic performance of companies was the result of the inability of managers to avoid unnecessary costs and to establish the necessary control over production processes.

The European Foundation for Quality Management (EFQM)³³ excellence model is a self-assessment framework for measuring strengths and areas for improvement in all its activities. The term 'excellence' is used because the excellence model focuses on what an organization does or could do to provide an excellent service or product to its customers, service users or stakeholders. One of the conceptual approaches to measuring the quality of medical care is that of Maxwell³⁴.

The patient as a criterion for the quality of medical care

Medical activity is a specific process of social relations between medical staff and patients (population). Therefore, more and more often the opinion of patients is imposed as a criterion for the quality of medical care.

The value of this criterion is demonstrated through the research of M. Popov, T. Vekov, K. Paschalidis and others³⁵.

Risk management in patient safety

³² <https://www.process.st/deming-cycle/>

³³ <https://www.efqm.org/index.php/efqm-model/>

³⁴ http://www.rcsi.ie/files/schoolofnursing/docs/20140307032948_Day 1 Lecture 4 - Quality.pdf

³⁵ Petkova, D., Based on evidence and values for improving the quality of health care, dissertation for awarding educational and scientific degree "Doctor", p. 13

The risk management process can be applied in any situation where an undesirable or unexpected result may be significant or where opportunities have been identified.

Risk management culture

Significant benefit of good risk management practice will come through ownership of risk management throughout the organization. Here, the importance of promoting a culture of openness in the learning environment is of paramount importance. Staff should be trained, encouraged and supported through strong leadership to play an active role in identifying and reporting risks and 'imminent gaps' and taking appropriate action to address source issues where possible. To this end, the incident reporting system should not be considered as part of the disciplinary process.

Healthcare Marketing

The activities related to the management and marketing of the hospital are considered as an important and inseparable component of health management. They are defined as "a management process to ensure the effective functioning of the health system (or the hospital) in order to achieve its objectives."

§ 3. E-health - part of the culture of patient safety

E-health, and gained widespread popularity since 2000 (McLendon), when its consequences were socially significant. It is a collective term that unites all forms of electronic health care, offered as information versions of health, health education and health commercial products and activities.

Guiding and coordinating the development of eHealth, reaching consensus on policy, protecting people and groups, and ensuring oversight and accountability in the various aspects related to the use of information and communication technologies (ICT) for health are part of the governance function. of e-health at national level. At the global level, eHealth governance affects the rights, rules, responsibilities and risks of stakeholders in areas such as the health internet, the use of health data and information systems³⁶.

E-Health Bulgaria Foundation³⁷

³⁶ <https://www.who.int/ehealth/governance/en/>

³⁷ <https://www.netlaw.bg/en/a/ehealth-bulgaria-foundation-bulgaria>

E-Health Bulgaria Foundation is a non-profit non-governmental organization. Created in order to stimulate the development of e-health at the national level as part of the e-government of the Republic of Bulgaria. The need to accelerate the health reform in Bulgaria requires the development of e-health as a cornerstone in our health system. In this process, the Foundation cooperates with all participants and stakeholders in the healthcare process - Ministry of Health, NHIF / National Health Insurance Fund /, private health insurance funds, hospitals, GPs, pharmacies, laboratories, doctors and patients. a strong will to partner and join forces with international institutions and associations, the European Commission and other European bodies that focus on the development of e-Europe and e-health as one of its vital components.

Health and digital literacy

The term health literacy refers to cognitive and social skills that determine people's motivation and ability to access health care, understand and use information in a way that promotes and maintains good health. Today, the term literacy is used to describe not only an individual's literacy skills, but also his or her knowledge in certain areas or subjects³⁸.

The publication *The Health Ombudsman - Good Practices and Perspectives for Bulgaria* discusses various aspects of the specialized institution Health Ombudsman and the possibilities for its introduction in Bulgaria. It provides an overview of existing good practices and foreign experience in the UK, Australia, Switzerland and Israel.

In modern Europe and in a number of countries on other continents, the institution of ombudsman is widespread and enjoys the trust of the public. First established two centuries ago in Sweden and other Scandinavian countries, it has come a long way in developing and establishing itself as a mechanism for controlling the administration and protecting human rights³⁹.

³⁸ <https://www.who.int/healthpromotion/conferences/7gchp/track2/en/>

³⁹ *The Health Ombudsman - Good Practices and Prospects for Bulgaria*, Center for the Study of Democracy Sofia 2006, ISBN-10: 954-477-136-0, ISBN-13: 978-954-477-136-2

§5. Error theories. error. The responsibility of the doctor according to the Bulgarian law

Adverse medical event

Accidental / adverse medical events are a global problem that harm patients to varying degrees. According to the WHO, up to 4 out of 10 patients are injured in primary and outpatient facilities, 134 million adverse events occur each year in hospitals in low- and middle-income countries (LMICs), contributing to 2.6 million deaths annually due to dangerous care. The damage inflicted on patients costs \$ 42 billion a year. to prevent the most common side effects, such as infections and complications associated with surgery, unnecessary tests, administrative errors. It is necessary to introduce a specific approach to promote safe practices that harm our health as patients. That is why patient safety is a global health priority. Most of these adverse medical events can be avoided, so the World Health Organization wants to draw global attention to the development and implementation of patient safety. According to WHO Director-General Dr. Tedros Adanom Gebreius, "No one should be harmed while receiving health care."⁴⁰

Medical errors can be defined as the failure of a planned action to be completed as intended or the use of the wrong plan to achieve a goal. Problems that often occur during health care delivery include adverse drug events and improper transfusions, surgical injuries and surgeries in the wrong place, suicide, restraint or death injuries, falls, burns, pressure ulcers. and erroneous patient identities. High error rates with serious consequences are most likely to be observed in intensive care units, operating rooms and emergency departments.

Medical error

The medical profession is a work of art that combines science, art and technology. The phrase "medical error" is used "in cases where as a result of certain actions or omissions performed by a specialist with medical education and qualification, in the process of providing assistance to an injured person, an unwanted illegal and criminal result is achieved - established after a properly conducted criminal trial ", writes Dobrinka Radoynova in her book " Medical Errors ". The term medical error has gained wide and traditional use in medical

⁴⁰ <https://www.mediapool.bg/milioni-patsienti-umirat-zaradi-meditsinski-greshki-i-szo-si-postavya-za-tsel-da-gi-namali-news298014.html?fbclid=IwAR3uZF3vetJGQ7KSB7MB1nbCItod54xt5M8HBILv-NxtEVkj8SJB4xDER6c>

and legal language, in medical deanthology (the science of debt in medicine), and in life. With the stipulation that "medical error" will be understood as medical error in general, this term remains the most successful, which is why it could retain its use in legal, forensic and life terms.⁴¹

Conclusions from the study on the types of errors in health care

As a concept, medical / medical error does not exist as a term in Bulgarian legislation. Different interpretations and definitions are used in it, but all assumptions and attempts for definitions have no application in law and cannot be binding. Medical error is rather a medical term that reflects the behavior of medical professionals in providing medical care to patients. From a legal point of view, a medical error is an act that is illegal and violates laws, rules and regulations.

Training and patient safety

Training is part of patient safety, and all research done in this area should serve as models in healthcare facilities to be applied in the future. It is for this purpose that health professionals need to receive the necessary training and understand that their activities can increase patient safety in hospitals when using health care.

In this regard, the WHO has recognized that patient safety education should begin at the bachelor's level. This training should be not only for medical students, but also for all students in health professions. In some countries, studies have been launched to include patient safety training. Countries such as the United States, Canada, and Australia have initiated a gradual approach to patient safety education by providing patient safety training in nursing homes and other health schools⁴².

In Bulgaria, the long-term qualification of doctors in the postgraduate education system is set. The continuous qualification of doctors expands, maintains and updates the knowledge acquired during the study and specialization. Doctors

⁴¹ Radoynova, D. Medical errors. Forensic point of view, Steno publishing house, 2013, p.27, ISBN 978-954-449-642-5

⁴² Palteki, T. Hasta güvenliği, Palme Yayınevi Ankara 2019, s.,494, ISBN 978-605-282-296-8

qualify of their own free will and prove their qualification with a certificate / s / issued by the Bulgarian Medical Union.

There are different forms of continuing education: course, individual training, seminar, conference, congress, presentation, symposium, distance learning, sitting visit, subscription to specialized medical publications / books, magazines /. When choosing the individual forms of education, the specificity of each specialty and the interdisciplinary topics must be taken into account.

On March 16, 2018, the first international conference of its kind was held, on the topic: "Continuing medical education - a guarantee of quality in professional practice and patient safety."⁴³ More than two years after the efforts of representatives of the Bulgarian Medical Union, the professional organization reached an agreement for long-term cooperation with UEMS / European Union of Medical Specialists /. This will allow the continuing medical training of doctors in Bulgaria to be a quality standard, both in the country and in Europe. The occasion of the event was the official signing of a cooperation agreement between the Bulgarian professional organization and the European institution. This will mark the beginning of unification of the criteria of PMO with those in Europe and will provide an opportunity for accreditation and certification of medical forums in our country according to European standards.

Recognition of the long-term qualification by the Bulgarian Medical Union

According to Art. 182 of the Health Act, BMA organizes the long-term qualification through contracts concluded with VMU, scientific organizations, associations, pharmaceutical companies and others. The contracts specify the terms and conditions for conducting the form of continuous qualification, as well as the financial relations. Each participant in the form of continuous qualification, who conducted the training, is issued a certificate according to a sample.

Continuing training with dentists is also a legal, professional and ethical obligation of every dental practitioner. Every dentist is obliged to constantly maintain and increase his professional knowledge and skills in accordance with the provisions of the law, the rules of good dental practice and in accordance with Art. 27 of the Code of Professional Ethics of the Dentist. Each different training brings different credits to dentist.

⁴³ <https://blsbg.com/bg/3312.balgarski-lekarski-sayuz-podpisa-znakov-dogovor-s-evropeiski-sayuz-na-medicinskite-specialisti.html>

Continuing education is directly related to patient safety and quality health care. The problem in Bulgaria of collecting the necessary loans during a certain period of time from continuing education is its optional nature. We offer *de lege ferenda* that the continuing training of the providers of medical and dental care should be of a mandatory nature, which obligation should be regulated by law, as well as attestation of all doctors every three years (anonymous) in order to monitor the level of each medical institution and the offered health care.

§ 6. Types of legal liability for medical error in Bulgarian law

There is rarely a profession in which the legal system regulates all forms of legal liability - criminal, administrative, civil and disciplinary. The reason for this is that the medical profession is risky, a source of increased danger and of great public importance. Legal liability is intended to protect the universally binding nature of legal norms, as well as the way they regulate public relations.

Civil liability for medical error is the mechanism by which the injured party can receive compensation for the wrongful acts of the doctor. Civil liability - (tortuous or contractual) is non-compliance with due care and violation of the rules - prohibition to harm others - Art. 45 para. 1 of the Law on Obligations and Contracts.

Administrative or administrative liability

Administrative liability is expressed in sanctions that are carried out within the health care system and are imposed by a competent authority provided by law: reprimand, fine, revocation of medical rights and disciplinary sanctions such as reprimand, warning of dismissal or disciplinary dismissal.

Criminal liability

Criminal liability for medical malpractice is provided for the most serious violations, which are explicitly listed in the Criminal Code (for example, causing death due to ignorance or negligent performance of the medical profession. This act is committed recklessly. When committed intentionally, then will be responsible for premeditated murder).

According to Bulgarian criminal law, negligence is the mildest form of guilt. Crimes for professional negligence are convicted when they have led to death or injury - Art. 123 and 134 of the Penal Code (here the form of guilt is always carelessness).

Professional Responsibility

The term "professional liability" is not a new one in our legal space. Its main field of application is insurance. The insurances are intended for persons practicing certain professions, where it is possible for damages to occur to third parties in the process of exercising the respective professions. The insurance protects the insured persons against claims that may be filed by clients or patients if they suffer damages from improper professional actions or omissions.

Disciplinary liability

Medical professionals may also be subject to disciplinary action and disciplinary action, such as dismissal, dismissal notice and reprimand. They may be imposed on them when they are not fulfilling their obligations. And according to art. 116, p. "B", item 12 of the PA The Medical Supervision Executive Agency may make proposals to the respective Minister for imposition of a disciplinary sanction and to the director of the medical institution.

The labour (disciplinary) responsibility is realized in case of labor violations. These are violations of the Labor Code, which lists both the violations and the sanctions provided for them. Disciplinary responsibility is an independent institute of labour law.

Conclusion

Public law aspects of patient safety are of interest not only in our country, but also in a number of foreign countries. Patient safety is a prerequisite for the implementation of quality health care in each country. It aims to introduce clear and precise criteria in each national legislation to improve health care in general and to minimize adverse medical events.

Globally, more and more governments are involved in creating rules and regulations for patient safety. Its future will certainly change and progress will be made in new research to improve health care. Health systems and healthcare leaders have ample opportunities to improve patient safety to prevent adverse medical events. The legal provisions, the service providers, the education, the

culture, the guidelines they will make in the process of change and the decisions that need to be taken will be the first positive steps that need to be taken for patient safety.

University and postgraduate education programs, as well as continuing professional development and on-the-job training, should accordingly address the issue of patient safety.

Patient safety is the key to the future development of healthcare in our country, and according to the Latin saying "Salus aegroti suprema lex" - patient welfare is the most important law.

As a summary of our research on the topic "Public law aspects of patient safety" the following proposals *de lege ferenda* were derived:

1. Definition of patient safety
2. Patient Safety Act
3. The position of the Executive Director of the Executive Agency „Medical Supervision” to be established as a national position
4. Establishment of a new directorate at the Executive Agency „Medical Supervision” named "Internal Supervision"
5. Territorial deployment of the Executive Agency „Medical Supervision”
6. Creation of new structural regulations of the Executive Agency „Medical Supervision”
7. Establishment of a Patient Safety Agency
8. Register for reporting adverse medical events
9. Introduction of full digitalization of all processes in healthcare
10. National register and internal registers at each medical establishment
11. Continuing postgraduate education to be compulsory
12. National Patient Compensation Fund

AUTHOR'S PUBLICATIONS ON THE TOPIC OF
THE DISSERTATION

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