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LEGAL ASPECTS OF SAFETY IN MEDICAL PROCEDURES: INTERNATIONAL STANDARDS AND PRACTICES

LAZZAT NIYAZBEKOVA,[1] ALESSANDRO CATTOLICO,[2] MARIELA GENEVA-POPOVA,[3] STANISLAVA POPOVA-BELOVA,[3] RAIMUNDAS JURKA[4]

[1] Kazakh State Medical University named after S.D. Asfendiyarov, Department of Pathological Physiology named after Professor A.N. Nurmukhambetov, Almaty, Kazakhstan
lazzatniyazbekova06@gmail.com
[2] University Hospital "Luigi Vanvitelli", Department of Orthopaedics and Spine Surgery, Naples, Italy
acattolico@outlook.com
[3] Medical University of Plovdiv, Department of Propedeutics of Internal Diseases, Plovdiv, Bulgaria
m-genevapopova@hotmail.com, s.popovabelova@outlook.com
[4] Utenos Kolegija Higher Education Institution, Faculty of Business and Technologies, Utena, Lithuania
r_jurka@hotmail.com

CORRESPONDING AUTHOR
lazzatniyazbekova06@gmail.com

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Abstract This paper examines the legal regulation of medical procedure safety and proposes avenues for legislative enhancement informed by international norms. A comparative legal analysis was performed utilising the cases of Bulgaria, Italy, and Kazakhstan. The study utilised a systematic methodology to evaluate legal efficacy and predictive techniques to delineate potential advancements. The findings reveal that all three countries acknowledge the right to healthcare at the constitutional level, but implementation strategies vary. Bulgaria and Italy utilise insurance-based healthcare systems that incorporate private sector involvement. Bulgaria faces challenges in harmonising its law enforcement with European norms, whilst Italy's decentralised Servizio Sanitario Nazionale results in regional disparities. Kazakhstan upholds a state-centric regulatory framework but lacks comprehensive legal safeguards for patients and medical practitioners, especially concerning liability insurance. No country possesses a comprehensive legal framework for digital medicine. Key proposals include improving insurance protections, harmonising national laws with international norms, and regulating emerging medical technologies.

Keywords
healthcare,
regulatory framework,
state regulation,
licensing,
civil liability

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1 Introduction

Ensuring the safety of medical procedures is an integral part of the enjoyment of the human right to health. States have a legal responsibility to establish a regulatory framework governing the activities of medical institutions, the quality of services rendered, and the protection of patients from possible risks. However, despite the existence of international standards, approaches to the legal provision of safety of medical procedures vary significantly depending on the specific socio-economic, historical, and legal features of particular countries. The need conditioned the relevance of the present study for a comprehensive comparative analysis of legal support for the safety of medical procedures in different countries.

Modern international law recognises the need for patient protection at the legislative level, but the effectiveness of the regulations and control mechanisms continues to be a matter of debate. Some countries, such as Kazakhstan, regulate and license, while others, such as Italy, operate under a universal Servizio Sanitario Nazionale primarily funded through general taxation, with regional health authorities overseeing healthcare delivery and civil liability for medical errors governed by a mixed system of contractual and tort law. These differences raise questions about the extent to which patient rights are protected, the effectiveness of legal mechanisms to prevent medical errors, and liability for violations of medical standards.

In the field of legal provision of safety of medical procedures, there is a significant body of scientific research covering various aspects of this problem. A substantial part of the studies addresses the analysis of international standards, their implementation in national legislation, judicial practice, and mechanisms of legal liability of medical workers. However, these studies demonstrate varying approaches and have their limitations, which necessitate a comparative analysis of legal models of different countries.

Thus, Glushkova et al. (2021) and Liu & Hyman (2020) paid considerable attention to the harmonisation of international and national legal provisions regulating the safety of medical procedures. The researchers noted that EU directives and recommendations of the World Health Organisation (WHO) play a key role in the formation of national legal systems. Still, their implementation in different countries

is uneven. Specifically, analyses of EU Member State legislation revealed that some countries (e.g., Germany and France) have a well-developed system of independent monitoring of medical services and compulsory professional liability insurance for doctors, while others (e.g., Bulgaria) face funding problems and insufficient regulatory mechanisms.

Hanganu et al. (2020) and Agarwal et al. (2019) focused on analysing court practices in medical error cases. The researchers compared approaches to such cases in multiple countries. They found that in legal systems with developed case law (e.g., Italy, despite its civil law tradition, where judicial precedents – especially from the Corte di Cassazione – play an increasingly influential role in shaping medical liability standards), court decisions substantially influence the law and practice of medical institutions. At the same time, in countries with a continental legal system, medical liability is more often regulated by strict rules of law, while the role of judicial practice is less significant.

Amir & Damayanti (2022) and Amin et al. (2020) investigated the role of insurance mechanisms in ensuring the safety of medical procedures. Their studies noted that the effectiveness of the health insurance system directly affects the level of legal protection of patients. For example, in countries with developed insurance medicine, doctors usually have professional liability insurance policies, which enable patients to receive compensation without the need for lengthy legal proceedings. In contrast, in countries where the insurance system is underdeveloped, patients are more likely to have to go to court, which increases the burden on the legal system and creates extensive time and financial costs.

Studies analysing the national health protection strategies also made a substantial contribution to the understanding of the legal regulation of the safety of medical procedures. For example, Adu-Gallant et al. (2024) and Seidanov et al. (2024) considered the problems of implementing medical safety standards in the post-Soviet countries. The researchers noted that the principal challenges for these states continue to be the insufficient legislative framework, the lack of effective control over the quality of medical services, and the low level of legal literacy of patients.

Despite the vast amount of research conducted, there are still some gaps in this area. For instance, most studies analyse legal models only within individual countries or regions, which complicates identifying common trends and best practices. Theoretical aspects dominate the existing studies, while empirical analyses (e.g., assessing the factual effectiveness of legislative provisions) are much less common.

The purpose of the present study was to analyse the legal regulation of the safety of medical procedures and identify areas for improving legislation based on international experience. To fulfil this purpose, the following objectives were set: to analyse international legal provisions governing the safety of medical procedures and their influence on national legislation; to investigate the specific features of legal regulation of the safety of medical procedures in Kazakhstan, Bulgaria, and Italy; to identify key problems and legal gaps in the regulation of medical safety at the national level.

2 Materials and Methods

The study of legal regulation of the safety of medical procedures in Bulgaria, Italy, and Kazakhstan was conducted using a set of special legal methods aimed at analysing national legislative systems and their compliance with international standards of medical safety. The principal method of the study was comparative legal analysis, which was employed to determine the best approaches to the legal regulation of the safety of medical procedures by comparing the national legislations of Bulgaria, Italy, and Kazakhstan with international standards. Within the framework of this analysis, the provisions of national legislation were compared with international regulations governing the rights of patients and obligations of medical workers. The selection of international legal instruments for this study was determined by their normative impact, global or regional legal authority, and historical importance in establishing norms for patient rights and medical safety.

The Universal Declaration of Human Rights (1948), the European Convention on Human Rights (1950), the International Covenant on Civil and Political Rights (1966), the International Covenant on Economic, Social and Cultural -Rights (1966), the Nuremberg Code (1947), the Charter of the Hospital Patient (1979) were considered as key international documents. Other significant international documents that were reviewed include: Recommendation of the Committee of

Ministers of the Council of Europe No. R(80)10 on Measures Against the Transfer and the Safekeeping of Funds of Criminal Origin (1980), Declaration on a Promotion on Patients' Rights in Europe (1994), European Charter of Patients' Rights (2002), Convention on Human Rights and Biomedicine (1997), Convention on the Rights of Persons with Disabilities (2006), Convention on the Rights of the Child (1989), Directive of the European Parliament and of the Council No. 2011/24/EU on the Application of Patients' Rights in Cross-Border Healthcare (2011).

The study analysed the regulations of Bulgaria, Italy, and Kazakhstan governing the safety of medical procedures. These included the Constitution of the Republic of Kazakhstan (1995), the Constitution of the Italian Republic (1947), the Constitution of the Republic of Bulgaria (2003), the Law of the Republic of Bulgaria No. 302-01-35 "On Health Protection" (2005), the Law of the Republic of Bulgaria "On Health Insurance" (1998), the Law of the Italian Republic No. 833 "Establishment of the National Health Service" (1978), Law of the Italian Republic No. 24 "Provisions on the Safety of Care and the Assisted Person, As Well As on the Professional Liability of Health Professionals" (2017), the Code of the Republic of Kazakhstan No. 360-VI "On the Health of the People and the Health Care System" (2020), and the State Programme of Development of Health Care of the Republic of Kazakhstan for 2020-2025 (2019). The analysis of these documents allowed us to identify the specific features of law enforcement in different jurisdictions and the legal gaps affecting the level of safety of medical procedures.

We employed the formal-legal method to examine the structure and content of national legislation aimed at regulating medical safety. Specifically, the study examined the regulatory language concerning standards of medical care, including requirements for the quality and safety of medical procedures, as well as medical licensing procedures covering the conditions and procedures medical institutions and practitioners must follow to obtain licences. A systemic approach was used to identify the institutional features of legal regulation of the safety of medical procedures in Kazakhstan, Bulgaria, and Italy. This analysis examined mechanisms of state control in the healthcare sector, models of interaction between the private and public sectors, and the degree of digitalisation of medical services.

Kazakhstan, Bulgaria, and Italy were selected to represent a varied array of legal, political, and healthcare governance frameworks, post-Soviet centralised regulation, an EU member state undergoing legal transition, and a developed Western European decentralised model, respectively. The analysis concentrated on delineating particular characteristics in each nation, encompassing constitutional health protections, medical licensing and accreditation mechanisms, informed consent standards, liability regime structures and effectiveness, and the deployment of digital health technologies.

Furthermore, we employed the SWOT analysis method to identify the strengths and weaknesses of the legal systems of each of the studied countries, to identify potential threats and opportunities for improving the legal regulation of medical safety.

3 Results and Discussion

3.1 Influence of International Legal Provisions on National Legislation in the Field of Safety of Medical Procedures

The formation of international legal provisions regulating the safety of medical procedures is a complex process due to a series of significant changes in the healthcare sector. Social changes include increasing patient demands for quality and safety of medical services, increasing awareness of the rights to healthcare, and legal protection. Economic factors are related to the globalisation of health services, increasing healthcare costs, and the need to optimise financial mechanisms to ensure accessibility and quality of healthcare. Technological changes are manifested in the active introduction of innovative methods of diagnosis and treatment, digitalisation of medical data, and the development of telemedicine, which requires the adaptation of legal regulation to new conditions and risks. This process began with the realisation of fundamental human rights and the need to protect patients from risks associated with medical interventions. The historical evolution of international regulation in this area demonstrates how global changes in medicine and society have influenced the development and adoption of international documents, as well as how these documents have affected the national legislations of different countries (Gerasymchuk et al., 2021).

One of the first steps towards the recognition of patients' rights was the Universal Declaration of Human Rights (1948), which set out the basic principles for the protection of human life, dignity, and health. This was the starting point for the further development of international legal mechanisms aimed at protecting patients. According to these principles, many countries began to form national legislation in the field of medical safety. For example, the USA developed laws regulating patients' rights, such as the Health Insurance Portability and Accountability Act (1996). Subsequently, the European Convention on Human Rights (1950) supplemented these provisions by emphasising the inadmissibility of inhuman treatment, which, specifically, applied to the medical sphere.

The findings of the study coincided with those of Beauchamp & Childress (2019), who noted that the basic principles of humanism and the protection of human rights are crucial for the formation of ethical norms in medicine. However, unlike in some Western countries, where reforms have been faster, in post-Soviet countries, the harmonisation of legislative provisions with international standards continues to be challenging due to a series of institutional and economic barriers.

In the 1960s and 1970s, the rapid development of medical technology, the introduction of new methods of treatment and diagnosis, and the increasing number of medical interventions led to the realisation of the need for more detailed legal regulation of medical activities. The International Covenant on Civil and Political Rights (1966) and the International Covenant on Economic, Social and Cultural Rights (1966) prescribed everyone the right to have access to healthcare, emphasising the significance of fair and safe provision of health services.

Germany and the United States were among the first countries to develop such legal standards. Germany adopted the Nuremberg Code (1947) after World War II and it became a crucial international document governing ethical standards for medical experimentation. USA passed the Patient Protection and Affordable Care Act in 1964, which included strict rules for medical research and established Ethics Committees responsible for overseeing experimental medicine. All these initiatives were part of a broader international movement to protect patients' rights and prevent abuses in medical practice.

The findings of the study were in line with the findings of Hulme (2020), who emphasised that the integration of international standards into national legislation requires a systematic approach that factors in not only the legal but also the technological changes, especially in the era of digitalisation and the introduction of innovative diagnostic and treatment methods.

A significant challenge for the healthcare system in the 1970s and 1980s was the commercialisation of health services and the increasing bureaucratisation of the industry, which increased the imbalance in the doctor-patient relationship. In response, documents such as the Charter of the Hospital Patient (1979) and Recommendation of the Committee of Ministers of the Council of Europe No. R(80)10 "On Measures Against the Transfer and the Safekeeping of Funds of Criminal Origin" (1980) were adopted, which were the first to emphasise the active participation of the patient in decisions about their own care. These initiatives were reflected in the national legislations of Western European countries, which began to introduce relevant provisions on patients' rights, including the right to information, confidentiality, and protection against unwarranted medical interference.

The international community's focus on patients' rights and medical safety came to a head in the 1990s with the adoption of the Declaration on the Promotion of Patients' Rights in Europe (1994) and the European Charter of Patients' Rights (2002). Under their influence, reforms were initiated in various countries to improve the protection of patients' rights and medical safety. In Germany, laws governing patient awareness of treatment and medical research have been strengthened. In France, new laws have been introduced to improve access to legal advice and improve patient awareness (Pajuk et al., 2024). In the UK, the Patients' Rights Act was passed, providing improved communication with healthcare providers. These documents have become significant benchmarks for national healthcare systems, contributing to the revision of approaches to the legal regulation of medical activities.

One of the key aspects of these documents was the expansion of the concept of patient safety and its recognition as a central element of medical law. Specifically, the European Charter of Patients' Rights prescribes principles such as the right to prevention, accessibility of health services, patient awareness, confidentiality, and protection of personal data. These provisions have become the cornerstone for

healthcare reforms in many countries, including in Italy and Eastern Europe, where previously patients' rights had often remained on the periphery of health policy.

Notably, the processes of harmonisation of national legislations with international standards have been uneven. Western European countries were quicker to adapt their systems to the new requirements. At the same time, the post-Soviet states, including Ukraine, Kazakhstan, and Kyrgyzstan, faced a series of institutional and economic challenges in implementing international provisions. One of the primary obstacles was the lack of an adequate legal framework, as well as the insufficient preparedness of state authorities to monitor and implementing international standards effectively. For example, in Ukraine, until the early 2000s, outdated Soviet regulations were in force in medical safety, which prevented the full protection of patients' rights. In Kazakhstan, healthcare legislation was fragmented, while implementing international standards was hampered by a weak institutional framework and insufficient funding (Tursynova et al., 2024). In Kyrgyzstan, problems implementing international standards were related to the lack of qualified specialists in medical law and healthcare.

The findings of the present study were in line with the studies conducted by other researchers. For instance, Ruppel et al. (2022) emphasised that the selective application of international standards substantially limits the equality of litigants and respect for human rights. Furthermore, analyses revealed that increased interaction between national judicial systems and international legal institutions is necessary to improve the effectiveness of law enforcement. Many studies, including Millar (2023), pointed out that international organisations substantially influence the reforming of judicial systems, but a lack of domestic politics will often limit their impact.

With advances in technology, increasing volumes of medical data, and growing cross-border cooperation in healthcare, international organisations such as the WHO and the World Medical Association have increased their focus on medical safety (Kachan et al., 2025). One of the key areas has been the introduction of digital technologies such as telemedicine, electronic medical records, and artificial intelligence, which have considerably affected the quality and safety of medical procedures. Telemedicine has increased access to health services, especially in remote regions, which has required the creation of new international standards to

protect patient privacy and regulate cross-border consultations (Del Carpio-Delgado et al., 2023; Shevchenko et al., 2023).

Electronic medical records have helped to improve diagnostic accuracy and reduce the risks associated with the loss or distortion of medical information, which prompted the adoption of international provisions on standardisation and protection of digital data. Introducing artificial intelligence into the healthcare system has improved decision-making and minimised medical errors but has also necessitated developing legal regulation concerning liability for algorithm-based decisions (Pētersone et al., 2020; Nowak & Grzybowski, 2013). In response to these challenges, international law has become more active in adapting to the new reality by adopting WHO recommendations on the use of digital technologies in healthcare and developing data protection standards under the General Data Protection Regulation in the EU. Thus, the digitalisation of healthcare has necessitated a revision of international legal provisions aimed at ensuring the safety of medical procedures and protecting patients' rights. The findings of the current study were consistent with the analysis of Bali et al. (2019), who noted that establishing a strong ethical and legal framework for the use of artificial intelligence in medicine is integral to current practice, highlighting the need to synchronise national legislation with international standards in this area.

The movement to actively develop national legislation regulating patients' rights and the safety of medical procedures began in Europe in the 1980s and 1990s. During this period, a series of countries adopted separate laws on patients' rights, which were largely based on international standards and recommendations. The first such act was the Act on the Status and Rights of the Patient, adopted in Finland in 1992. It mandated the basic rights of patients, such as the right to quality medical care, to be informed about their health status, and to be able to make their own decisions regarding medical interventions. A significant innovation was the introduction of a patient ombudsman, an official authorised to protect the interests of patients and consider their complaints. This practice was subsequently borrowed by other countries, including the Netherlands (1994), Israel (1996), Lithuania (1996), Iceland (1997), Denmark (1998), Norway (1999), Georgia (2000), France (2002), Moldova (2005), and others. In many countries, provisions regulating the safety of medical procedures and patients' rights have been incorporated into broad healthcare legislation.

Apart from the legislative acts, patient rights charters play a prominent role in regulating the safety of medical procedures. Government agencies, medical institutions, professional communities, and civil society organisations develop these documents. Unlike legislative acts, charters are often non-binding. Still, they nevertheless contribute to developing a legal culture, raising citizens' awareness of their rights, and creating mechanisms of public control over compliance with medical standards. For instance, in Portugal, the Consumer Charter has been incorporated into national legislation. In Germany, as early as 1975, the Social Code was supplemented by the Patients' Charter, which was a crucial step in developing a system for protecting patients' rights (Agarwal et al., 2019).

The practices of Great Britain deserve special attention, where protecting patients' rights and regulation of the safety of medical procedures is carried out mainly through case law. Unlike the countries of continental Europe, where legal provisions are prescribed in legislative acts, in the UK, the development of patient rights is based on court decisions. This creates a flexible but also less predictable system of regulation, as each new court case can set new legal standards. Such a system has both advantages and disadvantages. On the one hand, it allows the specifics of each case to be considered, ensuring an individualised approach to protecting patients' rights. On the other hand, the absence of a single regulation governing all aspects of medical safety can lead to legal uncertainty and complicate law enforcement practice. An illustrative example is the fact that the National Health Service in the UK must pay out hundreds of millions of pounds annually in patient claims for inappropriate care (Ravshanov et al., 2024).

Regarding the influence of international legal provisions on national legislation, one cannot fail to mention the harmonisation of legal systems, which is actively developing (Hulme, 2020). Within the EU, directives have been adopted to oblige EU member states to implement uniform standards of medical safety and to regulate issues related to patients' rights. The WHO and the Council of Europe have also developed recommendations for quality assurance of health services. These have become the basis for national patient safety strategies in many countries. However, the harmonisation of legislation faces serious challenges. Firstly, a considerable proportion of countries, especially developing countries, have financial constraints that complicate implementing international standards. Secondly, differences in the level of development of healthcare systems lead some states to successfully adopt

international provisions, while others only formally adopt laws with no real enforcement mechanism (Beauchamp & Childress, 2019). Thirdly, there is resistance from the medical community, including in Italy, where parts of the medical profession have expressed concerns that increasing legal oversight may hinder clinical discretion and increase the risk of defensive medicine.

Table 1: Influence of International Legal Provisions on National Legislation in the Field of Safety of Medical Procedures

Criterion	International legal provisions	National legislation	Results and trends
Patient's right to the safety of medical procedures	Established in international conventions (Convention on Human Rights and Biomedicine, etc.)	Included in patient rights laws, healthcare laws, codes of medical ethics	Improvement of safety standards, introduction of a patient-centred approach
Informed consent of the patient	Confirmed in international instruments (Declaration of Helsinki)	Regulated in laws on medical activities, acts on the protection of patients' rights	Increased transparency of medical interventions, reduction in the number of lawsuits
Control over the quality of medical services	Defined by the World Health Organisation and international standards (ISO, JCI)	Included in the system of licensing and accreditation of medical institutions	Improvement of the quality of medical care, strengthening of state control
Confidentiality of health information	Prescribed in international documents (General Data Protection Regulation, Council of Europe Convention 108)	Protected by laws on personal data, medical secrecy	Development of digital data protection systems, regulation of access to information
Liability for medical errors	Prescribed in international agreements on medical human rights	Provided for in criminal and civil legislation	Increase in the number of lawsuits, development of pre-trial settlement mechanisms
Protection of vulnerable groups (children, disabled, elderly)	Reflected in the Convention on the Rights of Persons with Disabilities, Convention on the Rights of the Child	Included in specialised laws on the healthcare of certain categories of the population	Development of targeted medical care programmes, strengthening social protection

Source: compiled by the authors based on Convention on Human Rights and Biomedicine (1997), Declaration of Helsinki (1967), Convention on the Rights of Persons with Disabilities (2006), Convention on the Rights of the Child (1989).

An analysis of the influence of international legal provisions on the national legislation of various countries revealed that integrating global standards into the sphere of medical law is taking place in several key areas. Firstly, international

documents set general guidelines for ensuring the safety of medical procedures, protecting patients' rights, and regulating the activities of medical institutions. Secondly, countries adopt these standards into their legal system by incorporating them into constitutions, specialised laws, and regulations. In Italy, for instance, the transposition of the European Charter of Patients' Rights and the adoption of Law of the Italian Republic No. 24 "Provisions on the Safety of Care and the Assisted Person, As Well As on the Professional Liability of Health Professionals" (2017) marked a significant step toward aligning national legislation with international principles on patient safety and medical liability Thirdly, implementing international standards is accompanied by changes in the regulation of aspects such as medical liability, protection of patients' personal data, access to health services for vulnerable groups, and healthcare quality control (Komilova et al., 2024). These aspects are systematised in Table 1.

Thus, international legal provisions governing the safety of medical procedures have been shaped by a series of factors: technological advances, ethical debates, social change, and the globalisation of the medical field. National legislation adopting international principles has faced various challenges, including institutional barriers, lack of funding, and the need to change public consciousness. Despite differences in pace and approach, the general trend in the development of medical law shows a desire to improve patient safety, as evidenced by the adoption of new international standards and their implementation in the legal systems of different countries.

3.2 Specific Features of Legal Regulation of Safety of Medical Procedures in Bulgaria, Italy, and Kazakhstan

The right to health protection in Bulgaria is guaranteed by Article 52 of the Constitution of the Republic of Bulgaria (2003). A series of legal acts regulates the safety of medical procedures, the principal ones being the Law of the Republic of Bulgaria No. 302-01-35 "On Health Protection" (2005), the Law of the Republic of Bulgaria "On Health Insurance" (1998). Bulgaria, as a member of the EU, has adapted its legislation to meet the requirements of Directive of the European Parliament and of the Council No. 2011/24/EU "On the Application of Patients' Rights in Cross-Border Healthcare" (2011).

A specific feature of the Bulgarian model is the combination of public and private health services with *strict state* control. For example, medical centres are subject to compulsory licensing by the Bulgarian Ministry of Health. National standards for medical procedures have been introduced, which are in line with WHO recommendations. One of the key areas in the field of legal regulation is the strengthening of the liability of medical professionals for medical errors (Zozulya et al., 2023; David-Tenorio & Torres-Rojas, 2025). The legislation mandates civil and criminal liability in cases of harm caused to a patient because of negligence or improper provision of medical care. However, despite formal compliance with European norms, there is still a series of unresolved problems in practice. Specifically, professional liability insurance for medical workers has not yet become an effective tool for protecting their rights, and patients often face challenges when trying to recover compensation for harm caused.

In their studies on legal aspects of medical safety in Bulgaria, Palm et al. (2021) and Pauliñska (2021) emphasised the active integration of European standards into national legislation, which was also identified in the analysis conducted during the present study. However, in contrast to the findings of Palm et al. (2021) and Pauliñska (2021), the present study emphasised the lack of protection for physicians in the insurance system, which may ultimately reduce the effectiveness of enforcement. In Italy, healthcare is a constitutional right set out in Article 32 of the Constitution of the Italian Republic (1947). The basis of legislation in the field of medicine is Law of the Italian Republic No. 833 "Establishment of the National Health Service" (1978), and Law of the Italian Republic No. 24 "Provisions on the Safety of Care and the Assisted Person, As Well As on the Professional Liability of Health Professionals" (2017).

The specific feature of the Italian system lies in the decentralised approach to regulating medical procedures. The powers in this sphere are distributed between the central government and regional authorities, which allows accommodating the specific needs of the population of different regions. However, this approach leads to some differences in the level of medical care and its quality control system depending on the territory.

The Gelli-Bianco Law represented a major reform in medical liability and patient safety. It mandated professional liability insurance for healthcare providers, introduced national guidelines to standardise clinical practice, and established the role of independent technical bodies (*collegi tecnici*) to assess alleged medical errors. One of the key aspects was a clear distinction between criminal and civil liability of medical professionals: criminal liability is now limited to cases of gross negligence, while most cases of alleged malpractice are resolved under civil law. The introduction of this law was prompted by the growing number of lawsuits against doctors, which created serious financial risks for medical professionals and even led to the phenomenon of "defensive medicine" (*quando i medici preferiscono non rischiare*).

Despite the existing regulatory framework, Italy still faces problems related to the overburdened judicial system and the complexity of proceedings in medical cases. The introduction of alternative dispute resolution methods, such as mediation and arbitration, could improve the protection of patients' and health professionals' rights (Karpushyna & Veresha, 2023). The Gelli-Bianco Law already promotes conciliation procedures as a mandatory step before litigation in certain cases, yet they have not been implemented evenly across regions.

The issues of medical security are widely considered in modern legal science. Yanovska et al. (2019) and Nozimakhon & Faringiz (2022) noted that the decentralised model of healthcare management leads to varying levels of quality of medical services in different regions, a conclusion we confirmed in the present study. These prior studies also observed a great degree of health workers' insurance coverage, which is in line with the findings presented in the current study. However, Borysowski et al. (2021) and Ruppel et al. (2022) pointed out that uncertainties remain in interpreting and enforcing liability rules, which may lead to ambiguous enforcement practices.

The right of Kazakh citizens to healthcare is prescribed in Article 29 of the Constitution of the Republic of Kazakhstan (1995). The most significant regulation governing the safety of medical procedures is the Code of the Republic of Kazakhstan No. 360-VI "On the Health of the People and the Health Care System" (2020). Unlike Bulgaria and Italy, Kazakhstan adheres to a centralised approach to regulating the medical sphere. The state exercises strict control over the provision of medical services, including mandatory accreditation of medical institutions,

certification of specialists, and control over the implementation of standards of medical care.

One of the priorities of the Kazakhstan model is introducing digital technologies to improve the safety of medical procedures. Within the framework of the State Programme of Development of Health Care of the Republic of Kazakhstan for 2020-2025 (2019), a unified electronic database of patients is being created, which allows for minimising the risks of medical errors, automating the processes of diagnosis and treatment, and increasing the transparency of medical services. However, there is a risk of patient personal data being leaked, which requires further legal regulation.

One of the unresolved problems continues to be the absence of a full-fledged mechanism to protect medical professionals from unjustified claims (Tulina, 2024). Even though Article 270 of the Health Code outlines the concept of a "medical incident" (the innocent infliction of harm on a patient), in practice, professional liability insurance for doctors is still a formal norm. This creates risks for medical personnel, who may be held liable even in cases where harm has been caused without their fault, as confirmed by Polac (2023) and Adu-Gallant et al. (2024), who noted the increase in digitalisation and the introduction of modern technologies in the medical field. The findings of the present study confirmed this thesis but revealed the need to improve the mechanisms to legally protect patients and to regulate the liability of medical workers, which partially contradicts the conclusions of the above-mentioned researchers, who considered the existing regulatory framework of Kazakhstan sufficient.

An analysis of the legal regulation of the safety of medical procedures in Bulgaria, Italy, and Kazakhstan revealed both shared features and fundamental differences, reflecting the specifics of the socio-economic and legal systems of each country. In all three countries, the safety of medical procedures is ensured at the level of the constitutional right to healthcare. However, the mechanisms employed to fulfill the countries' constitutional mandates differ. Italy and Bulgaria employ the model of insurance medicine with active participation of private medical structures, while in Kazakhstan, the state plays a leading role in controlling and organising medical care. This factor substantially impacts assuring the safety of medical procedures and protecting the rights of patients and health workers (Millar, 2023).

The Italian model is characterised by the decentralised management of the healthcare system, which has the advantage of being able to accommodate specific regional features. Each region of Italy organises the provision of healthcare differently, such as, for example, variations in access to innovative technologies and levels of insurance coverage. This decentralised approach has disadvantages as well because it has created an imbalance in the quality and availability of health services, which in turn has sparked a debate on the need to more fairly harmonise regulatory standards to better ensure health security across all of Italy. For example, some regions have adopted more advanced digital systems and risk management protocols, while others lag behind, exacerbating healthcare inequalities.

Bulgaria is oriented towards European standards of medical safety, as evidenced by the fact it has actively implemented EU directives and regulations. However, in practice, the country faces challenges in law enforcement. One of the key challenges facing Bulgaria is protecting doctors' rights in the context of medical errors and professional liability. Although Bulgarian legislation provides for a system of professional liability insurance for medical professionals, the mechanisms used to implement the legislation have yet to be perfected, sometimes leading to litigation and a lack of reliable guarantees for doctors. These shortcomings can be remedied through not only a review of existing insurance mechanisms but also by introducing stricter legal guarantees for medical professionals, which is in line with the findings of Palm et al. (2020) on the need for a comprehensive approach to the protection of the rights of participants in the medical process.

Kazakhstan is actively introducing digital technologies into its healthcare system. In recent years, the country has seen active digitalisation of medical processes, including the creation of a unified medical database, the use of telemedicine, and the development of electronic medical records. However, gaps persist in the legal regulations that protectboth doctors and patients. For instance, despite introducing medical liability provisions, Kazakh practices lack a clear mechanism to protect medical professionals from unfair accusations, and patients do not always have sufficient tools to assert their rights.

The findings of the present study suggest that adopting digital technologies has a twofold impact: positively, they significantly improve process efficiency; negatively, they increase the risk of privacy breaches. This is in line with the observations of

Beauchamp & Childress (2019), who highlighted the significance of developing robust data protection mechanisms in the digitalisation of healthcare.

Table 2: SWOT-Analysis of Legal Regulation of Safety of Medical Procedures in Bulgaria, Italy, and Kazakhstan

Country	Strengths	Weaknesses
Bulgaria	Compliance with European standards of medical safety (EU directives). Developed insurance medicine. Protection of patients' rights within the framework of EU legislation	Underfunding of the healthcare system. Problems with the performance of insurance obligations. Lack of effective legal protection for health workers
Italy	Decentralised healthcare system tailored to regional needs. Legally codified procedures for informed consent. Implementation of national safety guidelines (e.g., Gelli-Bianco) with variable regional oversight	Regional disparities in service quality and access. Migration and demographic imbalances strain public health infrastructure. Lengthy and costly medical litigation contributes to defensive medicine
Kazakhstan	State control over medical security. Introduction of digital technologies in the sphere of healthcare. The latest legislation in the field of medical safety	Inadequate insurance coverage for health workers. Complexity of law enforcement practice. Bureaucratic barriers in the implementation of new medical standards
Country	**Opportunities**	**Threats**
Bulgaria	Further harmonisation of legislation with EU standards. Strengthening of the health insurance system. Development of programmes to protect patients' rights	Insufficient protection of doctors' rights may lead to a decrease in the quality of medical care. Outflow of qualified specialists to more developed EU countries
Italy	Potential for a national digital platform to harmonise safety monitoring. Strengthening interdisciplinary education in medicine and law. Expansion of structured alternative dispute resolution systems	Pressure on hospital capacity may hinder risk management. Regional autonomy in legislation may challenge legal consistency and equal protection of patient rights.
Kazakhstan	Creation of an effective system of professional liability insurance for doctors. Further digitalisation of medicine. Improvement of the regulatory framework based on international practices	Risk of corruption factors in the system of state regulation. Ineffective application of digital solutions without adaptation to the reality of healthcare

Source: compiled by the authors based on Code of the Republic of Kazakhstan No. 360-VI "On the Health of the People and the Health Care System" (2020), Constitution of the Republic of Kazakhstan (1995), Constitution of the Italian Republic (1947), Constitution of the Republic of Bulgaria (2003).

To compare the legal regulation of the safety of medical procedures in Bulgaria, Italy, and Kazakhstan more clearly, it is advisable to conduct a SWOT analysis. The SWOT method is useful not only because it helps to reveal the strengths and weaknesses of each system, but also because it can identify potential threats and opportunities for its further development. Considering the analysis, each country employs its unique approaches due to historical, socio-economic, and legal factors. However, despite their differences, all three countries have common ground, such as the desire to improve the quality of healthcare and protect the rights of patients

and physicians. The SWOT analysis presented below helps systematize the principal aspects of legal regulation of the safety of medical procedures in the countries under study (Table 2).

Each of the states under study adopts a system of regulating the safety of medical procedures depending on its socio-economic reality. The Italian practices demonstrate the effectiveness of insurance protection for medical workers, minimising financial risks for doctors and patients. The Italian experience shows the importance of balancing regional autonomy with the need for uniform national standards, especially in areas like medical liability, data protection, and the use of clinical guidelines. Recent reforms have aimed to reduce variability and improve equity, but challenges remain in enforcement and coordination. The Bulgarian model shows the significance of adherence to European quality standards, although it requires further improvement of law enforcement practices. Kazakhstan relies on digitalisation and state control, which can increase access to medical care, but requires clarification of legal mechanisms to protect all participants in the medical process.

In the long term, each of these countries can learn useful lessons from the practices of the others. Italy could strengthen the harmonisation of medical safety standards, Bulgaria could improve the protection of medical professionals, and Kazakhstan could develop more explicit legal provisions governing professional liability and insurance in the medical field. Only a comprehensive approach and harmonising national legislation with international standards will help achieve a greater level of safety in medical procedures and the protection of the rights of all stakeholders.

3.3 Prospective Areas of Improvement of Legislation Considering the Best International Practices

The analysis of legal regulation of the safety of medical procedures in Bulgaria, Italy, and Kazakhstan, as well as the results of SWOT analysis, allows identifying promising areas for improving the legislation, considering the best international practices. The crucial task is to develop a system of medical workers' insurance protection, which has proven effective in Italy. Guaranteed insurance of doctors' professional liability helps not only to protect medical personnel from unjustified claims, but also to increase the general level of confidence in the healthcare system.

In Bulgaria and Kazakhstan, this mechanism still needs to be further developed: uniform insurance standards must be introduced, transparent procedures for dealing with medical incidents must be established, and a fair balance must be struck between the rights of patients and the responsibilities of medical institutions.

Another key area is the harmonisation of national legislation with international standards. Bulgaria, as an EU member state, has already largely adapted its legal regulations to the requirements of the EU. However, Kazakhstan should increase alignment with international documents such as the Convention on Human Rights and Biomedicine of the Council of Europe. At the same time, Italy – already bound by these instruments as an EU and Council of Europe member – should focus on ensuring they are consistently implemented across regions. This includes the uniform application of Directive of the European Parliament and of the Council No. 2011/24/EU "On the Application of Patients' Rights in Cross-Border Healthcare" (2011), the WHO recommendations, and the General Data Protection Regulation in managing digital health data. This will help to create a unified system for protecting patients' rights and ensuring uniform law enforcement.

Another vital aspect is the expansion of digitalisation and the introduction of medical information systems (Bali et al., 2019). Kazakhstan is already actively using digital technologies in the healthcare sector, but further development requires improved legal regulation in personal data protection. Italy, despite having a solid data protection framework under the General Data Protection Regulation and the Privacy Code of the Italian Republic (2003), still faces challenges in uniformly implementing digital security protocols across regions and healthcare facilities. Strengthening legal provisions in this area will not only increase citizens' trust in medical institutions but also minimise the risks of confidential data leakage, which is especially relevant in the era of digitalisation.

An equally significant area is the creation of uniform standards for the safety of medical procedures. Even though each of the countries under study already regulates medical safety at the level of national legislation, considerable differences persist in practice. Introducing mandatory international standards based on the recommendations of the WHO and the European Centre for Disease Prevention and Control will help minimise medical errors, improve the level of medical care, and unify approaches to safety in the medical sphere.

Other major steps in developing legislation should be the strengthening of state control and developing public monitoring. In Kazakhstan, the state plays the dominant role in ensuring the safety of medical procedures, while independent public institutions are not yet sufficiently involved in this process. In Italy and Bulgaria, independent expert organisations are more actively involved, and there are also social movements, which, in tandem, enable more transparent control of the quality of medical services. To improve legal regulation in this area, Kazakhstan must develop mechanisms of public control and independent expertise. At the same time, Bulgaria must strengthen state regulation to improve the efficiency of implementing existing provisions.

Finally, improving liability mechanisms for breaches of medical safety standards should be an essential area of reform. In the decentralised structure of the Servizio Sanitario Nazionale, resulting in heterogeneous application of medical liability laws and enforcement procedures across regions in Bulgaria, there are gaps in law enforcement, and Kazakhstan lacks clarity in professional liability insurance. Introducing more transparent and clear mechanisms of liability – administrative, civil, and criminal – would not only strengthen the protection of patients' rights but also create a fairer environment for health care workers, eliminating cases of unfounded accusations.

The findings of the present study demonstrate that the legal regulation of the safety of medical procedures in Bulgaria, Italy, and Kazakhstan has both common features and significant differences due to the specificity of national legal systems, economic conditions and the level of development of their healthcare systems. Comparison of the data with the results of previous studies confirms that integrating international standards into national legal systems requires continuous monitoring and adaptation of the regulatory framework, which is consistent with the findings of Ruppel et al. (2022). Introducing uniform standards and control mechanisms is the key to improving the quality of medical care and ensuring the protection of patients' rights.

4 Conclusions

The research that was conducted helped to identify the specific features and problems of legal regulation of the safety of medical procedures in Bulgaria, Italy, and Kazakhstan, as well as to assess the effects of international provisions on

national healthcare systems. In each of the countries under study, the right to healthcare is set out at the constitutional level, but the mechanisms for fulfilling those constitutional mandates differ significantly. In Bulgaria, a mixed model of public and private care with insurance-based elements prevails. In Italy, the healthcare system is based on a universal, tax-funded public model, Servizio Sanitario Nazionale, where private structures also operate under accreditation by the public sector, which ensures a strong level of standards, but also creates problems related to accessibility of medical care. Kazakhstan, on the contrary, is oriented towards state regulation, which guarantees medical services for a broad audience, but requires stronger legal protection for patients and doctors.

An analysis of national legislation has identified key problems that must be addressed. One of them is that medical professionals are inadequately protected from legal risks. Bulgaria and Kazakhstan lack effective mechanisms for professional liability insurance, leaving doctors vulnerable to legal action. In Italy, although such a system is in place, its practical implementation and effectiveness still vary across regions due to differences in the interpretation of national guidelines and the availability of insurance plans. Another problem is inadequate patient protection mechanisms. In Bulgaria, despite implementing European standards, there are still challenges in law enforcement. In Kazakhstan, legal safeguards for patient protection must be improved, especially in the context of actively introducing digital technologies. Furthermore, there is no unified approach to the regulation of the latest medical technologies. In Italy, the decentralised healthcare system enables regions to independently set requirements for innovative procedures, which leads to heterogeneity in law enforcement practice. This variability adversely affects not only access to innovation but also the consistency of legal protections across regions. In Kazakhstan, the regulation of digital medicine is just emerging, which creates potential legal gaps.

To solve these problems, it is necessary to improve legislation that considers the best international practices. Critically, developing a system of professional liability insurance for medical workers, following the example of Italy, will help protect doctors from unfounded accusations and improve the quality of medical services. It is also necessary to strengthen control over observing patients' rights, including through adoption of mechanisms that can independently assess the quality of medical care. Introducing effective dispute resolution procedures is another reform

that protects the interests of both patients and healthcare workers. A significant task is to harmonise national legal provisions with international standards. This is particularly crucial for Bulgaria within the framework of integration with the EU legal system. Italy, as an EU member, already complies with major international instruments, but should improve uniform application across its regions and reduce the disparity in enforcement practices. Furthermore, a unified legislative framework to regulate innovative medical technologies is required, as this will both minimise legal risks and increase the level of medical safety.

Thus, improving legislation in the field of safety of medical procedures should include enacting comprehensive measures to protect the rights of patients and medical workers, integrating international standards, and developing new legal mechanisms to regulate medical innovations. These steps will help improve the level of safety and quality of medical care in each of the countries under consideration and create a more effective and balanced system of regulation in this area.

The present study had certain limitations. Differences in law enforcement practices within each country complicate the proposal of universal recommendations. Furthermore, the analysis was based on existing regulations, but the dynamics of legislative changes require constant updating of data. This study focused primarily on the legal aspects of the safety of medical procedures, but further research could focus on a comprehensive analysis, including economic and social factors.

Prospects for further research in this area may be related to analysing the effectiveness of introducing digital technologies into the medical security system and investigating the legal aspects of the use of artificial intelligence in diagnostics and treatment. Also beneficial would be a comparative study of the national legislations of different countries to identify best practices and to develop unified international standards. Furthermore, a significant area of future research is to assess the effects of legal regulation on the quality of medical services and the degree of protection of patients' rights, which will help to create a more effective and balanced system of regulation in this area.

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Povzetek v slovenskem jeziku

Ta članek preučuje pravno ureditev varnosti medicinskih posegov in predlaga možnosti za zakonodajne izboljšave, oblikovane na podlagi mednarodnih standardov. Opravljena je bila primerjalnopravna analiza, ki je vključevala primere Bolgarije, Italije in Kazahstana. Študija je uporabila sistematično metodologijo za oceno pravne učinkovitosti ter napovedne tehnike za opredelitev možnih izboljšav. Ugotovitve razkrivajo, da vse tri države na ustavni ravni priznavajo pravico do zdravstvenega varstva, vendar se strategije izvajanja razlikujejo. Bolgarija in Italija uporabljata na zavarovanju temelječ zdravstveni sistem, ki vključuje sodelovanje zasebnega sektorja. Bolgarija se sooča z izzivi pri usklajevanju svoje zakonodaje z evropskimi standardi, medtem ko decentralizirani Servizio Sanitario Nazionale v Italiji povzroča regionalne razlike. Kazahstan ohranja državno usmerjen regulativni okvir, vendar mu primanjkuje celovitih pravnih zaščit za paciente in zdravstvene delavce, zlasti glede zavarovanja odgovornosti. Nobena izmed držav nima celovitega pravnega okvira za digitalno medicino. Ključni predlogi vključujejo izboljšanje zavarovalnih zaščit, uskladitev nacionalne zakonodaje z mednarodnimi standardi ter regulacijo novih medicinskih tehnologij.