The Harmonization of Criminal Responses to Medical Malpractice in Europe: Comparative and International Law Perspectives

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Abstract

This article analyzes criminal law approaches to responding to medical errors and professional negligence in the provision of medical care in several European countries: Ukraine, Moldova, Romania, Poland, and Germany. The study focuses on the legal basis for the criminal liability of medical professionals and how medical malpractice is qualified in various legal systems, including requirements for the professional standard of care, forms of culpability, establishing causation, and the use of medical examination in criminal proceedings. The article aims to identify similarities and differences in national models of criminal law responses and assess the potential for their functional convergence within the European legal space. The study employs comparative legal and formal legal analysis, as well as a functional approach, taking into account international standards and the practice of the European Court of Human Rights. The analysis demonstrates that, despite the absence of uniform criminal law provisions on medical negligence, European legal systems demonstrate convergence in terms of liability criteria and procedural guarantees. It is concluded that further harmonization is primarily associated with the agreement of standards of evidence, the role of examination and approaches to acceptable medical risk, and not with the formal unification of criminal legislation.

Keywords: *medical malpractice; criminal liability; criminal negligence; acceptable medical risk; standards of proof; comparative criminal law.*

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1. Introduction

The matter of criminal liability for medical errors and professional negligence in healthcare is becoming increasingly prominent in European legal discourse. The growing technological complexity of medicine, increasing clinical risks, cross-border patient mobility, and the rise of human rights discourse mean that adverse medical outcomes are increasingly becoming the subject of legal assessment. Under these conditions, criminal law is becoming involved in regulating relationships characterized

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by a high degree of uncertainty and probabilistic choice, challenging traditional approaches to determining fault, causation, and the professional standard of care.

The relevance of this matter stems from the need to find a balance between two competing values: the effective protection of the patient's life and health and the prevention of excessive criminalization of medical activity. Modern doctrine emphasizes that increased criminal law enforcement in the medical field can conflict with patient safety goals, stimulating the development of defensive medicine and transforming clinical behavior not through improved quality of care, but through strategies of legal self-defense.[2]

1.1. Literature Review and Theoretical Framework

In the scientific literature, medical negligence is increasingly examined through the prism of human rights standards and the principles of limiting criminal intervention. The European Convention for the Protection of Human Rights and Fundamental Freedoms does not establish specific criminal offences for medical activities, but it does impose on states the obligation to ensure effective investigation of cases of possible death or serious harm caused by medical care. The case law of the European Court of Human Rights has consistently held that the Convention does not require the automatic criminalization of every adverse medical outcome, but it does oblige states to establish effective mechanisms for finding the circumstances and liability where sufficient grounds exist.[3] An additional normative context is provided by the Convention on Human Rights and Biomedicine and, in European Union law, by Directive 2011/24/EU on patients' rights in cross-border healthcare.[4]

In the absence of unified European criminal law provisions specifically addressing medical negligence, comparative legal analysis of national liability models is crucial for doctrine and enforcement. Research shows that different legal systems address matters of acceptable medical risk, the standard of care, proof of causation, and the role of expert knowledge in criminal proceedings differently. These differences manifest themselves not so much in the wording of criminal codes as in the functioning of procedural filters in criminal prosecution and the relationship between criminal liability and civil and disciplinary mechanisms for patient protection.

Comparative doctrine emphasizes that the most developed models of criminal law response to medical errors are oriented towards the ultima principle ratio and on the

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[2] Margaret Brazier and Neil Allen, "Criminalizing Medical Malpractice," in *The Criminal Justice System and Health Care*, ed. Charles A. Erin and Suzanne Ost (Oxford: Oxford University Press, 2007), 15–28, https://doi.org/10.1093/acprof:oso/9780199228294.003.0002; Livio Garattini and Anna Padula, "Defensive Medicine in Europe: A 'Full Circle'?," *The European Journal of Health Economics* 21, no. 2 (2020): 165–170, https://doi.org/10.1007/s10198-019-01144-0.

[3] European Court of Human Rights, *Calvelli and Ciglio v. Italy* [GC], no. 32967/96, judgment of January 17, 2002; European Court of Human Rights, *Vo v. France* [GC], no. 53924/00, judgment of July 8, 2004.

[4] Council of Europe, *Convention on Human Rights and Biomedicine (ETS No. 164)* (Oviedo, April 4, 1997); Perihan Elif Ekmekci, "Patients' Rights in Cross-Border Healthcare (Directive 2011/24/EU) and How It Applies to Turkey as a Negotiating Candidate Country," *European Journal of Health Law* 24, no. 4 (2017): 432–444, https://doi.org/10.1163/15718093-12341423.

assessment of the doctor's behavior ex ante, taking into account clinical uncertainty and acceptable professional risk. In this context, the German model is seen as an example of a developed dogmatics of negligence and restrained criminal intervention, while the legal orders of Central and Eastern Europe demonstrate different trajectories of the evolution of criminal policy in the medical sphere. In post-socialist systems, including Ukraine and Moldova, criminal law often retains a more pronounced symbolic function in responding to socially sensitive medical conflicts.[5]

1.2. Research Aim and Contribution

The aim of this research is to comparatively assess the criminal law models of response to medical negligence in Ukraine, Moldova, Romania, Poland and Germany. In this regard, the article aims to analyze the following research questions: how do national criminal law systems distinguish between acceptable medical risk and criminally punishable professional negligence; what criteria for the standard of care, form of guilt and causation are used in the criminal law assessment of the behavior of a healthcare professional; what role does medical examination play in forming conclusions about the existence of criminal liability and what procedural risks are associated with its dominance; and to what extent do international standards and the practice of the European Court of Human Rights contribute to the functional convergence of national approaches to the criminal law response to medical errors.

The study's underlying hypothesis is that harmonization of criminal law responses to medical errors in Europe can be achieved primarily through the harmonization of functional criteria of liability and procedural safeguards – including standards of proof, the role of medical expertise and an understanding of acceptable professional risk – rather than through formal unification of criminal law norms.[6]

The article's scientific contribution lies in the development of a functional model for the comparative analysis of criminal liability for medical errors, shifting the focus from a formal comparison of offenses to identifying criteria that effectively define the limits of criminal interference in medical practice. This study compares the models of Ukraine, Moldova, Romania, Poland, and Germany, taking into account the standard of care, acceptable medical risk, the role of medical examination and procedural filters in criminal prosecution, as well as the influence of the practice of the European Court of Human Rights as a tool for indirect harmonization.[7]

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[5] Kenneth Watson and Rob Kottenhagen, "Patients' Rights, Medical Error and Harmonisation of Compensation Mechanisms in Europe," *European Journal of Health Law* 25, no. 1 (2018): 1–23, https://doi.org/10.1163/15718093-12460348.

[6] Anne-Maree Farrell, Amel Alghrani, and Melinee Kazarian, "Gross Negligence Manslaughter in Healthcare: Time for a Restorative Justice Approach?," *Medical Law Review* 28, no. 3 (2020): 526–548, https://doi.org/10.1093/medlaw/fwaa013.

[7] Alexandra Mullock, "Gross Negligence (Medical) Manslaughter and the Puzzling Implications of Negligent Ignorance: *Rose v R* [2017] EWCA Crim 1168," *Medical Law Review* 26, no. 2 (2018): 346–356, https://doi.org/10.1093/medlaw/fwy021.

2. Research Methodology

The methodology of this study was developed taking into account the complexity and multi-layered nature of the criminal law response to medical errors, which cannot be adequately analyzed solely through the text of the criminal law. The initial methodological premise is an understanding of medical malpractice as a phenomenon at the intersection of criminal law, medical regulation, and human rights standards. Therefore, the study relies on a combination of complementary methods of legal analysis, allowing us to integrate the normative, doctrinal, and practical dimensions of criminal liability of medical professionals.

The comparative legal method occupies a central place in the study. The comparison is conducted between the legal systems of Ukraine, Moldova, Romania, Poland, and Germany and is aimed not at a mechanical comparison of the wording of criminal codes, but at identifying the functional characteristics of criminal liability that determine its real impact on medical practice and criminal proceedings. The key parameters of comparison include criteria for distinguishing between acceptable medical risk and criminal negligence, approaches to establishing the standard of care, constructs of causality, the role of expert knowledge, and the presence of procedural filters in criminal prosecution. This functional approach is consistent with the classical principles of comparative law, which views law as a functioning system rooted in a specific legal culture and institutional context.

The formal legal method is used to analyze criminal codes and related regulatory sources defining the professional responsibilities of healthcare professionals. This method examines the elements of criminal offenses, the forms and degrees of culpability, the criteria for negligence, as well as the normative constructs of causation and acceptable professional risk. Particular attention is paid to how medical standards, clinical protocols, and rules of care are incorporated into the legal assessment of physician conduct, as it is here that the problems of legal certainty and predictability of criminal law intervention become most acute.[8]

The functional analysis is used to evaluate the practical impact of criminal law mechanisms in the medical field. In this context, national judicial practice and the results of empirical studies reflecting the impact of legal risks on clinical behavior are taken into account. In particular, research on the phenomenon of defensive medicine is used to demonstrate that the perception of the threat of liability may alter medical decisions and generate behavioral distortions unrelated to improving the quality of medical care. The use of such data is justified by the fact that criminal law in the medical field influences not only through sanctions but also through the expectations and fears of the professional community.[9]

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[8] Kenneth McK. Norrie, "Medical Negligence: Who Sets the Standard?," *Journal of Medical Ethics* 11, no. 3 (1985): 135–137, https://doi.org/10.1136/jme.11.3.135.

[9] Nathalie Baungaard et al., "How Defensive Medicine Is Defined in European Medical Literature: A Systematic Review," *BMJ Open* 12, no. 1 (2022): e057169, https://doi.org/10.1136/bmjopen-2021-057169; Maurizio Catino, "Blame Culture and Defensive Medicine," *Cognition, Technology & Work* 11, no. 4 (2009): 245–253, https://doi.org/10.1007/s10111-009-0130-y.

An important element of the methodology is the analysis of international legal sources and supranational judicial practice. The practice of the European Court of Human Rights is considered as a normative benchmark, shaping the requirements for the effectiveness of investigations, access to justice, and the reasoning of decisions in cases related to the provision of medical care, as well as a factor facilitating the functional convergence of national approaches without the formal unification of criminal norms.[10]

A system analysis allows us to consider criminal liability for medical errors in interaction with civil and disciplinary mechanisms for the protection of the patient, based on the understanding of criminal law as ultima ratio, the effectiveness and legitimacy of which depend on the state of the entire complex of legal means of response in the healthcare sector. Additionally, interpretive and critical methods are used to evaluate the identified models in terms of the principles of fairness, proportionality, and legal certainty, as well as to identify the risks of retrospective "outcome penalty" in conditions of clinical uncertainty.[11]

3. Results

3.1. Theoretical and Normative Context

The results of the analysis show that the concept of medical malpractice in the European legal tradition lacks a single normative definition and encompasses a wide range of diverse phenomena, including clinical errors, professional negligence, deficiencies in patient communication, violations of informed consent requirements, as well as organizational and systemic failures in the provision of medical care. International approaches to patient safety view error as either the incorrect performance of a medical action or the choice of an erroneous treatment strategy, with key importance being placed on the preventability of harm and the role of systemic factors in its occurrence.[12] This multifaceted nature of medical malpractice necessitates a comprehensive criminal law analysis that goes beyond the assessment of the physician's individual conduct.

The legal perspective complements managerial and medical approaches with the concepts of due diligence, predictability, and acceptable professional risk. The study's results confirm that, in the criminal law context, the distinction between an adverse treatment outcome, acceptable medical risk, and punishable negligence is crucial. The coincidence of medical intervention and harm caused is not sufficient

[10] Aart Hendriks, "European Courts: European Court of Human Rights," *European Journal of Health Law* 9, no. 4 (2002): 399–412.

[11] Henry Johansson, "The Swedish System for Compensation of Patient Injuries," *Upsala Journal of Medical Sciences* 115, no. 2 (2010): 88–90, https://doi.org/10.3109/03009730903350749.

[12] Ewoud Hondius, "Comparative Medical Liability in Europe," in *Festschrift für Hans Stoll zum 75. Geburtstag*, ed. Gottfried Hohloch, Rainer Frank, and Peter Schlechtriem (Tübingen: Mohr Siebeck, 2001), 185–194; Agatha Parks-Savage et al., "Prevention of Medical Errors and Malpractice: Is Creating Resilience in Physicians Part of the Answer?," *International Journal of Law and Psychiatry* 60 (2018): 35–39, https://doi.org/10.1016/j.ijlp.2018.07.003.

grounds for criminal liability if the healthcare professional's behavior complied with an objective professional standard and was carried out under conditions of clinical uncertainty. Thus, the criminal law analysis of medical malpractice is structured around an assessment of behavior, not solely the outcome.

In continental Europe, criminal law responses to medical negligence are typically based on the general offences of negligently causing death or bodily harm. However, a comparative analysis shows that the practical implications of these offences vary significantly. In some jurisdictions, criminal law is applied primarily in cases of gross and obvious violations of professional standards, while the primary burden of compensating for damages and responding to medical errors falls to civil and disciplinary mechanisms. In other systems, criminal law plays a more prominent role in public response and is perceived as a tool for restoring social justice in medical conflicts.[13]

Doctrinal studies indexed in Scopus and Web of Science consistently indicate that an excessive reliance on criminal prosecution in the medical field can conflict with patient safety goals. The development of a culture of individual blame and fear of legal liability reduces the willingness of medical organizations and professionals to openly report errors and engage in institutional learning from adverse outcomes. Empirical studies of the defensive medicine phenomenon demonstrate that perceptions of legal risk influence clinical behavior by increasing the tendency to over-diagnose and over-treat, as well as to avoid complex or high-risk clinical situations.[14] Although these studies do not exhaust the diversity of European contexts, they do reveal a consistent relationship between the design of criminal liability and the professional expectations of the medical community.

The international legal context for criminal law responses to medical errors is shaped primarily by the provisions of the 1950 European Convention for the Protection of Human Rights and Fundamental Freedoms. The Convention does not establish specific criminal offences for medical situations, but it does establish a framework of legal protection that is key to medical cases, in particular within Article 2 (the right to life) and its procedural dimension, Article 6 (the right to a fair trial), and Article 13 (the right to an effective remedy). The case-law of the European Court of Human Rights has developed the approach that the state is obliged to ensure an effective response system to establish the circumstances of death or serious harm caused in the provision of medical care and to ensure liability where there are sufficient grounds, while the Convention does not require an inevitable criminal conviction as a universal result.[15]

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[13] Erwin Deutsch, "Revision of the Medical Malpractice Law? Malpractice in an International Comparison," *Zeitschrift für ärztliche Fortbildung und Qualitätssicherung* 92, nos. 8–9 (1998): 574–578; Jean V. McHale, "Medical Malpractice in England: Current Trends," *European Journal of Health Law* 10, no. 2 (2003): 135–151, https://doi.org/10.1163/092902703769681597.

[14] Amel Alghrani et al., "Balancing the Scales of Safety: The Criminal Law's Impact on Patient Safety and Error Reduction," *British Journal of Oral and Maxillofacial Surgery* 62, no. 3 (2024): 229–232, https://doi.org/10.1016/j.bjoms.2023.11.018; Oliver Quick, "Outing Medical Errors: Questions of Trust and Responsibility," *Medical Law Review* 14, no. 1 (2006): 22–43, https://doi.org/10.1093/medlaw/fwi042.

[15] European Court of Human Rights, *Calvelli and Ciglio v. Italy* [GC], no. 32967/96, judgment of January 17, 2002; European Court of Human Rights, *Vo v. France* [GC], no. 53924/00, judgment of July 8, 2004.

Particular importance for criminal law analysis is the Grand Chamber's decision in the case Lopes de Sousa Fernandes v. Portugal, in which the Court clarified the criteria for the applicability of Article 2 of the Convention in medical situations. The Court drew a fundamental distinction between cases of isolated medical error and situations of systemic dysfunction in a healthcare organization that could raise the matter to the level of state responsibility. The analysis shows that this distinction influences national approaches to the classification of medical cases, stimulating attention to the institutional context of care delivery and the procedural aspects of the investigation.[16]

The 1997 Convention on Human Rights and Biomedicine, which enshrines the primacy of human dignity, informed consent, and patient safety, complements the normative framework of international standards. In European Union law, Directive 2011/24/EU on patients' rights in cross-border healthcare indirectly influences the criminal justice assessment of medical errors, as the comparability of quality and safety standards in medical care inevitably raises the matter of the legal consequences of defects in care and liability for harm caused.[17]

Taken together, the results of the analysis allow us to view the harmonization of criminal law approaches in the field of medical malpractice not as a project of formal unification of criminal codes, but as a process of gradual convergence of functional liability criteria and procedural guarantees. Comparative legal literature emphasizes that pan-European compatibility is achieved primarily through the harmonization of approaches to the standard of care, the role of expert knowledge, and the requirements for reasoning in judicial decisions, rather than through the copying of criminal law structures.

3.2. National Models of Criminal-Legal Response to Medical Errors

A comparison of national models of criminal law responses to medical errors reveals how common international guidelines and similar social challenges are transformed into different legal constructs. The analysis reveals that differences between legal systems manifest themselves not so much in the formal structure of criminal law, but rather in how clinical uncertainty is translated into the criminal law categories of guilt, causation, and professional standards of conduct. It is this translation that determines the actual boundaries of physician criminal liability and the extent of criminal law's involvement in healthcare.

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[16] Julia Kapelańska-Pręgowska, "Medical Negligence, Systemic Deficiency, or Denial of Emergency Healthcare? Reflections on the European Court of Human Rights Grand Chamber Judgment in *Lopes de Sousa Fernandes v. Portugal* of 19 December 2017 and Previous Case-Law," *European Journal of Health Law* 26, no. 1 (2019): 26–43, https://doi.org/10.1163/15718093-12550407.

[17] Council of Europe, *Convention on Human Rights and Biomedicine (ETS No. 164)* (Oviedo, April 4, 1997); Natasha Azzopardi-Muscat et al., "The Impact of the EU Directive on Patients' Rights and Cross Border Health Care in Malta," *Health Policy* 119, no. 10 (2015): 1285–1292, https://doi.org/10.1016/j.healthpol.2015.08.015.

3.2.1. Ukraine

In Ukrainian criminal law, medical errors are not defined as a separate category of crime, but are covered by general and specific criminal law provisions. The provision on improper performance of professional duties by a medical or pharmaceutical worker resulting in serious consequences is of key importance in the medical context. The analysis shows that this provision functionally links criminal liability with professional standards of medical care, including clinical protocols and treatment rules.[18]

The doctrine emphasizes that the inclusion of medical standards in the criminal law assessment of physician conduct expands the ability to respond to deficiencies in medical care, but it simultaneously complicates legal certainty, as medical standards are dynamic and multi-layered. As a result, criminal law qualification depends not only on the text of the criminal law but also on the current state of medical regulation.[19]

The practice of qualifying medical cases focuses on establishing causation and proving a violation of the standard of care. Forensic medical examination plays a key role, enhancing the importance of expert knowledge and increasing the requirements for procedural oversight of its use.[20]

3.2.2. The Republic of Moldova

The Moldovan model of criminal liability for medical negligence is similar in many ways to the Ukrainian model in its regulatory structure, as it provides for a special provision addressed to medical workers and linking criminal liability to the violation of professional requirements and the occurrence of serious consequences. At the same time, the content and scope of this norm determine its application in conjunction with the general elements of negligent causing of death or harm to health, which can be used in the classification of medical cases not covered by the special design or located in the limit of its application.

Under these conditions, the criminal law assessment of medical activity shifts significantly to the sphere of proving the content of the professional standard of conduct, the nature of its violation, as well as the causal relationship between the defects committed and the ensuing consequences. The national doctrine emphasizes that the key challenges in this area are not related to the admissibility of criminal liability per se, but to the uncertainty of the legal status of medical standards and their varying applicability across institutions and regions.

As a result, criminal law arguments often rely on bylaws and clinical protocols, the significance of which remains debatable for criminal classification purposes. Law enforcement practice demonstrates a relative restraint in criminal law enforcement in medical cases, reflecting a desire not to turn criminal proceedings into a universal

[18] Zaid Ibrahim Yousef Gharaibeh, "The Impacts of Applications of Criminal Law on Medical Practice," *Medical Archives* 76, no. 5 (2022): 377–382, https://doi.org/10.5455/medarh.2022.76.377-382.
[19] Kenneth McK. Norrie, "Medical Negligence: Who Sets the Standard?," 136.
[20] Council of Europe, *Report on Medical Liability (CDCJ)* (Strasbourg: Council of Europe, 2005–2006).

mechanism for settling medical conflicts.[21] However, given the limited effectiveness of civil compensation, criminal law retains a pronounced symbolic significance.

3.2.3. Romania

The Romanian model of criminal law response to medical errors is being developed in the context of the country's membership in the European Union and the active development of national doctrines of criminal and medical law. The Romanian Criminal Code does not provide for the specific offence of malpraxis, but it does establish liability for the negligent causing of death and injury to health, which also applies to medical activities. The analysis shows that the Romanian legal system places key importance on distinguishing between an adverse medical outcome and criminally significant professional negligence, which is consistent with pan-European approaches to limiting the criminalization of medical activities.[22]

The Romanian doctrine emphasizes that a physician's criminal liability is permissible only in the presence of a proven and substantial deviation from the professional standard of care, whereby the harm caused was objectively foreseeable and preventable. The criminal law is viewed as an ultima ratio, applicable in cases where other legal remedies fail to adequately protect the patient's rights. An analysis of judicial practice and doctrinal sources indicates increasing attention to the procedural aspects of proving causation and the role of expert knowledge, as well as consideration of the institutional context of medical care.

This orientation is consistent with the approach of the European Court of Human Rights, which distinguishes between individual medical error and systemic defects in the organization of healthcare, and promotes the interoperability of the Romanian model with international standards for the protection of human rights.

3.2.4. Poland

The Polish model of criminal liability for medical errors combines the general concepts of negligent homicide and injury to health with the application of the rules on creating an immediate danger in cases where harm has not yet occurred but the risk has been specified. The analysis shows that Polish doctrine places significant emphasis on the concept of acceptable medical risk and the need to take clinical uncertainty into account when assessing a physician's conduct under criminal law.[23]

The scientific literature emphasizes that criminal liability should not be based solely on an unfavorable treatment outcome if the physician acted in accordance with professional standards and in the patient's best interests. This approach contributes to

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[21] Jean V. McHale, "Medical Malpractice in England: Current Trends," 138.

[22] Athanasios Panagiotou, "Medical Liability in Europe at the Dawn of Cross-Border Healthcare: Time to Reflect on the Possibility of Harmonising the Policies Regarding Medical Liability?," *European Journal of Health Law* 23, no. 4 (2016): 350–372, https://doi.org/10.1163/15718093-12341390.

[23] Alexander McCall Smith, "Criminal Negligence and the Incompetent Doctor," *Medical Law Review* 1, no. 3 (1993): 336–349, https://doi.org/10.1093/medlaw/1.3.336.

the development of additional procedural filters for criminal prosecution.[24]

A distinctive feature of the Polish context is the development of compensatory and quasi-judicial mechanisms for settling medical disputes, which reduces the burden of criminal law and supports its application as an ultima ratio.[25] Violation of clinical protocol in itself is not considered automatic proof of criminal negligence, limiting the broad attribution of liability.

3.2.5. Germany

The German model of criminal liability for medical errors is characterized by a high degree of dogmatic and procedural certainty. The German Criminal Code does not contain specific provisions for medical activity, and physicians are generally liable for negligently causing death or bodily injury. The analysis shows that an objective standard of care, well-developed criteria for negligence, and strict requirements for establishing causation and attribution are crucial.[26]

This approach allows for consideration of clinical uncertainty and avoids retrospective evaluation of medical decisions from the standpoint of "perfect knowledge." Criminal proceedings are primarily used in cases of gross and obvious violations of professional duties.[27]

The majority of medical conflicts are resolved through civil and professional procedures, as well as through institutional mechanisms for ensuring the quality and safety of medical care. This reduces the pressure of criminal law on medical practice and maintains its ultima ratio nature, ensuring the interoperability of national criminal law with European standards of legal certainty and procedural efficiency.

3.3. Functional Comparison of National Models of Criminal Liability

It is advisable to compare the national models under study not through an isolated comparison of individual criminal law provisions, but by identifying the parameters that actually shape the practical framework of criminal liability for medical errors. This analysis uses six functional criteria: the nature of the criminal offense, the subject of liability, qualifying circumstances, the scope of sanctions, standards of proof, and the specifics of judicial practice.[28] It is the combination of these elements that determines the degree of criminal law's impact on medical practice and the limits of permissible criminal law intervention.

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[24] Ash Samanta and Jo Samanta, "Gross Negligence Manslaughter and Doctors: Ethical Concerns Following the Case of Dr Bawa-Garba," *Journal of Medical Ethics* 45, no. 1 (2019): 10–14, https://doi.org/10.1136/medethics-2018-104938.

[25] Henry Johansson, "The Swedish System for Compensation of Patient Injuries," 89.

[26] Erwin Deutsch, "Revision of the Medical Malpractice Law? Malpractice in an International Comparison," 575.

[27] Suzanne Ost, "Drs Bramhall and Bawa-Garba and the Rightful Domain of the Criminal Law," *Journal of Medical Ethics* 45, no. 3 (2019): 151–155, https://doi.org/10.1136/medethics-2018-105135.

[28] Athanasios Panagiotou, "Medical Liability in Europe at the Dawn of Cross-Border Healthcare: Time to Reflect on the Possibility of Harmonising the Policies Regarding Medical Liability?," 360.

A comparative legal analysis of criminal law regulation of liability for harm caused in the course of medical practice in Ukraine, Moldova, Romania, Poland, and Germany reveals different approaches to the legal framework for negligent professional liability of healthcare workers. However, the models used by legislators - both those that provide specific provisions for medical and pharmaceutical workers and those that rely on general provisions on negligent liability – do not determine in themselves the nature and intensity of the criminal law response.[29]

It is significantly important in this area the specific interpretations of relevant regulations, methods for establishing the content of professional duties and standards of medical care, and approaches to assessing the causal relationship between violations and adverse consequences. Under these circumstances, specific and general provisions on negligently causing death or harm to health operate in conjunction with each other, complementing each other and being applied based on the specific circumstances of the case.

The Polish model deserves special attention. It uses, in addition to assessing the actual harm caused, the concept of criminal liability for creating an immediate danger to life or health. This allows for situations where a socially dangerous risk has been specified, but no harm has occurred.[30] Overall, the comparative analysis suggests that the decisive role in shaping the criminal law response is played not so much by formal differences in the construction of the offences, but by law enforcement practice and doctrinal approaches to interpreting negligent medical practice.

In terms of the subject of liability, individual criminal liability of the individual healthcare worker predominates in all five legal systems. However, differences emerge in the extent to which law enforcement takes into account the institutional context of healthcare delivery. In Germany and, to a significant extent, Romania, attention to organizational and systemic factors is more pronounced, consistent with international standards distinguishing between individual medical error and systemic healthcare dysfunction.

In Ukraine and Moldova, individualization of liability is more pronounced, reflecting public expectations of a personalized "response" in the event of serious outcomes and the lower institutional density of alternative response mechanisms. Qualifying circumstances in all the systems under consideration largely correlate with the severity of the consequences, but the legal and procedural filters for their application differ significantly.[31]

In legal systems where the standard of care and causation are more dogmatically and procedurally developed, criminal classification is less dependent on the worst possible outcome. In the German model, this is achieved through strict requirements for reconstructing the clinical situation at the time of medical intervention and a restrained attitude toward retrospective assessment. In Polish law, a similar function is served by

[29] Erwin Deutsch, "Revision of the Medical Malpractice Law? Malpractice in an International Comparison," 576.
[30] Alexander McCall Smith, "Criminal Negligence and the Incompetent Doctor," 340.
[31] Kenneth Watson and Rob Kottenhagen, "Patients' Rights, Medical Error and Harmonisation of Compensation Mechanisms in Europe," 15.

distinguishing between acceptable medical risk and criminal negligence.[32] In Ukraine and Moldova, the vulnerability manifests itself in the greater reliance of criminal law assessment on expert opinion and the limited institutionalization of alternative means of restoring justice, which increases pressure on the criminal process.

The sanctions frameworks are generally comparable and consistent with the continental criminal law model, providing for imprisonment, restriction of liberty, or a fine, often with additional measures such as a ban on professional activity. However, a comparative analysis shows that in medical cases, sanctions rarely serve as the primary regulator of behavior. The real differences between the more "restrained" and more "interventional" models arise from evidentiary standards, the structure of expert examinations, and procedural guarantees, rather than from maximum sentences.[33]

Standards of evidence and the role of medical expertise are a key dividing factor between national models, as confirmed by comparative studies of physician criminal liability and medical risk in European law. In all legal systems studied, expert knowledge is a necessary element of criminal proceedings, but the degree of its procedural review varies significantly. Where the court maintains an active role in assessing expert findings and compares them with legal criteria of guilt and causation, the risk of retrospective attribution of liability based on the outcome is reduced.[34]

In systems where expert opinion effectively predetermines the legal conclusion, the risk of expert monopoly and a shift in emphasis from behavioral analysis to outcome assessment increases. International standards, primarily the practice of the European Court of Human Rights, strengthen requirements for procedural integrity and a motivated investigation, which indirectly stimulates an improvement in the quality of evidentiary argumentation in medical cases.

A comparison of judicial practice reveals that the most high-profile criminal cases in all legal systems center on serious medical outcomes. In Germany, criminal proceedings are used primarily in cases of gross violations of professional duties, while the majority of medical disputes are resolved through civil and professional mechanisms.[35] In Poland and Romania, there is a trend toward strengthening procedural filters and developing alternative forms of response. In Ukraine and Moldova, the limited effectiveness of civil and disciplinary instruments increases the public burden on criminal law and contributes to its perception as the primary channel for restoring justice.

4. Discussion

A comparison of the five legal systems examined confirms that differences in criminal law responses to medical errors are only limited by the wording of criminal

[32] Alexandra Mullock, "Gross Negligence (Medical) Manslaughter and the Puzzling Implications of Negligent Ignorance: *Rose v R* [2017] EWCA Crim 1168," 350.
[33] Anne-Maree Farrell, Amel Alghrani, and Melinee Kazarian, "Gross Negligence Manslaughter in Healthcare: Time for a Restorative Justice Approach?," 530.
[34] Aart Hendriks, "European Courts: European Court of Human Rights," 401.
[35] Suzanne Ost, "Drs Bramhall and Bawa-Garba and the Rightful Domain of the Criminal Law," 152.

codes. A significantly more significant factor is how national legal systems translate clinical uncertainty into criminal law categories—primarily, fault, causation, and the professional standard of care. It is at this level that the real boundaries of physician criminal liability and the extent of permissible criminal law intervention in medical practice are determined.

In legal systems with a developed dogma of negligence and established criteria for an objective standard of conduct, particularly in Germany, criminal law analysis is focused on reconstructing the situation of medical decision-making ex ante. This approach allows criminal law to be kept in the ultima ratio mode and limits retrospective attribution of liability based primarily on an unfavorable treatment outcome. In countries with post-socialist legal systems, including Ukraine and Moldova, criminal law assessment of medical cases relies to a greater extent on expert opinion and on the social demand for personalized liability in the event of serious consequences.

As a result, the risk increases that the line between an unavoidable complication, an acceptable clinical error, and criminally punishable negligence is drawn post factum and unevenly, which reduces the predictability of law enforcement and increases the tension between the goals of patient safety and criminal repression. In the broader European context, there is a persistent trend toward shifting the focus from the admissibility of physician criminal liability per se to the criteria for just criminal intervention.[36]

Contemporary Western European doctrine emphasizes that the key issue lies not in the existence of a criminal prohibition, but in the quality of filters that distinguish punishable negligence from errors committed within the framework of acceptable medical risk and limited healthcare resources. The study's results indicate that Poland and Romania are more focused on strengthening such filters through the development of alternative compensation mechanisms and professional oversight, which reduces pressure on the criminal process and helps preserve its character as a measure of last resort.

In Ukraine and Moldova, functional harmonization is hampered by the lower institutional density of civil and disciplinary mechanisms, as a result of which public expectations of justice are more often transformed into demands for criminal prosecution. The phenomenon of defensive medicine is of particular importance for the interpretation of the obtained results, as it demonstrates how legal risks are transformed into clinical decisions.[37]

Large empirical studies conducted in various jurisdictions confirm the link between the perception of the threat of liability and the tendency of physicians to engage in defensive behavior, including excessive diagnostic or therapeutic interventions and the avoidance of difficult clinical cases. European systematic reviews emphasize the heterogeneity of the definition of defensive medicine and the need for caution in transferring empirical findings across countries, but confirm the general mechanism by which legal risk influences professional behavior. These data indicate that the design of criminal liability influences medical practice not only through sanctions but also

[36] Margaret Brazier and Neil Allen, "Criminalizing Medical Malpractice," 20.
[37] Livio Garattini and Anna Padula, "Defensive Medicine in Europe: A 'Full Circle'?," 167.

through the formation of expectations and strategies of professional behavior.

The role of international standards in this area is manifested not as a requirement to expand criminalization, but as an obligation of the state to ensure an effective and procedurally fair system for protecting patients' rights. The case-law of the European Court of Human Rights consistently assumes that the state is obliged to ensure the effective establishment of the circumstances of death or serious harm and access to justice, but does not consider criminal prosecution as a universal and inevitable response to every adverse medical outcome.[38]

Of particular significance is the Court's position in the case of Lopes de Sousa Fernandes v. Portugal, which drew a fundamental distinction between an isolated medical error and a systemic dysfunction in the organization of healthcare. This distinction allows for a new assessment of the role of institutional factors in medical tragedies and establishes a procedural "corridor" for functional harmonization: while maintaining national autonomy of substantive criminal law, states must ensure comparable effectiveness of investigation and protection of rights.[39]

Taken together, the obtained results show that harmonization problems are most acute in legal systems with diverse historical experiences and varying symbolic weight of criminal law. Where trust in civil and disciplinary mechanisms remains low, criminal law inevitably becomes the primary channel for public expectations of justice, leading to its more active and expansive application. Consequently, the functional harmonization of criminal law responses to medical errors requires not only adjusting the criteria for criminal liability but also strengthening alternative patient protection mechanisms.[40]

5. Conclusions

A comparative analysis suggests that criminal law responses to medical errors in Europe are shaped by a persistent tension between two equally important goals: effectively protecting the life and health of patients and preventing excessive criminalization of professional medical activity. The study's results demonstrate that, despite the regulatory heterogeneity of the legal systems of Ukraine, Moldova, Romania, Poland, and Germany, their enforcement reveals similar structural elements that are crucial to practice. These include the definition of professional standards of care, establishing causality in conditions of clinical uncertainty, the role of medical examination in criminal proceedings, and the relationship between criminal liability and other forms of legal response. It is these elements, rather than differences in terminology and the formal constructions of criminal codes, that largely determine the actual boundaries of criminal interference in medical activity.

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[38] European Court of Human Rights, *Vo v. France* [GC], no. 53924/00, judgment of July 8, 2004.

[39] European Court of Human Rights, *Lopes de Sousa Fernandes v. Portugal* [GC], no. 56080/13, judgment of December 19, 2017; Julia Kapelańska-Pręgowska, "Medical Negligence, Systemic Deficiency, or Denial of Emergency Healthcare? Reflections on the European Court of Human Rights Grand Chamber Judgment in *Lopes de Sousa Fernandes v. Portugal* of 19 December 2017 and Previous Case-Law," 30.

[40] Oliver Quick, "Outing Medical Errors: Questions of Trust and Responsibility," 30.

A comparative analysis confirms that the differences between the models under study are primarily functional. Germany demonstrates a strong focus on the ultima ratio principle through a developed dogmatic approach to negligence, strict standards of proof, and the effective interaction of criminal law with civil and professional liability mechanisms. Poland and Romania, while maintaining common criminal offences of negligence, have consistently strengthened procedural filters for criminal prosecution and developed alternative patient protection mechanisms, increasing the functional compatibility of their models with Western European approaches. In Ukraine and Moldova, criminal prosecution continues to play a more pronounced symbolic role in medical cases, which is associated with institutional deficiencies in civil and disciplinary mechanisms and a higher dependence of criminal law qualifications on the expert element.

This confirms the hypothesis put forward in the study that the prospects for harmonization are associated primarily with the harmonization of liability criteria and procedures, rather than with the unification of the elements of crimes. Practical guidelines for harmonizing criminal law approaches to medical negligence in Europe should be formulated at the level of functional standards.

A significant area is the development of common benchmarks for assessing professional standards of care and acceptable medical risk, including in the form of recommendations and guidelines applicable to courts and experts without transforming them into rigid criminal law constructs. A second area is increasing the transparency and procedural oversight of medical examinations, including requirements for the justification of expert opinions and their connection to the specific clinical context, which reduces the risk of expert monopoly and retrospective "punishment for the outcome".[41]

A third area is strengthening alternative mechanisms for compensation and disciplinary action, since their institutional effectiveness allows criminal law to retain its ultima ratio character and reduces the risk of defensive medicine, as confirmed by empirical studies of the impact of legal risk on clinical decisions.

Prospects for the further development of the scientific and political-legal agenda are associated with the deepening of interdisciplinary research combining criminal law, medical ethics, sociology, and healthcare economics, as well as the accumulation of European empirical data on the impact of legal liability models on clinical behavior and patient safety culture. In the political-legal dimension, the development of forms of European cooperation that ensure the harmonization of procedural standards and approaches to evidence while maintaining national autonomy in substantive criminal law remains a pressing task.[42]

In this context, the further evolution of the case law of the European Court of Human Rights and the deepening of the dialogue between national courts and European institutions can play a key role in the formation of a balanced and interoperable model

[41] Aart Hendriks, "European Courts: European Court of Human Rights," 402.
[42] Perihan Elif Ekmekci, "Patients' Rights in Cross-Border Healthcare (Directive 2011/24/EU) and How It Applies to Turkey as a Negotiating Candidate Country," 435.

of criminal-law response to medical malpractice in Europe.[43]

This study has certain limitations due to its methodological design. The analysis deliberately focuses on the normative, doctrinal, and judicial dimensions of criminal liability for medical errors and does not involve a quantitative or statistical study of judicial practice in the jurisdictions under consideration. Furthermore, the comparative framework is limited to five European legal orders, selected as representative of different legal traditions and institutional contexts, which does not allow for capturing the full diversity of national models in Europe.[44] These limitations do not affect the validity of the study's main findings, but they do indicate avenues for further research, in particular empirical studies of law enforcement and a more detailed analysis of the interaction of criminal, civil, and disciplinary mechanisms in healthcare.

Bibliography

I. Doctrine and legislation

1. Alghrani, Amel, Umar Rehman, Mohammad S. Sarwar, and Peter A. Brennan. "Balancing the Scales of Safety: The Criminal Law's Impact on Patient Safety and Error Reduction." *British Journal of Oral and Maxillofacial Surgery* 62, no. 3 (2024): 229–232. https://doi.org/10.1016/j.bjoms.2023.11.018.
2. Azzopardi-Muscat, Natasha, et al. "The Impact of the EU Directive on Patients' Rights and Cross Border Health Care in Malta." *Health Policy* 119, no. 10 (2015): 1285–1292. https://doi.org/10.1016/j.healthpol.2015.08.015.
3. Baungaard, Nathalie, et al. "How Defensive Medicine Is Defined in European Medical Literature: A Systematic Review." *BMJ Open* 12, no. 1 (2022): e057169. https://doi.org/10.1136/bmjopen-2021-057169.
4. Brazier, Margaret, and Neil Allen. "Criminalizing Medical Malpractice." In *The Criminal Justice System and Health Care*, edited by Charles A. Erin and Suzanne Ost, 15–28. Oxford: Oxford University Press, 2007. https://doi.org/10.1093/acprof:oso/9780199228294.003.0002.
5. Catino, Maurizio. "Blame Culture and Defensive Medicine." *Cognition, Technology & Work* 11, no. 4 (2009): 245–253. https://doi.org/10.1007/s10111-009-0130-y.
6. Council of Europe. *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (ETS No. 164).* Strasbourg: Council of Europe, 1997. https://rm.coe.int/168007cf98.
7. Council of Europe. *Report on Medical Liability (CDCJ).* Strasbourg: Council of Europe, 2005–2006. https://rm.coe.int/1680700281.
8. Deutsch, Erwin. "Revision of the Medical Malpractice Law? Malpractice in an International Comparison." *Zeitschrift für ärztliche Fortbildung und Qualitätssicherung* 92, nos. 8–9 (1998): 574–578.
9. Ekmekci, Perihan Elif. "Patients' Rights in Cross-Border Healthcare (Directive 2011/24/EU) and How It Applies to Turkey as a Negotiating Candidate Country." *European Journal of Health Law* 24, no. 4 (2017): 432–444. https://doi.org/10.11

[43] European Court of Human Rights, *Lopes de Sousa Fernandes v. Portugal* [GC], no. 56080/13, judgment of December 19, 2017.
[44] Ewoud Hondius, "Comparative Medical Liability in Europe," 189.

63/15718093-12341423.
10. European Parliament and Council of the European Union. "Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the Application of Patients' Rights in Cross-Border Healthcare." *Official Journal of the European Union* L 88 (April 4, 2011): 45–65. https://eur-lex.europa.eu/eli/dir/2011/24/oj/eng.
11. Farrell, Anne-Maree, Amel Alghrani, and Melinee Kazarian. "Gross Negligence Manslaughter in Healthcare: Time for a Restorative Justice Approach?" *Medical Law Review* 28, no. 3 (2020): 526–548. https://doi.org/10.1093/medlaw/fwaa013.
12. Garattini, Livio, and Anna Padula. "Defensive Medicine in Europe: A 'Full Circle'?" *The European Journal of Health Economics* 21, no. 2 (2020): 165–170. https://doi.org/10.1007/s10198-019-01144-0.
13. Gharaibeh, Zaid Ibrahim Yousef. "The Impacts of Applications of Criminal Law on Medical Practice." *Medical Archives* 76, no. 5 (2022): 377–382. https://doi.org/10.5455/medarh.2022.76.377-382.
14. Hendriks, Aart. "European Courts: European Court of Human Rights." *European Journal of Health Law* 9, no. 4 (2002): 399–412.
15. Hondius, Ewoud. "Comparative Medical Liability in Europe." In *Festschrift für Hans Stoll zum 75. Geburtstag*, edited by Gottfried Hohloch, Rainer Frank, and Peter Schlechtriem, 185–194. Tübingen: Mohr Siebeck, 2001.
16. Johansson, Henry. "The Swedish System for Compensation of Patient Injuries." *Upsala Journal of Medical Sciences* 115, no. 2 (2010): 88–90. https://doi.org/10.3109/03009730903350749.
17. Kapelańska-Pręgowska, Julia. "Medical Negligence, Systemic Deficiency, or Denial of Emergency Healthcare? Reflections on the European Court of Human Rights Grand Chamber Judgment in *Lopes de Sousa Fernandes v. Portugal* of 19 December 2017 and Previous Case-Law." *European Journal of Health Law* 26, no. 1 (2019): 26–43. https://doi.org/10.1163/15718093-12550407.
18. McCall Smith, Alexander. "Criminal Negligence and the Incompetent Doctor." *Medical Law Review* 1, no. 3 (1993): 336–349. https://doi.org/10.1093/medlaw/1.3.336.
19. McHale, Jean V. "Medical Malpractice in England: Current Trends." *European Journal of Health Law* 10, no. 2 (2003): 135–151. https://doi.org/10.1163/092902703769681597.
20. Mullock, Alexandra. "Gross Negligence (Medical) Manslaughter and the Puzzling Implications of Negligent Ignorance: *Rose v R* [2017] EWCA Crim 1168." *Medical Law Review* 26, no. 2 (2018): 346–356. https://doi.org/10.1093/medlaw/fwy021.
21. Norrie, Kenneth McK. "Medical Negligence: Who Sets the Standard?" *Journal of Medical Ethics* 11, no. 3 (1985): 135–137. https://doi.org/10.1136/jme.11.3.135.
22. Ost, Suzanne. "Drs Bramhall and Bawa-Garba and the Rightful Domain of the Criminal Law." *Journal of Medical Ethics* 45, no. 3 (2019): 151–155. https://doi.org/10.1136/medethics-2018-105135.
23. Panagiotou, Athanasios. "Medical Liability in Europe at the Dawn of Cross-Border Healthcare: Time to Reflect on the Possibility of Harmonising the Policies Regarding Medical Liability?" *European Journal of Health Law* 23, no. 4 (2016): 350–372. https://doi.org/10.1163/15718093-12341390.
24. Parks-Savage, Agatha, et al. "Prevention of Medical Errors and Malpractice: Is Creating Resilience in Physicians Part of the Answer?" *International Journal of Law and Psychiatry* 60 (2018): 35–39. https://doi.org/10.1016/j.ijlp.2018.07.003.
25. Quick, Oliver. "Outing Medical Errors: Questions of Trust and Responsibility."

Medical Law Review 14, no. 1 (2006): 22–43. https://doi.org/10.1093/medlaw/fwi042.
26. Samanta, Ash, and Jo Samanta. "Gross Negligence Manslaughter and Doctors: Ethical Concerns Following the Case of Dr Bawa-Garba." *Journal of Medical Ethics* 45, no. 1 (2019): 10–14. https://doi.org/10.1136/medethics-2018-104938.
27. Watson, Kenneth, and Rob Kottenhagen. "Patients' Rights, Medical Error and Harmonisation of Compensation Mechanisms in Europe." *European Journal of Health Law* 25, no. 1 (2018): 1–23. https://doi.org/10.1163/15718093-12460348.

II. Judicial Decisions

1. *Calvelli and Ciglio v. Italy* [GC], no. 32967/96, Judgment of January 17, 2002, European Court of Human Rights. https://hudoc.echr.coe.int/eng?i=001-60329.
2. *Lopes de Sousa Fernandes v. Portugal* [GC], no. 56080/13, Judgment of December 19, 2017, European Court of Human Rights. https://hudoc.echr.coe.int/eng?i=001-179556.
3. *Vo v. France* [GC], no. 53924/00, Judgment of July 8, 2004, European Court of Human Rights. https://hudoc.echr.coe.int/fre?i=002-4246.