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Compensation for damage caused by medical error in private international law: Comparative legal analysis

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Abstract
This study aimed to conduct a systematic, comparative legal analysis of approaches to determining the legal grounds for compensating for damage caused by medical errors in legal relationships involving a foreign element. Comparative legal, formal legal and conflict-of-laws methods were employed, alongside case study and typological methods, to analyse regulatory frameworks and judicial practice in the field of medical liability. The comparative analysis revealed that, although they differ in the normative formulation of the standard of medical care and the mechanisms for its procedural proof, the legal systems under consideration all retain the principle of fault as a mandatory condition for civil liability for medical harm. The German model was found to ensure the highest degree of legal certainty due to the codification of the treatment contract and statutorily defined presumptions. The Czech model was found to institutionalise treatment as a specific contractual type, applying the criterion of care provided in accordance with generally recognised professional medical standards, and allowing for the concurrence of contractual and tortious qualifications. The French model was found to combine the classical construction of civil liability with an institutional mechanism for compensating harm through national solidarity, implemented via the Office national d'indemnisation des accidents médicaux (ONIAM) system. The Italian model was found to be characterised by

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differentiated liability between medical practitioners and healthcare institutions following legislative reform on patient safety. On the basis of the comparative analysis, a generalised model of proof in medical disputes involving a foreign element was formulated, integrating the following components: substantive grounds of liability determined by contractual or tortious qualification; procedural mechanisms of proof, including presumptions, expert evidence, and redistribution of the burden of proof; and transnational factors, taking into account the application of conflict-of-laws rules, the lex fori principle, and supranational mechanisms of the European Union concerning jurisdiction and the taking of evidence. The practical significance of the findings lies in their potential use by courts and legal representatives for forecasting the risks of refusal to recognise and enforce judgments in cross-border medical disputes

Keywords:
presumption; fault; treatment contract; medical liability/medical malpractice; private international law

Introduction

The growth in cross-border population mobility, medical tourism and the digitalisation of healthcare services has led to an increase in legal relationships associated with the provision of medical care involving a foreign element. Patients receive treatment outside their country of habitual residence, conclude contracts with foreign clinics, and use telemedicine services operating across multiple jurisdictions. Under such conditions, the issue of compensation for damage caused by medical error extends beyond national tort law and acquires a dimension of private international law.

The problem lies in the complexity of determining the correct jurisdiction and applicable law, as well as the mechanisms for recognising and enforcing judicial decisions in cases of medical liability involving a foreign element. For example, a medical error may occur in one state, the patient may be a citizen of another state, and the insurance company may be registered in a third state. In such circumstances, the question arises as to which state's law should govern liability grounds, compensation scope, and limitation periods. The absence of a unified approach leads to the fragmentation of judicial practice and inequality in the legal position of the parties involved. At the same time, the complexity of cross-border medical disputes stems from the need to define the standard of medical care and the criteria for establishing a medical error in different legal systems. Standards of treatment, the scope of a physician's professional duties, rules on informed consent and the limits of acceptable professional risk differ depending on national legal regulation. This directly affects the assessment of unlawfulness and the causal link between the actions of a medical professional and the resulting harm. The lack of harmonised approaches to defining the standard of medical care makes it difficult to provide an equal level of protection for patients' rights in cross-border legal relations.

Scholarly discourse on compensation for damage caused by medical errors has shifted from a purely substantive analysis of tort liability to a more comprehensive understanding of the standard of proof, causation and allocation of burden. K. Hajková (2024) showed that causal uncertainty in medical disputes is not just a procedural issue, but a systemic feature of these types of case. The researcher showed that the traditional model of requiring full proof of causation does not reflect the nature of medical interventions, where outcomes are affected by various factors. Consequently, the researcher concluded that the standard of proof could be adjusted through presumptions and the redistribution of the burden of proof. C. Campiglio (2024) showed that the development of cross-border telemedicine within the European Union has led to the partial harmonisation of professional and product liability approaches. However, this harmonisation is incomplete. The author revealed that regulatory fragmentation persists in defining the standard of due care and the limits of physicians' professional autonomy. It was concluded that the cross-border nature of medical services creates jurisdictional competition and complicates the determination of applicable law. M. Kvirkvia (2025) demonstrated, in a comparative study of the burden of proof, that European legal systems are gradually moving away from the rigid "*onus probandi incumbit actori*" model in medical disputes. They found that flexible models of burden redistribution had been introduced in cases of informational asymmetry or breaches of the duty to maintain medical records in the legal systems of Germany, France, and Italy. These findings confirm a trend towards strengthening procedural protection for patients. T. Holčapek *et al*. (2023) demonstrated that the rapid development of telemedicine necessitates a re-evaluation of the traditional standard of medical care. The authors found that digital communication formats change the way professional risk is structured and make it more difficult to assess whether a physician's conduct is adequate. They concluded that criteria for evaluating professional activity must be adapted to new technological conditions.

O.O. Mendelia (2022) developed an approach to civil liability for medical errors under Ukrainian law, emphasising that the presumption of fault does not negate the obligation to prove unlawfulness and causation. The author substantiated that the national model combines elements of tort liability with procedural guarantees of adversarial proceedings. P.G. Peters (2024)

showed that modernising the standard of medical negligence in American law must consider the evolution of clinical practice and evidence-based medicine. The author found that excessive formalisation of the standard could distort the assessment of professional conduct and increase procedural costs. Particular attention was paid to the role of expert opinion as decisive proof. A.V. Shevel *et al*. (2023) distinguished between the concepts of 'medical error' and 'medical negligence', showing that not every adverse treatment outcome constitutes grounds for legal liability. The authors emphasised the importance of establishing deviation from the professional standard as a key liability criterion and concluded that clear normative delineation of the limits of fault is necessary. However, the issue of how these concepts are qualified across borders and their impact on applicable law remains insufficiently explored. M. Šolc (2022) analysed the context of the pandemic and substantiated that the standard of due medical care must be assessed in light of the dynamics of scientific knowledge and resource constraints. The author concluded that retrospectively evaluating a physician's actions without considering the context creates a risk of unjustly imposing liability. Conversely, V. Myronenko & M. Skrynyk (2022) found that the improper performance of professional duties by medical and pharmaceutical workers in Ukraine is associated with challenges in establishing the subjective element of the offence, as well as insufficient specialised procedural mechanisms. They emphasised the need to improve the regulatory framework to enhance the effectiveness of combatting offences in the medical sphere.

Thus, analysis of scholarly sources shows that considerable depth has been given to the issues of the standard of medical care, causal uncertainty and allocation of the burden of proof. However, the interrelation of these elements with the mechanisms of private international law, namely the determination of applicable law, jurisdictional competition and the recognition and enforcement of judicial decisions, remains insufficiently systematised.

This article aims to conduct a comparative legal analysis of the mechanisms used to determine applicable law and the conditions for compensating for damage caused by medical errors involving a foreign element. To this end, the following research objectives were defined: analysing theoretical approaches to qualifying medical errors in cross-border legal relations as a basis for contractual or non-contractual liability, and identifying the specific features of determining the standard of medical care and proving fault in different legal systems.

Materials and Methods

The study was conducted within the framework of a qualitative comparative legal analysis. The sample included the legal systems of the Czech Republic, Germany, France and Italy, which are continental legal orders that have developed different normative constructions for regulating liability in the field of medical activity and for compensating harm caused by improper medical care. The legal categories of "medical error", "standard of medical care", "informed consent", "fault" and "models of compensation" were systematised using the comparative legal method. Within the Czech legal system, the analysis was based on the provisions of the Civil Code of the Czech Republic[1], particularly those concerning contracts for the provision of medical care, as well as the Law of the Czech Republic No. 372/2011[2], which defines the duty to inform patients and the conditions for lawful medical intervention. The German model was examined based on the provisions of the Civil Code of Germany[3], including the rules concerning treatment contracts, the standard of due medical care and the allocation of the burden of proof in disputes relating to medical errors. The French legal order was analysed in relation to the provisions of the Public Health Code of the French Republic[4], which define patients' rights, the conditions for informed consent and the organisational mechanisms for compensating for harm. It was also analysed in relation to Law of the French Republic No. 2002-303[5]. The Italian model was examined based on Law of the Italian Republic No. 24[6] and Law of the Italian Republic No. 219[7], which establish the legal framework for the liability of medical professionals, the duty to inform patients, and the conditions for the lawfulness of medical intervention.

The formal legal method was employed to analyse EU legal acts that regulate the procedural and conflict-of-laws aspects of cross-border medical liability disputes, as well as the national legislation of Member States. The provisions of the following regulations were

[1] Civil Code of the Czech Republic. (2012, February). Retrieved from https://www.refworld.org/legal/legislation/natlegbod/2012/122919.
[2] Law of the Czech Republic No. 372/2011 "On Health Services and Conditions of Their Provision". (2011, December). Retrieved from https://www.zakonyprolidi.cz/translation/cs/2011-372?langid=1033.
[3] Civil Code of Germany. (1896, August). Retrieved from https://www.gesetze-im-internet.de/englisch_bgb/englisch_bgb.html.
[4] Public Health Code of the French Republic. (2002, March). Retrieved from https://www.legifrance.gouv.fr/codes/texte_lc/LEGITEXT000006072665.
[5] Law of the French Republic No. 2002-303 "On Patients' Rights and the Quality of the Health System". (2002, March). Retrieved from https://www.legifrance.gouv.fr/loda/id/JORFTEXT000000227015.
[6] Law of the Italian Republic No. 24 "On Patient Safety and Professional Liability of Healthcare Professionals". (2017, March). Retrieved from https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:legge:2017-03-08;24.
[7] Law of the Italian Republic No. 219 "On Informed Consent and Advance Healthcare Directives". (2017, December). Retrieved from https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:legge:2017-12-22;219.

examined: Regulation of the European Parliament and of the Council No. 2020/1783[1]; General Data Protection Regulation[2]; Regulation of the European Parliament and of the Council No. 910/2014[3]; Directive of the European Parliament and of the Council No. 2011/24/EU[4]; and Regulation of the European Parliament and of the Council No. 1215/2012[5]. The conflict-of-laws method was used to analyse the conflict-of-laws aspects of determining applicable law in medical harm disputes. The case study method was employed to empirically analyse judicial practice in medical liability cases involving an international element, and to identify practical approaches to allocating the burden of proof, establishing causation and assessing the standard of medical care. The following decisions were analysed in particular: the judgment of the Bundesgerichtshof in case VI ZR 108/23 (Federal Court of Justice of Germany, 2024); the decision of the Decision of the Court of Cassation of France No. 19-15.035[6]; the Judgment of the Supreme Court of the Czech Republic No. 25 Cdo 2937/2020[7]; and the decision of the Corte di Cassazione, Sez. III, No. 28985/2019 (Di Massimo, 2019).

The typological method was then used to create a generalised model of the relationship between contractual and tortious grounds of liability, methods of normatively fixing the standard of medical care and mechanisms for adjusting the burden of proof. The criteria for typologisation included the dominant liability model; the level of codification of the standard of treatment; the presence or absence of specific presumptions; the role of medical documentation and expert evidence; and the degree of integration between substantive standards and procedural guarantees.

Results

The standard of medical care and the peculiarities of proving fault in medical error cases. The concept of "medical error" as a basis for liability shapes the way authors establish fault and causation, as well as the overall structure of the case. This includes determining which rules, whether contractual or tortious, apply, the possibility of relying on both grounds simultaneously, the applicable limitation period, the scope of compensation, and the elements that constitute the civil wrong (Gutorova *et al*., 2019). From a comparative perspective, three approaches can be distinguished: contractual (breach of the terms of the therapeutic obligation); tortious (causing harm to life and health as absolute values); and mixed (simultaneous relevance of both contractual and tortious rules, depending on the factual circumstances and the claims advanced).

The starting point of the continental model, which includes the Czech Republic and Germany, is the idea of a "dual" nature of the doctor-patient relationship. Treatment is provided within the framework of obligations (a contract for the provision of medical care), but any resulting injury to health is protected by tort law. The Czech approach demonstrates a more pronounced institutionalisation of treatment as a specific type of contract, making it possible to speak specifically of contractual liability for breach of the duty to provide care in accordance with professional standards, while preserving the possibility of relying on general tortious grounds. Medical services are provided on the basis of a contract for the provision of medical care, which is a specific type of contract regulated by § 2636 of the Civil Code of the Czech Republic[8]. Depending on the chosen legal construction, the claimant can either claim for breach of a contractual obligation or for breach of a statutory duty. This creates a normative basis for concurrence of grounds in the sense of procedural alternatives: the same factual event (improper treatment) can be described in terms of breach of a contractual obligation (defective service) or in terms of tort (causing harm to health through breach of the duty to act properly). This choice affects the structure of proof, the scope of compensation and the applicable limitation periods.

As in other areas of civil law, liability for medical harm in Germany is based on the principle of fault. However, the law specifically regulates matters of proof in cases of medical error. For example, § 630h of the Civil Code of Germany[9] sets out rules for allocating the burden of proof that deviate from the general model. Notably, when a gross treatment error (grober Behandlungsfehler) is proven, a presumption of causation be-

[1] Regulation of the European Parliament and of the Council No. 2020/1783 "On Cooperation Between the Courts of the Member States in the Taking of Evidence in Civil or Commercial Matters (Recast)". (2020, November). Retrieved from https://surl.li/bjgoka.
[2] General Data Protection Regulation. (2016, April). Retrieved from https://eur-lex.europa.eu/eli/reg/2016/679/oj.
[3] Regulation of the European Parliament and of the Council No. 910/2014 "On Electronic Identification and Trust Services for Electronic Transactions in the Internal Market (eIDAS Regulation)". (2014, July). Retrieved from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0910.
[4] Directive of the European Parliament and of the Council No. 2011/24/EU "On the Application of Patients' Rights in Cross-Border Healthcare". (2011, March). Retrieved from https://eur-lex.europa.eu/eli/dir/2011/24/oj.
[5] Regulation of the European Parliament and of the Council No. 1215/2012 "On Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters (Recast)". (2012, December). Retrieved from https://eur-lex.europa.eu/eli/reg/2012/1215/oj.
[6] Decision of the Court of Cassation of France No. 19-15.035. (2021, October). Retrieved from https://www.legifrance.gouv.fr/juri/id/JURITEXT000044183628.
[7] Judgment of the Supreme Court of the Czech Republic No. 25 Cdo 2937/2020. (2022, October). Retrieved from https://www.zakonyprolidi.cz/judikat/nscr/25-cdo-2937-2020.
[8] Civil Code of the Czech Republic. (2012, February). Retrieved from https://www.refworld.org/legal/legislation/natlegbod/2012/122919.
[9] Civil Code of Germany. (1896, August). Retrieved from https://www.gesetze-im-internet.de/englisch_bgb/englisch_bgb.html.

tween the breach and the harm is permitted, and the burden of proving that there is no causal link falls upon the defendant. Similarly, if the physician has failed to properly document the treatment, the court may assume that the relevant medical measures were not carried out. Therefore, while German law does not abandon the principle of fault, it redistributes the burden of proof in cases where the patient lacks access to full information about the course of treatment by means of special presumptions. The German model is illustrative of a mixed system offering a high level of legal certainty, as it combines a clear typology of the treatment contract (Behandlungsvertrag) with general tort liability for violations of absolute rights, while also codifying specific rules of proof in cases of medical error. The central provision in this sphere is § 630a of the Civil Code of Germany[1], which normatively defines the physician's duties in relation to treatment and documentation of medical intervention, whereas § 630h specifies the procedural aspects of allocating the burden of proof in cases concerning treatment and informational breaches, including the establishment of presumptions in favour of the patient.

French law establishes a distinct model for regulating liability for medical harm, combining classical civil law tort mechanisms with an institutional system of out-of-court compensation. The modern system is based on Law of the French Republic No. 2002-303[2], the provisions of which are integrated into the Public Health Code of the French Republic[3]. According to Article L1142-1 of the Code, medical professionals and healthcare institutions are liable for harm caused to a patient if a breach of professional treatment standards is proven. At the same time, French legislation provides a special compensation mechanism for medical incidents without proof of fault in cases of accidents thérapeutiques, where harm results from treatment but is not associated with a breach of professional standards. In such cases, compensation may be provided through the administrative compensation system involving the Office national d'indemnisation des accidents médicaux (ONIAM), which operates in accordance with the provisions of the Public Health Code of the French Republic[4]. This system aims to reduce the evidential burden on patients in cases of complex medical complications, ensuring swifter compensation without the need to prove fault on the part of the doctor. Thus, the French model combines classical civil liability for breach of the standard of medical care with elements of a socialised system of compensation for medical harm. From an evidential point of view, establishing the physician's fault remains the key condition for judicial liability. However, the law provides an alternative compensation mechanism in certain cases, operating outside the boundaries of the classical tortious construction.

The Italian law on liability for medical harm was transformed by the adoption of Law of the Italian Republic No. 24[5]. This statute introduced a differentiated liability model for doctors and medical institutions, combining contractual and tortious elements. Under this new system, healthcare institutions are contractually liable to patients for failing to properly organise medical care, whereas individual doctors are liable under tort law. This distinction affects the burden of proof and limitation periods, as a longer period of protection is afforded to contractual claims. Another notable feature of the Italian model is the normative recognition of the role of clinical recommendations and professional standards. According to the law, the assessment of whether a physician's conduct was appropriate is conducted in light of the clinical guidelines and proper medical practice in force at the time of treatment[6]. This creates a defined criterion for assessing professional conduct, while also affecting the evidential structure of disputes, as deviation from clinical recommendations may indicate a breach of the treatment standard.

Thus, a higher degree of predictability in the application of law is associated with a mixed continental model, provided there is a system of proof that is normatively defined. In the German legal system, the regulation of medical liability is linked to the codification of treatment contracts and specific provisions regarding the allocation of the burden of proof. In the Czech Republic, structural coherence is ensured through the contractual typology of medical care combined with the possibility of alternative legal argumentation. France has a mixed model combining tortious liability of physicians with administrative mechanisms for compensating medical incidents. Italy, for its part, has a reformed liability model that distinguishes between the contractual liability of the healthcare institution and the tortious liability of the doctor. This model also integrates clinical recommendations as a criterion for assessing the proper standard of treatment. A comparative analysis of liability models shows that the degree of legal certainty in cases of medical error depends on how the standard of medical care is formulated and procedurally integrated into the relevant legal system. It is precisely through this standard that the unlawful-

[1] Civil Code of Germany. (1896, August). Retrieved from https://www.gesetze-im-internet.de/englisch_bgb/englisch_bgb.html.
[2] Law of the French Republic No. 2002-303 "On Patients' Rights and the Quality of the Health System". (2002, March). Retrieved from https://www.legifrance.gouv.fr/loda/id/JORFTEXT000000227015.
[3] Public Health Code of the French Republic. (2002, March). Retrieved from https://www.legifrance.gouv.fr/codes/texte_lc/LEGITEXT000006072665.
[4] Ibidem, 2002.
[5] Law of the Italian Republic No. 24 "On Patient Safety and Professional Liability of Healthcare Professionals". (2017, March). Retrieved from https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:legge:2017-03-08;24.
[6] Ibidem, 2017.

ness of the doctor's conduct is specified, the boundary of acceptable professional risk is determined and the evidential structure of the dispute is established. In medical error cases, the standard of medical care performs the function of a substantive legal criterion for assessing the propriety of professional conduct, while simultaneously serving as an instrument for specifying unlawfulness within the structure of the civil wrong (De Ravin *et al*., 2022). By establishing the content of the standard, the court can determine whether a deviation has occurred from the proper level of professional care, and whether one of the key elements of liability has therefore been satisfied. From a comparative perspective, the differences between legal systems lie not so much in the very idea of "proper treatment" as in the way it is normatively fixed and procedurally incorporated into the evidential model of the dispute.

In France, the content of the standard of medical care is formed through a combination of the general duty to provide care in accordance with professional rules, and the specific legislative regulation of patients' rights. This model's normative basis is set out in the Public Health Code of the French Republic[1] and Law of the French Republic No. 2002-303[2]. The French model is based on the idea that a breach of the treatment standard is determined by comparing the physician's actions with the requirements of proper professional practice. If fault is present on the part of the medical professional or institution, the traditional model of civil liability applies. At the same time, French law provides that, in the absence of fault but where there has been a serious medical incident, an iatrogenic condition, or a nosocomial infection, compensation may be granted through the mechanism of national solidarity (au titre de la solidarité nationale) pursuant to Article L1142-1 of the Public Health Code of the French Republic. This means that in the French system the standard of medical care functions not only as a criterion of fault, but also as the boundary between fault-based liability and a special compensation mechanism.

In Germany, the standard of medical care is set out in the provisions on treatment contracts, which oblige physicians to provide treatment in accordance with the professional standards recognised at the time the care is provided (§ 630a of the Civil Code of Germany[3]). This criterion is established through special rules on the allocation of the burden of proof (§ 630h of the Bürgerliches Gesetzbuch), which specify the consequences of breaches relating to treatment and documentation. This ensures the integration of the substantive standard and the procedural mechanisms for its application: the court determines whether the physician's actions met the established professional standard and, in certain cases, applies presumptions in favour of the patient. In German law, the standard is linked to the level of development of medical science and practice at the time of the intervention, thus excluding retrospective assessment from the standpoint of later scientific advances.

Czech law recognises treatment as a specific type of contract and obliges healthcare providers to act in accordance with professional rules and contemporary advances in medical science Civil Code of the Czech Republic[4]. The standard is defined by generally recognised professional standards (lege artis), which serve as the substantive test of the propriety of treatment. Procedurally, this enables a breach to be classified as either improper performance of a contractual obligation or causing harm through breach of a professional standard. In both cases, the content of the standard is determined through expert assessment, taking into account the physician's area of expertise and the clinical recommendations in force at the time of treatment.

In Italy, the standard of medical care is formed within the framework of a reformed mixed model, updated by Law of the Italian Republic No. 24[5]. This model links the assessment of a physician's professional conduct to clinical recommendations, guidelines and proper medical practice. This means that determining unlawfulness is based not only on the general concept of professional care, but also on whether the doctor acted in accordance with the applicable clinical standards in the given situation. The normative recognition of the role of guidelines enhances the predictability of legal application since it enables the court to compare the medical professional's conduct with formalised criteria of proper practice. At the same time, the Italian model does not reduce the assessment to an exclusive mechanical check of compliance with a protocol, as the clinical features of the case in question, the complexity of the intervention and the justification of the physician's professional decision are also significant factors.

A comparative analysis shows that, in all the systems considered, the standard of medical care takes into account the physician's specialisation, the clinical circumstances and the level of medical scientific development at the time of the intervention. However, the methods of its normative formulation and procedural application differ. In France, for example, the standard is combined with a model of civil liability based on fault and a compensation mechanism founded on national

[1] Public Health Code of the French Republic. (2002, March). Retrieved from https://surl.li/rhgtxc.
[2] Law of the French Republic No. 2002-303 "On Patients' Rights and the Quality of the Health System". (2002, March). Retrieved from https://www.legifrance.gouv.fr/loda/id/JORFTEXT000000227015.
[3] Civil Code of Germany. (1896, August). Retrieved from https://www.gesetze-im-internet.de/englisch_bgb/englisch_bgb.html.
[4] Civil Code of the Czech Republic. (2012, February). Retrieved from https://www.refworld.org/legal/legislation/natlegbod/2012/122919.
[5] Law of the Italian Republic No. 24 "On Patient Safety and Professional Liability of Healthcare Professionals". (2017, March). Retrieved from https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:legge:2017-03-08;24.

solidarity. In Germany, on the other hand, the standard is integrated into a codified model with a defined allocation of the burden of proof. In the Czech Republic, it is linked to the contractual typology of treatment, while in Italy, it is connected with a reformed model of liability oriented towards clinical recommendations and the distinction between the liability of the doctor and that of the healthcare institution. In cross-border disputes, the determination of the standard's content depends on the applicable law, which directly affects liability predictability in the context of medical tourism.

Alongside determining the professional standard of treatment, the doctrine of informed consent is an independent element of medical liability (Kmucha, 2020). While the standard of medical care determines whether the medical intervention corresponds to the professional level, informed consent determines whether the intervention itself was legitimised from the perspective of patient autonomy. In the evidential structure, this means that a defect in the provision of information may constitute a separate ground of liability, even in the absence of an error in treatment. A comparative analysis reveals that different jurisdictions have different criteria for determining the appropriate level of information: some rely on the professional standard (what a reasonable doctor would disclose), while others use the reasonable patient criterion (what information is important to the patient's decision).

In Germany, the principle of informed consent is enshrined in the provisions governing treatment contracts. In particular, § 630e of the Civil Code of Germany[1] sets out the physician's duty to explain all material circumstances to the patient, including the nature, scope and manner of the intervention, the expected consequences, the risks and the availability of alternative treatment methods where these differ in terms of risks or prognosis. Thus, the law directly defines the structural elements of proper disclosure, thereby increasing the certainty of the subject matter of proof. The German model combines the professional standard with an objective test of the materiality of risk: the court assesses whether the information provided was sufficient for an informed decision to be made, taking medical standards and the specific clinical situation into account. Similarly, Czech law recognises the necessity of voluntary and informed patient consent as a prerequisite for the legality of the intervention. Law of the Czech Republic No. 372/2011[2] defines the information that must be provided to patients, including details of their health, the proposed treatment, potential risks and alternatives. In Italy, the doctrine of informed consent has autonomous legislative regulation in Law of the Italian Republic No. 219[3]. This law defines informed consent as a prerequisite for lawful medical intervention and stipulates that information provided to patients must cover diagnosis, prognosis, the benefits and risks of diagnostic and therapeutic measures, possible alternatives, and the consequences of refusing treatment. The law also stipulates that any form of consent must be recorded in medical documentation and the electronic medical record. This increases evidential certainty, as it links the adequacy of disclosure to both the content of the information communicated and the duty to document it. In France, the duty to inform and the requirement to obtain consent are set out in the Public Health Code of the French Republic[4]. Article L1111-2 in particular provides for a person's right to information concerning their state of health, the proposed examinations and treatment, their benefits, urgency, consequences, and the ordinary or serious foreseeable risks and possible alternatives, as well as the consequences of refusing treatment. Article L1111-4 establishes that no medical intervention or treatment may be carried out without a person's free and informed consent, which they can withdraw at any time. The consolidation of these provisions into a formalised model means that a defect in disclosure can be classified as an independent breach of duty, regardless of the technical quality of the treatment. From an evidential perspective, decisive importance is attached to medical records, records of the information provided and documents confirming the patient's wishes. Although this construction is based on the German model, the content of proper disclosure is determined through expert assessment and analysis of the documentation in procedural terms. A comparative analysis shows that, in all the systems under consideration, informed consent is regarded as a necessary condition for the lawfulness of medical intervention. However, the degree of normative detail of this duty, and how it is integrated into the evidential model of dispute, differ. In France and Italy, the content of disclosure is clearly set out in special legislation, reducing variability in judicial interpretation. In Germany, the relevant requirements are integrated into the codified treatment contract model. In the Czech Republic, they derive from special legislation on medical services. Thus, in cross-border cases, the doctrine of informed consent depends directly on the applicable law, since it determines the criteria for proper disclosure and the evidential requirements for proving patient consent.

[1] Civil Code of Germany. (1896, August). Retrieved from https://www.gesetze-im-internet.de/englisch_bgb/englisch_bgb.html.
[2] Law of the Czech Republic No. 372/2011 "On Health Services and Conditions of Their Provision". (2011, December). Retrieved from https://www.zakonyprolidi.cz/translation/cs/2011-372?langid=1033.
[3] Law of the Italian Republic No. 219 "On Informed Consent and Advance Healthcare Directives". (2017, December). Retrieved from https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:legge:2017-12-22;219.
[4] Public Health Code of the French Republic. (2002, March). Retrieved from https://www.legifrance.gouv.fr/codes/texte_lc/LEGITEXT000006072665.

Irrespective of whether claims are qualified as contractual or tortious, the rules governing the allocation of the burden of proof, the possibility of applying evidential presumptions, the role of forensic medical expert evidence, and the admissibility of special procedural doctrines are of decisive importance in medical error cases. In France, the general model of liability for medical harm remains linked to the principle of fault; however, alongside this there operates a special mechanism for compensating medical incidents without proof of fault by virtue of national solidarity, provided that the conditions laid down in Article L1142-1 of the Public Health Code of the French Republic are met. In cases of fault-based liability, proof of breach of the treatment standard and of causation, as a rule, requires expert determination. At the same time, the very existence of the special compensation procedure through ONIAM reduces the procedural burden on the patient in cases where the harm suffered is serious but cannot be explained by culpable conduct on the part of the physician or institution. In Germany, the principle of fault likewise remains the basis of liability, but the allocation of the burden of proof is detailed in special rules. Thus, §630h of the Civil Code of Germany[1] provides for a number of presumptions in cases of medical error, in particular where there has been a gross breach of the professional standard or inadequate documentation. Where a gross error exists, the burden of proving causation may be shifted to the defendant. Such a construction is aimed at compensating for the informational asymmetry between the patient and the medical institution. Czech law proceeds from the general provisions on liability for harm, which require proof of unlawfulness, harm, and causation; however, judicial practice allows defects in documentation to be taken into account when assessing the evidence. In Italy, the reformed liability model distinguishes between the contractual liability of the medical institution and the tortious liability of the individual practitioner. This distinction directly affects the evidential structure of disputes (Cascini *et al*., 2020). Under this model, claims against the healthcare institution are considered in terms of a breach of the contractual duty to organise and provide proper medical care. In contrast, claims against the doctor are primarily assessed through a tortious construction. Establishing a breach of the treatment standard involves analysing clinical guidelines, proper medical practice, medical records and expert conclusions. Thus, unlike German law, the Italian model does not establish a presumption of fault, but it increases the predictability of disputes by distinguishing between the parties liable and by giving clinical guidelines a formalised role in the court's assessment of physicians' conduct. Accordingly, the key difference between the two systems does not lie in abandoning the principle of fault, but in the degree to which the substantive standard of medical care and the procedural mechanisms for proving it are integrated into the legal system, which directly affects the level of legal certainty in cases involving medical errors.

Recognition and enforcement of foreign judgments in medical liability cases. In cross-border disputes involving medical errors, obtaining proof is complicated by the fact that key evidence, such as medical records, the institution's internal protocols, staff explanations and primary digital records of diagnostic systems, is located within the jurisdiction of another state (Laarman & Akkermans, 2018). This affects both the speed at which evidence can be obtained and its procedural status. The court must ensure that the evidence is requested properly, and that the documents are authentic and admissible. The court must also reconcile access to medical data with the regime governing its protection. Regulation of the European Parliament and of the Council No. 2020/1783[2] is the basic instrument for taking evidence in civil and commercial matters. It aims to accelerate cooperation between the courts of the Member States and formalise standard procedural channels. It provides for two principal models: (1) a court in one state requesting a court in another state to carry out a specific procedural act (e.g., obtaining documents, examining a witness/expert or inspecting evidence); (2) a court in the requesting state directly taking evidence in the territory of another state under established conditions, including by means of videoconferencing or other remote communication technologies. This is of practical significance for medical disputes, since it enables a doctor, clinic representative or expert to be examined without the physical movement of the parties, while ensuring that the court hearing the case retains procedural control. The Regulation also uses standardised forms for requests and notifications, reducing the risk of refusal due to procedural errors and increasing the predictability of the evidential process.

However, even where a procedural mechanism for obtaining evidence exists, the key limiting factor in medical cases is the legal regime governing medical information as a special category of personal data. In the EU, data concerning health is generally prohibited from processing, unless an exception under Article 9 of General Data Protection Regulation[3] applies. The most relevant exception for judicial disputes is the necessity "for the establishment, exercise or defence of legal claims" (Article 9(2)(f)). Therefore, the transfer of medical documentation for judicial proceedings may be lawful, but only within the limits of necessity and

[1] Civil Code of Germany. (1896, August). Retrieved from https://www.gesetze-im-internet.de/englisch_bgb/englisch_bgb.html.
[2] Regulation of the European Parliament and of the Council No. 2020/1783 "On Cooperation Between the Courts of the Member States in the Taking of Evidence in Civil or Commercial Matters (Recast)". (2020, November). Retrieved from https://surl.li/bjgoka.
[3] General Data Protection Regulation. (2016, April). Retrieved from https://eur-lex.europa.eu/eli/reg/2016/679/oj.

proportionality. This involves minimising the volume of data and ensuring appropriate safeguards for access, as well as considering whether there is a procedural duty to provide such data (e.g., pursuant to a court order or in compliance with a request under Regulation of the European Parliament and of the Council No. 2020/1783[1]). Accordingly, in a cross-border case, the court and the parties must synchronise two regimes: the evidential regime (requesting/obtaining evidence) and the data protection regime (legal basis, limits and safeguards).

Alongside the procedural mechanisms for obtaining evidence, the legal regulation of cross-border medical disputes in the European Union includes instruments for determining international jurisdiction and the choice of applicable law. A key role is played by Regulation of the European Parliament and of the Council No. 1215/2012[2], which establishes rules of international jurisdiction and ensures the recognition and enforcement of judgments in civil and commercial matters between Member States. In cases concerning medical harm, this means that an action may be brought not only before the courts of the state where the defendant is domiciled, but also before the courts of the place where the damage occurred, which is of particular importance for patients who received treatment abroad. The choice of applicable law in medical liability cases is made in accordance with Regulation of the European Parliament and of the Council No. 864/2007[3], which provides for the application of the law of the state in which the damage occurred, unless the circumstances of the case indicate otherwise. This means that the legal regime of medical liability in cross-border disputes may be determined by different conflict-of-laws instruments of EU law depending on whether the claim is characterised as tortious or contractual. Such a construction makes it possible to align the court's procedural jurisdiction with the substantive rules of liability applicable in the particular case.

If the dispute falls outside the EU or if cooperation is required with a state not covered by the Regulation-based mechanism, the Convention on the Taking of Evidence Abroad in Civil or Commercial Matters[4]. The Convention relies on letters of request, which are sent via central authorities. The evidence is then gathered by the competent authority of the requested state in accordance with its procedural law. Special procedures can be taken into account, provided they do not conflict with the law of the requested state. This is important for medical disputes where an official route is required to obtain medical records, examine staff or request materials that are subject to professional secrecy. The Convention establishes a channel of cooperation while preserving the role of national procedural limitations, affecting the predictability of time limits and the scope of evidence.

Another aspect of the international dimension is the admissibility of electronic evidence, particularly electronic medical records, digital event logs of medical information systems, image files, electronic signatures of physicians on records and electronic timestamps. Regulation of the European Parliament and of the Council No. 910/2014[5] is the key normative foundation for the judicial "legalisation" of electronic evidence. It enshrines the principle of non-discrimination, meaning that an electronic signature cannot be denied legal effect or admissibility as evidence solely because it is in electronic form. A qualified electronic signature has a legal effect equivalent to that of a handwritten signature. In the context of medical disputes, this regulation establishes a procedural framework for verifying the authenticity of documentation. The court will examine whether the signatory has been identified, whether the record's integrity is intact, and whether the time of creation or modification of the record can be verified. Meanwhile, the parties must demonstrate the chain of custody of the digital files. When it comes to the structure of proof, it is important to note that the "international element" in a medical case extends beyond the mere technical request for documents. Rather, it determines which procedural channel applies (Regulation 2020/1783[6] within the EU or the Convention on the Taking of Evidence outside the EU), whether there is a legal basis for the transfer of medical data and to what extent (GDPR[7], particularly Article 9(2)(f)), and which criteria of authenticity and admissibility apply to digital records (Regulation (EU) No. 910/2014, which establishes the framework for electronic signatures and trust services). A further specific element of the legal regime governing cross-border medical disputes is Directive of the European Parliament and of the Council

[1] Regulation of the European Parliament and of the Council No. 2020/1783 "On Cooperation Between the Courts of the Member States in the Taking of Evidence in Civil or Commercial Matters (Recast)". (2020, November). Retrieved from https://surl.li/bjgoka.
[2] Regulation of the European Parliament and of the Council No. 1215/2012 "On Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters (Recast)". (2012, December). Retrieved from https://eur-lex.europa.eu/eli/reg/2012/1215/oj.
[3] Regulation of the European Parliament and of the Council No. 864/2007 "On the Law Applicable to Non-Contractual Obligations (Rome II)". (2007, July). Retrieved from https://eur-lex.europa.eu/eli/reg/2007/864/oj.
[4] Convention on the Taking of Evidence Abroad in Civil or Commercial Matters. (1970, March). Retrieved from https://www.hcch.net/en/instruments/conventions/full-text/?cid=82.
[5] Regulation of the European Parliament and of the Council No. 910/2014 "On Electronic Identification and Trust Services for Electronic Transactions in the Internal Market (eIDAS Regulation)". (2014, July). Retrieved from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0910.
[6] Regulation of the European Parliament and of the Council No. 2020/1783 "On Cooperation Between the Courts of the Member States in the Taking of Evidence in Civil or Commercial Matters (Recast)". (2020, November). Retrieved from https://surl.li/bjgoka.
[7] General Data Protection Regulation. (2016, April). Retrieved from https://eur-lex.europa.eu/eli/reg/2016/679/oj.

No. 2011/24/EU[1], which establishes the normative framework for patients' access to safe and high-quality healthcare in other EU Member States and also provides for mechanisms for reimbursement of costs and the exchange of medical information between national healthcare systems. In the context of judicial disputes, this is relevant for determining the legal status of treatment received abroad and for assessing the standards of medical care that may be applicable to a particular clinical situation. As a result, proof of fault and causation in a cross-border case depends not only on medical facts, but also on the parties' ability procedurally correctly to "transfer" evidential material between jurisdictions in compliance with the rules of evidence and data protection. The regulatory mechanisms set out above do not operate in isolation. In a cross-border medical dispute, they cover not only the taking of evidence, but also the determination of international jurisdiction, the choice of applicable law, and the subsequent recognition and enforcement of judgments (Table 1).

Table 1. Legal structure of the consideration of cross-border medical liability disputes in European Union law

Analytical criterion	Regulatory framework
Characterisation of the claim	Claims concerning medical harm may be characterised as contractual (breach of the therapeutic obligation) or tortious (causing harm to life and health). This characterisation determines the application of the relevant conflict-of-laws rules of EU law
International jurisdiction	Determined in accordance with Regulation (EU) No. 1215/2012[2] (Brussels I bis): an action may be brought before the courts of the state where the defendant is domiciled or before the courts of the place where the damage occurred (Article 7(2))
Choice of applicable law	Tortious claims are governed by Regulation (EU) No. 864/2007[3] (Rome II), under the general rule the law of the state where the damage occurred (Article 4). Contractual claims are governed by Regulation (EU) No. 593/2008[4] (Rome I)
Substantive conditions of liability	Determined by the law selected in accordance with Regulation (EU) No. 593/2008 or Regulation (EU) No. 864/2007[5], and encompass the standard of medical care, the existence of fault, causation, and the scope of compensation
Evidence	Questions of evidence are governed by the law of the court seised of the case. The taking of evidence in cross-border disputes is carried out in accordance with Regulation (EU) 2020/1783[6]
Recognition and enforcement of judgments	Judgments of Member States are recognised and enforced in accordance with Regulation (EU) No. 1215/2012[7] without an exequatur procedure, save for grounds of refusal connected with public policy or infringement of the right of defence

Source: compiled by the authors based on Regulations of the European Parliament and of the Council

A comparative analysis reveals that the substantive elements of liability, particularly the standard of medical care, the presence of fault and causation, are determined by the chosen law in accordance with conflict-of-laws rules. In contrast, the procedural mechanisms for acquiring and assessing evidence are governed by the law of the forum (*lex fori*). Consequently, the evidential model of a cross-border case emerges at the intersection of several legal regimes: the conflict-of-laws regulation, the procedural law of the forum state and special instruments of international legal assistance. This multi-layered structure gives rise to specific transnational evidential risks, such as the territorial fragmentation of evidence, informational asymmetry between parties, the protection of medical data and the admissibility of electronic evidence. At the same time, European Union law and international procedural mechanisms form a system of legal instruments aimed at mitigating these risks and ensuring procedural fairness in cross-border disputes (Table 2).

[1] Directive of the European Parliament and of the Council No. 2011/24/EU "On the Application of Patients' Rights in Cross-Border Healthcare". (2011, March). Retrieved from https://eur-lex.europa.eu/eli/dir/2011/24/oj.
[2] Regulation of the European Parliament and of the Council No. 1215/2012 "On Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters (Recast)". (2012, December). Retrieved from https://eur-lex.europa.eu/eli/reg/2012/1215/oj.
[3] Regulation of the European Parliament and of the Council No. 864/2007 "On the Law Applicable to Non-Contractual Obligations (Rome II)". (2007, July). Retrieved from https://eur-lex.europa.eu/eli/reg/2007/864/oj.
[4] Regulation of the European Parliament and of the Council No. 593/2008 "On the Law Applicable to Contractual Obligations (Rome I)". (2008, June). Retrieved from https://eur-lex.europa.eu/eli/reg/2008/593/oj.
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[7] Regulation of the European Parliament and of the Council No. 1215/2012 "On Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters (Recast)". (2012, December). Retrieved from https://eur-lex.europa.eu/eli/reg/2012/1215/oj.

Table 2. Transnational evidential risks in medical liability cases and the mechanisms of their legal compensation

Structural risk in a cross-border dispute	Source of the risk	Compensatory effect on the standard of proof
Informational asymmetry between the patient and the medical institution	Control of evidence (medical records, internal protocols) by the defendant	Ensuring procedural access to evidence; reducing imbalance in proving causation
Territorial fragmentation of evidence	Evidence is located in different jurisdictions	Preserving the integrity of the evidential basis; minimising loss of evidence
Restrictions on access due to the data protection regime	Medical information as a special category of personal data	Reconciling the right to evidence with the right to privacy; legitimising data transfer for judicial protection
Risk of inadmissibility of digital evidence	Electronic form of medical documentation	Ensuring the legal force of electronic records; supporting evidential reliability
Differences in national standards of proof	Differences in the allocation of the burden of proof and presumptions	Protecting the stability of the judgment; limiting review on the merits at the recognition stage
Procedural imbalance between the parties	Limited possibility of rebutting evidence or a presumption	Maintaining the legitimacy of the judgment in international circulation

Source: compiled by the authors based on Regulation of the European Parliament and of the Council No. 910/2014[1], General Data Protection Regulation[2], Convention on the Taking of Evidence Abroad in Civil or Commercial Matters[3]

Thus, the international dimension of medical liability cases transforms the process of providing proof from a national procedural process into a multi-level system of interaction between legal regimes. Each regulatory instrument – from mechanisms for obtaining evidence to the regime of electronic authentication – compensates for a specific structural risk. Consequently, the standard for proving fault and causation is influenced not only by medical facts, but also by the parties' capacity to exercise their procedural rights amid territorial and normative fragmentation. For this reason, the procedural mechanisms for obtaining evidence in cross-border disputes are important for establishing the facts of the case and for the subsequent recognition and enforcement of the judgment in another state. While the standards of proof applied by the court of the state of origin are not subject to review on the merits, they can be indirectly evaluated in terms of fair trial guarantees and the public policy of the enforcing state. This is clearly reflected in the practice of the Federal Court of Justice of Germany (2024). In judgment VI ZR 108/23 (Bundesgerichtshof, the court drew a detailed distinction between Befunderhebungsfehler (error in collecting diagnostic findings) and therapeutische Aufklärung (therapeutic disclosure). This had a direct impact on the application of § 630h BGB with regard to the redistribution of the burden of proof. In that context, a presumption of causation was possible only where the breach was clearly classified as one that had created evidential uncertainty. This approach shows that, while German law allows the standard of proof to be adjusted, this can only be done within predictable and normatively defined criteria. This structured nature reduces the risk of a judgment being refused recognition in another EU Member State, since redistribution of the burden does not appear as an arbitrary restriction of the right to defence. A similar issue of balancing the burden of proof can be seen in French judicial practice.

In Decision of the Court of Cassation of France No. 19-15.035[4] emphasised that establishing medical error requires a thorough evaluation of medical records, expert opinions and clinical circumstances. The court stated that a negative outcome of a medical intervention does not indicate a breach of the standard of medical care in itself, and that a causal link between a doctor's actions and damage must be established through medical-scientific analysis. This approach aims to strike a balance between protecting patients' rights and preventing the automatic imposition of liability on medical personnel. In Czech judicial practice, the category of *lege artis* (in accordance with generally recognised professional standards of medical practice) does not function as a declaratory formula of proper treatment; rather, it is an evidential criterion whose content is established through expert assessment and analysis of the clinical situation. In Judgment of the Supreme Court of the Czech Republic No. 25 Cdo 2937/2020[5], the court assessed the physician's conduct based on the circumstances known when the medical decision was made. This implements the function of an objective

[1] Regulation of the European Parliament and of the Council No. 910/2014 "On Electronic Identification and Trust Services for Electronic Transactions in the Internal Market (eIDAS Regulation)". (2014, July). Retrieved from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0910.
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[4] Decision of the Court of Cassation of France No. 19-15.035. (2021, October). Retrieved from https://www.legifrance.gouv.fr/juri/id/JURITEXT000044183628.
[5] Judgment of the Supreme Court of the Czech Republic No. 25 Cdo 2937/2020. (2022, October). Retrieved from https://www.zakonyprolidi.cz/judikat/nscr/25-cdo-2937-2020.

"*lege artis*" standard, whereby the doctor's actions are assessed based on medical knowledge and practice at the time of treatment rather than the outcome of the intervention. In the context of international recognition, this reduces the risk of the judgment being characterised as incompatible with another state's public policy, since the standard of proof is based on normatively defined and foreseeable criteria for evaluating professional conduct. Similar issues arise in the practice of the Italian Court of Cassation in the context of legislation on the safety of medical care and the liability of healthcare professionals (Chambers *et al*., 2025).

In Sez. III, Judgment No. 28985/2019, the Court emphasised that establishing a causal link between a medical intervention and harm requires scientifically sound expert analysis and an evaluation of the particular clinical context (Di Massimo, 2019; Clayton *et al*., 2020). At the same time, the Court emphasised that a negative treatment outcome is not in itself sufficient proof of medical error. This approach aims to strike a balance between protecting patients' rights and preventing the automatic imposition of liability on medical personnel, which is important for ensuring the stability of judicial decisions in the context of international legal circulation. Thus, judicial practice demonstrates that standards of proof in medical disputes have a transnational effect. They determine not only the outcome of the dispute, but also how resilient the judgment is in the process of international recognition.

Based on the comparative analysis conducted, it can be concluded that the elements of the structural-functional model for resolving cross-border disputes concerning compensation for damage caused by medical errors encompass the essential stages and components of the process, including the categorisation of the claim as contractual or tortious, the determination of international jurisdiction, the selection of applicable law, the establishment of substantive liability conditions, the organisation of proof (including the standard of medical care and the informed consent doctrine), and the procedures for recognising and enforcing foreign judgements. Consolidating these elements into a single model clearly delineates the normative and procedural framework of the dispute, increases the predictability of legal application and ensures the integration of national and transnational mechanisms for protecting patients' rights.

Discussion

The findings showed that the liability model for medical errors is determined not only by substantive rules, but primarily by the structure of proof, which shapes the procedural opportunities available to the parties involved. It was established that the differing degree of legal certainty in the examined jurisdictions is determined by the extent to which the standard of medical care is integrated into the mechanisms for allocating the burden of proof. Synthesising the material confirmed that it is precisely the procedural construction of proving causation and fault that constitutes the system-forming factor of liability.

In their work, I. Ketsekioulafis *et al*. (2026) conducted a narrative review of legislative models and insurance mechanisms of medical liability in different countries. The authors concluded that the overwhelming majority of legal systems retain a liability model based on the principle of fault, but apply different methods of adjusting the burden of proof procedurally. They emphasised that the effectiveness of patient protection depends largely on access to evidence and the role of medical documentation. The findings in this article are consistent with these conclusions but supplement them with a detailed analysis of how contractual and tortious characterisation influences the structure of proof. V.P. Maroudas (2024) examined the German and Greek liability models in the context of artificial intelligence systems and observed that, even amidst the technological complexity of medical decision-making, the principle of fault retains systemic significance. The author demonstrated that the German special rules on the allocation of the burden of proof perform a compensatory function in cases of informational asymmetry. The results of the present study confirm this: it was found that codified presumptions in German law increase the predictability of dispute outcomes without abandoning the principle of fault. At the same time, the article broadened the analytical perspective by focusing not only on the technological factor, but also on the systemic role of legal characterisation. In contrast, A.G. Grasso (2025) analysed liability rules in the field of medical artificial intelligence, noting that the expansion of algorithmic autonomy poses a risk to the traditional concept of fault. The author argued for preserving the structural logic of tortious liability and warned against transitioning to an objective model without justification. The findings of this study confirmed that the principle of fault had not been replaced by a model of strict liability in the legal systems examined, and that the differences concerned only the procedural mechanisms of proof. Thus, the results are consistent with A.G. Grasso's (2025) position regarding the systemic stability of the traditional approach to liability.

Meanwhile, A. Vozikis *et al*. (2021) proposed a tool for analysing litigation risk in medical liability cases, demonstrating that predicting case outcomes depends on identifying the elements of wrongdoing and evaluating the evidential potential of the parties involved. The authors emphasised the importance of causation as a key element of the dispute. This study established that the normative model of allocation of the burden of proof determines the degree of risk for the parties within a particular jurisdiction. Unlike A. Vozikis *et al*.'s (2021) instrumental approach, this article conducted a normative-comparative analysis to explain

why disputes are more or less predictable in the examined legal systems.

The results obtained indicate that in cross-border medical liability disputes, the proof process structurally extends beyond the national civil procedure model and is shaped by the complex interaction between evidential law regimes, personal data protection regimes, and international judicial cooperation mechanisms. The study found that it is precisely this combination of regimes that determines both the possibility of gathering evidence and the subsequent resilience of the judgment at the recognition and enforcement stage. This conclusion aligns with comparative approaches presented in contemporary medical liability doctrine, while also specifying them in terms of the procedural "export" of evidence between jurisdictions. As discussed in the collective monograph edited by D. Bach-Golecka (2021), the effectiveness of compensation mechanisms in healthcare depends not only on the liability model (tortious, contractual, or mixed), but also on the availability of procedural instruments that enable the injured party to access evidence and expert information. The authors emphasise that informational asymmetry between patients and medical institutions is a systemic feature of most legal systems and therefore requires institutional compensation through presumptions, the redistribution of the burden of proof or special disclosure procedures. The results of the present study are consistent with this approach but extend it to the transnational level. It is demonstrated that in cross-border cases, asymmetry is exacerbated by territorial fragmentation of evidence and differences in admissibility standards. In a purely national context, compensation for asymmetry is achieved through procedural presumptions. In an international dispute, however, decisive importance is attached to the parties' ability to use mechanisms for taking evidence internationally and to transfer medical data legitimately, in accordance with protection regimes. M.J. Bono *et al*. (2022) analyse medical negligence through the prism of the classical American model, in which proving deviation from the standard of due medical care and the causal link between the breach and the harm is of central importance. The authors emphasise the pivotal role of expert opinion as a key evidential tool, highlighting that while procedural nuances transform the structure of proof, the obligation to provide the defendant with the opportunity to refute a presumption remains. The findings obtained partly coincide with these conclusions: it was established that the transformation of the structure of proof through presumptions or inferences directly impacts the subsequent evaluation of a judgment in the procedure of international recognition. However, the study also shows that, in a cross-border context, significance attaches not only to the internal logic of the standard of proof, but also to compliance with procedural guarantees. These guarantees may be reviewed by the court of the enforcing state through the lens of public policy and the right to a fair trial.

The article by M. Nioi *et al*. (2025) is devoted to medical liability in the field of ophthalmic surgery. It demonstrates a tendency towards the "trivialisation" of certain medical procedures. This does not reduce the level of legal risks for medical institutions. The authors showed that an increase in routine interventions is accompanied by an increase in claims, and that the assessment of treatment standards is increasingly reliant on documentation, digital records and formalised protocols. These conclusions resonate with the findings of the present study, which established that electronic medical records and digital event logs are becoming key evidence in disputes with an international element. However, in a cross-border context, their significance is complicated by the need to confirm their authenticity, integrity and legitimacy of transfer in accordance with personal data protection rules. This was not the central focus of the study by M. Nioi *et al*. (2025), but it becomes decisive when a foreign judgment is recognised. G. Nittari *et al*. (2020) analysed the ethical and legal challenges of telemedicine, including the cross-border transfer of medical data, jurisdictional uncertainty and differences in regulatory standards. The authors pointed out that providing medical services remotely creates a new liability allocation model and increases conflict-of-laws risks, especially when the doctor and patient are located in different states. The present study's findings confirm and specify these observations in evidential terms: it demonstrates that the telemedical format complicates not only the determination of applicable law, but also the procedure for requesting and legitimately transferring evidence containing health data. Thus, the conclusions of M. Nioi *et al*. (2025) regarding the normative fragmentation and ethical vulnerability of telemedicine are consistent with the thesis of this study, which emphasises the need to align the evidential and data protection regimes in cross-border disputes.

Overall, the analysis makes it possible to conclude that, while the contemporary doctrine of medical liability pays considerable attention to the substantive grounds of compensation and the transformation of standards of proof, it does not examine their impact on the stage of international recognition and enforcement of judgments sufficiently or systematically. Within the framework of this study, it has been demonstrated that the procedural structuring of proof, the predictability of the redistribution of the burden of proof and compliance with guarantees determine the cross-border resilience of a judgment. Accordingly, the results obtained extend existing scholarly approaches by combining the analysis of standards of proof with issues of international judicial cooperation and the protection of medical data regime, which is of fundamental importance for the effective recognition and enforcement of judgements in medical liability cases.

Conclusions

The comparative legal analysis revealed that the classification of medical error as a basis for liability affects the proof required in disputes. This includes the elements to be proven, the allocation of the burden of proof between parties, the application of procedural presumptions and the limits of compensation for harm. In continental legal systems, the relationship between doctors and patients is mixed, combining the contractual basis of treatment with tort law protection of life and health. Consequently, the same instance of improper treatment may result in both contractual and tortious liability, impacting the evidential model and the structure of legal argumentation.

Comparative analysis shows that German law ensures a high level of legal certainty due to the codification of the standard of medical care and the special rules of proof set out in the provisions on the treatment contract. The legislative establishment of presumptions and the possibility of redistributing the burden of proof in cases of gross medical error or defective documentation aims to compensate for the information asymmetry between patients and medical institutions. French law combines the classical model of civil liability with institutional mechanisms for out-of-court compensation. The introduction of a compensation system based on national solidarity, implemented through ONIAM, enables compensation for harm caused by medical risks or treatment complications, even in the absence of proven fault on the part of the medical professional.

Following the reform, the Italian model is characterised by a differentiation between the liability of medical professionals and that of healthcare institutions. This differentiation affects the structure of proof and the allocation of procedural risks between the parties. Meanwhile, Czech law institutionalises treatment as a specific type of contract and allows for the alternation of contractual and tortious liability, ensuring procedural flexibility in choosing the legal basis of the claim. In cross-border medical liability disputes, it was established that proof acquires a multi-level character. Substantive liability elements are determined by the chosen law, in accordance with conflict-of-laws rules, whereas procedural mechanisms for obtaining and evaluating evidence are governed by *lex fori*. Within the European Union, this system is supplemented by supranational mechanisms for determining jurisdiction, selecting applicable law and admitting evidence. This increases the predictability of the procedural aspects of cross-border disputes.

Systematising the study's findings enabled the identification of key transnational evidential risks in medical disputes, such as informational asymmetry between parties, territorial fragmentation of evidence, restrictions on access to medical data, and differences in national standards of proof. Analysis of judicial practice in Germany, France, Italy and the Czech Republic showed that compensation for these risks is ensured through a combination of procedural presumptions, expert evidence and mechanisms for redistributing the burden of proof. Such procedural balance contributes to ensuring a fair trial and increases the stability of judicial decisions in the process of their international recognition and enforcement. Further research should be directed towards the analysis of the harmonisation of standards of proof and models of compensation for harm in medical liability cases within the European Union, in particular in the light of the development of cross-border healthcare and the digitalisation of medical documentation.

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Компенсація шкоди, завданої лікарською помилкою, у міжнародному приватному праві: порівняльно-правовий аналіз

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Анотація
Метою цього дослідження було проведення систематичного порівняльно-правового аналізу підходів до визначення правових підстав для відшкодування шкоди, завданої лікарськими помилками, у правовідносинах, що мають іноземний елемент. Для аналізу нормативно-правових баз і судової практики у сфері медичної відповідальності було застосовано порівняльно-правові, формально-правові та колізійні методи поряд з методами вивчення конкретних випадків і типологічними методами. Порівняльний аналіз засвідчив, що хоча вони відрізняються нормативним формулюванням стандарту медичної допомоги та механізмами його процесуального доказування, усі розглянуті правові системи зберігають принцип вини як обов'язкову умову цивільної відповідальності за медичну шкоду. Було виявлено, що німецька модель забезпечує найвищий ступінь правової визначеності завдяки кодифікації договору про лікування та законодавчо визначеним презумпціям. Було виявлено, що чеська модель інституціоналізує лікування як специфічний договірний вид, застосовуючи критерій надання допомоги відповідно до загальновизнаних професійних медичних стандартів, допускаючи збіг договірних і деліктних кваліфікацій. Французька модель поєднує класичне тлумачення цивільної відповідальності з інституційним механізмом компенсації шкоди через національну солідарність, що реалізується через систему Національного управління з відшкодування збитків у медичних випадках. Встановлено, що італійська модель характеризується диференційованою відповідальністю між лікарями та закладами охорони здоров'я після законодавчої реформи щодо безпеки пацієнтів. На основі порівняльного аналізу було сформовано узагальнену модель доказування в медичних спорах, що мають іноземний елемент, яка об'єднує такі компоненти: матеріальні підстави відповідальності, визначені договірною або деліктною кваліфікацією; процесуальні механізми доказування, зокрема презумпції, експертні докази та перерозподіл тягаря доказування; транснаціональні фактори, з огляду на застосування колізійних норм, принцип lex fori; наднаціональні механізми Європейського Союзу щодо юрисдикції та отримання доказів. Практичне значення висновків полягає в їх потенційному використанні судами та законними представниками для прогнозування ризиків відмови у визнанні та виконанні рішень у транскордонних медичних спорах

Ключові слова:
презумпція; вина; договір про лікування; медична відповідальність/лікарська недбалість; міжнародне приватне право