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The Challenges of Proving Causation in Medical Malpractice

Abstract

This article addresses the issue of establishing causation in medical disputes. Special attention is given to causation as an essential condition for the emergence of an obligation, as well as to the standard of burden of proof allocation in medical disputes. In this regard, both national and international legislation and judicial practice are analyzed.

The present article thoroughly examines the regulation of patient rights protection and the liability of the medical service provider in modern medical practice. The paper aims, based on the national legislation of Georgia, to describe the nature of the medical service contract, the parties to this contract, as well as the forms of civil liability of medical personnel. Particular focus is placed on the fundamental elements decisive for imposing liability on the medical service provider. Specifically, the notions of unlawful conduct and damage, the problem of establishing causation, and fault are reviewed.

The paper is enriched with both Georgian and German judicial practice and thoroughly considers the precedent decisions of the courts of both countries.

Keywords: Medical Law, Civil liability of medical personnel, Causation, Burden of Proof, Medical Service Contract.

Introduction

It is universally acknowledged that the protection of patients' rights serves as a foundational pillar in all democratic countries. Article 28 of the Constitution of Georgia enshrines the right of every citizen to accessible and high-quality healthcare services, a right that is legally safeguarded. This constitutional provision also imposes a corresponding positive obligation on the state. In fulfillment of this duty, the state is mandated to supervise healthcare institutions, ensure the quality and safety of medical services, and regulate both the production and distribution of pharmaceutical products.

Unlike Germany, in Georgia the legal provisions governing these matters are not codified within a single chapter of the Civil Code, but are scattered across multiple normative acts. The legal norms concerning the imposition of civil liability on medical service providers are articulated in Chapter III of the Civil Code of Georgia, which governs tortious obligations, as well as by the general part of the Law of Obligations concerning compensation for contractual

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damages. Furthermore, Article 10 of the Law of Georgia on Health Protection grants patients or their legal representatives the right to seek judicial remedy, including the ability to claim compensation for both pecuniary and non-pecuniary damages.

Medical disputes, due to their specific nature, constitute a complex legal matter. In many cases, the submission of evidence by a party is not only difficult but may even prove to be impossible. This difficulty is further exacerbated by the challenge of establishing a causal link between the conduct of the medical service provider and the harm sustained by the patient—a connection that, in certain cases, cannot be reliably determined. The issue becomes even more intricate when multiple medical institutions or healthcare professionals are involved, making it exceedingly difficult to demonstrate that the harm was not caused by their actions. Consequently, courts frequently dismiss such claims due to the inability to establish a legally significant causal relationship.

This article seeks to explore the legal challenges surrounding the establishment of causation in medical malpractice disputes. To this end, the analysis will encompass both national and international legal frameworks, along with pertinent judicial practice.

1. Regulation of Patients' Rights in Georgian National Legislation

According to Article 28 of the Constitution of Georgia, the citizen's right to accessible and high-quality healthcare services is guaranteed by law. Furthermore, the provision imposes a positive obligation on the state, stipulating that the state shall oversee all healthcare institutions and the quality of medical services, and shall regulate pharmaceutical production as well as the circulation of pharmaceutical products.

The legislative framework governing healthcare in Georgia is comprised of several core normative acts. Among these are the Law of Georgia on Health Protection and the Law of Georgia on Patients' Rights. These laws, in conjunction with the Civil Code, provide the legal basis for seeking compensation in cases involving harm caused to patients. Notably, Article 10 of the Law on Patients' Rights establishes the right of the patient or their legal representative to claim compensation for both pecuniary and non-pecuniary damage resulting from medical treatment.

According to the Law of Georgia on Patients' Rights, a patient or their legal representative is entitled to apply to the court and seek:

a) Compensation for pecuniary and non-pecuniary damages arising from:
   a.a) a violation of the patient's rights;
   a.b) medical malpractice;

a.c) other deficiencies in the operation of a medical institution;
a.d) improper supervision or regulatory action by the state;

b) Suspension or revocation of a medical professional license;

c) Amendment of state medical and sanitary standards.

2. The Medical Services Contract and the Contracting Parties

Under German law, a medical services contract is classified as a type of *service-like* agreement. The German legislator distinguishes it from a contract for work. In contrast, Georgian legislation governs medical services contracts under the provisions applicable to contracts for work. It is critically important to distinguish between these two types of contracts. The key distinction between a service contract and a contract for work lies in the obligation to achieve a specific outcome. A service contract is a bilateral agreement whereby the service provider undertakes to perform a certain action, while the recipient of the service is obliged to pay the agreed remuneration.[2] In the case of a contract for work, the agreement is likewise bilateral; however, the subject of the obligation is the attainment of a predetermined result, which is mutually agreed upon by the parties. The conclusion of such a contract presupposes the client's legitimate expectation that the promised result will be achieved. In essence, a contract for work is result-oriented, whereas a service contract is oriented toward the performance of activity or effort.[3]

Unlike German legislation, Georgian law does not recognize the medical services contract as a distinct contractual category. Instead, it is subsumed under service agreements[4] and is governed by the legal provisions applicable to contracts for work[5]. This legislative classification, however, remains a matter of debate whether the approach adopted in Georgian law is appropriate. In the context of medical services, the physician undertakes to perform a medical procedure in accordance with established professional standards, but does not assume responsibility for achieving a specific outcome. Accordingly, the object of the contract is the diligent execution of the medical intervention, rather than the attainment of a predetermined

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[2] *Kropholler, J.*, German Civil Code (Study Commentary), Tbilisi, 2014, 457.
[3] Ibid
[4] Civil Chamber of the Supreme Court of Georgia, Decision No. AS-539-512-2015, 28 July 2015.
[5] *Motsonelidze, N.*, Peculiarities of a Doctor's Professional Liability – A Comparative Legal Analysis, Law Journal, No. 1, 2019, p. 86. Cited: Title 10, Civil Code of Georgia, Official Gazette of the Parliament of Georgia, No. 31, Registration No. 786, 26/06/1997. <https://www.tsu.ge/data/file_db/faculty-law-public/2019-1-LAWJOUR-GEO.pdf> [31 May 2020].

result—an element that is central to contracts for work[6]. In light of this distinction, the prevailing legal approach in Georgia—which qualifies medical service contracts as contracts for work—remains subject to debate, despite its established status in legal practice.

As a general rule, the claimant in medical malpractice disputes is either the patient or a close relative. This principle is explicitly codified in Article 1007 of the Civil Code of Georgia, which stipulates that the right to claim compensation for harm inflicted upon a patient is vested in the patient or their family member. In the event of the patient's death, a third party may assert three types of claims. Most notably, compensation may be sought by a person who was financially dependent on the deceased at the time of death.

As for the defendant, it is typically the medical institution providing the healthcare service[7]. It is important to note that, as a rule, the defendant is usually the institution rather than an individual physician. However, in cases where a physician operates an independent medical practice, they may be personally named as the respondent in judicial proceedings.[8] Furthermore, it must be acknowledged that the definition of medical personnel extends beyond physicians. It includes nurses, pharmacists, and all other professionals whose activities are directly connected to the diagnosis, treatment, or rehabilitation of patients.[9]

3. Normative Grounds for the Liability of Medical Service Providers

The liability of medical service providers in Georgian law is primarily regulated by Article 1007 of the Civil Code of Georgia, which sets forth the general principles governing compensation for harm caused by medical institutions. The provision states: *"Harm caused to an individual's health during treatment in a medical institution shall be compensated in accordance with general principles. The person who caused the harm shall be released from liability if it is proven that they were not at fault for the occurrence of the harm."*

In addition to this article, other legal provisions—dispersed across various legislative acts—are also applicable[10]. Accordingly, in judicial disputes, Article 1007 must be applied in conjunction

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[6] Civil Chamber of the Supreme Court of Georgia, Decision No. AS-539-512-2015, 28 July 2015. Motskholadze, N., Peculiarities of a Doctor's Professional Liability – A Comparative Legal Analysis, Law Journal, No. 1, 2019, p. 86. Cited: Title 10, Civil Code of Georgia, Official Gazette of the Parliament of Georgia, No. 31, Registration No. 786.

[7] Collective Authors, Human Rights in the Field of Healthcare, Tbilisi, 215.

[8] Ibid

[9] Law of Georgia on Healthcare, Article 3^1 (prima), 05/05/2020. Available at: <https://matsne.gov.ge/ka/document/view/16978?publication=15>

[10] The right to health in Georgia is protected by the following normative acts: the Law of Georgia on Healthcare and the Law of Georgia on Patients' Rights.

with the relevant articles from the General Part of the Civil Code, as well as other normative acts.

One such provision is Article 103 of the Law of Georgia on Health Protection, which establishes that: *"Responsibility for the deterioration of a patient's physical or mental condition, or for death, as well as for moral or material damage caused by the action or inaction of healthcare personnel, shall be determined in accordance with Georgian legislation."*

In addition, Article 10 of the Law of Georgia on Patients' Rights provides patients or their legal representatives with the right to file a claim in court and seek:

a) Compensation for pecuniary and non-pecuniary damages arising from:
   a.a) a violation of the patient's rights;
   a.b) medical malpractice;
   a.c) operational deficiencies within a medical institution;
   a.d) improper supervision or regulatory failure by the state;

b) Suspension or revocation of the license of a medical professional;

c) Amendment of existing state medical and sanitary standards[11].

Unlike the Georgian legal framework, German legislation codifies the regulation of medical relationships within a single chapter.[12] This chapter was added to the Code in 2013, with most of its provisions developed in consideration of issues accumulated in German judicial practice. It reinforces the principles of transparency and legal certainty within German medical law.

4. Damage Caused by the Medical Service Provider

Under German civil law, *natural damage* encompasses any form of harm or loss affecting an individual's legally protected interests, such as property, health, or dignity. The concept of damage includes both pecuniary (material) and non-pecuniary (non-material) harm, with the applicable legal standards differing based on the type of damage sustained.[13] It is a well-established principle that compensation is available only for damage that can be objectively remedied[14]. To qualify as compensable, the harm must be legally significant and protected [15]—

[11] Article 10 of the Law of Georgia on Patients' Rights.
[12] German Civil Code, Untertitel 2, *Behandlungsvertrag*
[13] German Civil Code, BGB <https://www.gesetze-im-internet.de/englisch_bgb/index.html>
[14] *Menyhárd, A.* In Koziol, H. eds. "Basic Questions of Tort Law from a Comparative Perspective". Vienna ·Graz. 2015, 287.
[15] *Zoidze, B.*, Comment on the Civil Code of Georgia, Book III, Tbilisi, 2001, 366.

meaning it must not be excluded by law and must, according to the norms of commercial circulation, be considered subject to compensation.[16]

Pursuant to Article 10 of the Law of Georgia on Patients' Rights, a patient or their legal representative has the right to claim compensation for both pecuniary and non-pecuniary damage through judicial proceedings. Pecuniary damage may consist of a reduction in existing property or its loss. A reduction in property includes losses that have already occurred.[17] Loss of income, on the other hand, refers to the earnings that the party would have reasonably acquired in the future, but was prevented due to the unlawful conduct of the tortfeasor.[18] Moreover, pecuniary damage may also include increased expenses or costs incurred.[19]

Claims for non-pecuniary (moral) damage present significantly greater complexity than those involving pecuniary harm, which can typically be assessed through objective evaluation. In the case of moral damage, the principal aim of compensation is to mitigate the psychological suffering and emotional distress. Accordingly, the determination of the amount of compensation for moral damage falls within the scope of judicial activity, which means that the establishment of the relevant criteria lies within the judge's prerogative.[20] Monetary compensation serves as a mechanism for alleviating the impact of psychological harm and supporting the injured party's reintegration into a stable life.[21] Accordingly, the purpose of compensating moral damage is to "replace the victim's emotional suffering with a positive emotion.[22]" As the Supreme Court of Georgia notes, although moral suffering may indeed take place, compensation for moral damage is granted only in cases explicitly provided for by law.[23]

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[16] *Danelia, T.*, Liability for Moral Damages Resulting from Bodily Injury or Harm to Health, Master's Thesis, Tbilisi, 2019, . 5.

[17] *ugarman, S. D.* ((forthcoming 2013)). ,,Tort Damages for Non-economic Losses (in cases of physical injury to the person) ". In Bussani, M. and Sebok, A. eds., A Chapter from Comparative Tort Law. Edward Elgar. 201.

[18] Tbilisi Court of Appeals, Ruling No. 2ბ/2771-15 (23 March 2016). Supreme Court of Georgia, Ruling No. ას-153-2019 (8 May 2019). Supreme Court of Georgia, Ruling No. ას-1851-2018 (2 May 2019).

[19] *Dzlierishvili, Z.*, Compensation for Damage Caused by a Source of Increased Danger: On the Example of Article 999 of the Civil Code, *Lawyer*, No. 2, 2013, p. 32.

[20] *Barabadze, N.*, *Criteria for Determining the Amount of Moral Damages*, *Human and the Constitution*, No. 2 (2004), 80. *Tsiskadze, M.*, *T*he Issue of Compensation for Non-Pecuniary Damage for Bodily Injury in Georgian Legislation, *Justice and Law,* No. 2(17) (2008), p. 18.

[21] *Barabadze, N.*, Moral Damage and the Problem of Its Compensation, Tbilisi, 2012, p. 68. Supreme Court of Georgia, Decision of 20 July 2018 (Case No. ას-660-660-2018). *Magnus, U.*, *Damages for Non-Pecuniary Loss in German Contract and Tort Law, The Chinese Journal of Comparative Law*, 2015, . 299.

[22] *Dzlierishvili, Z.*, *Compensation for Damage Resulting from the Operation of a Vehicle (Commentary on Court Practice)*, *Student Law Journal*, 2012, 111.

[23] Civil Chamber of the Supreme Court of Georgia, 20 January 2012, Case No. ას-1156-1176-2011.

A similar approach is found in German law.[24] In one of its decisions, the court explains that non-pecuniary damage refers to harm affecting emotional feelings and relationships. In addition to the fact that an error by a medical institution or its staff may result in property damage, expressed in additional expenses, in certain cases the victim may also experience emotional suffering.[25] Naturally, the amount of compensation should correspond to the extent of the damage caused.[26] However, in practice, whether this principle is truly upheld remains debatable.

7. Causation as a Necessary Element for the Arising of Liability

7.1. Theories of Causation

In order for an action to be objectively attributed to a person, it is necessary to establish a causal link between the person who committed the act and the resulting consequence. Various theories exist regarding the determination of causality; however, the theory of direct and indirect causation is considered to be the most closely aligned with practical application. According to this theory, the decisive factor in establishing causality is the existence of an objective connection between events. A person's unlawful act constitutes the cause of damage only if it is directly and immediately linked to the harm.[27]

Another significant theory is the **equivalence theory**, which is based on the principle of *conditio sine qua non*—meaning that the harm would not have occurred *but for* the individual's conduct. According to this approach, the act of the person causing the harm must be considered the determining factor in the infringement of a legally protected interest. If the damage would have arisen independently of the conduct, then a causal relationship is deemed absent.

In medical disputes, the establishment of a causal link holds paramount importance as without it, not all the essential elements required for assigning liability would be present.[28] Therefore, the existence of a causal connection between the act or omission of the healthcare provider

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24 *Lowisch M.* New Law of Obligations in Germany, Rirsumeikan Law review, 2003,148.

25 *Osakve, K.*, The Concept, Classification, and Compensation of Moral Damage in Anglo-American Law, Tbilisi, 2015, . 2.

26 Supreme Court of Georgia, Decision of 4 April 2019 (Case No. ას-1322-2018). Supreme Court of Georgia, Ruling of 15 June 2018 (Case No. ას-250-250-2018). *Rusiashvili, G.*, Online Commentary on the Civil Code: Article 408.

27 *Akhvlediani, Z.*, Law of Obligations, Tbilisi, 1999, . 68.

28 *Determann, P.*, *Recht der Schuldverhältnisse,* Vol. I, 1928, 50, as cited in: *C*ommentary on the Civil Code of Georgia, Vol. III, *Zoidze, B.*, 369.

and the resulting harm is a necessary and mandatory condition for the occurrence of damage, including damage caused by improper medical treatment.[29]

The Civil Code of Georgia gives preference to the theory of direct causation.[30] Direct causation is characterized by the existence of a causal relationship only when the unlawful act is the immediate and direct cause of the result. Accordingly, the consequence would not have occurred in the absence of such conduct.

The Civil Code of Georgia gives precedence to the theory of direct causation. This theory is characterized by the existence of a causal link only when the unlawful act is the immediate and direct cause of the result. Accordingly, the outcome would not have occurred in the absence of such conduct.[31]

7.2. Challenges in Establishing Causation

In any legal dispute initiated against a medical institution it is essential that the patient proves that the physician's actions did not conform to generally accepted medical standards.[32] Accordingly, in order for a claim for compensation to be granted, the patient must also establish the existence of a causal link.[33]

In medical malpractice cases, establishing a causal link between the actions of the healthcare provider and the harm suffered by the patient presents a particular challenge. This complexity is often due to the interplay of multiple factors or actions, each of which—either independently or in combination—may constitute a necessary condition for the resulting harm.[34] While a specific act may indeed serve as the cause of the damage, it is essential to recognize that, in matters concerning a patient's health, a wide range of additional factors may influence the outcome. These may include the individual characteristics of the patient's body, psychological condition, delayed access to medical care, and other relevant circumstances.

Judicial determination of causation relies heavily on expert medical opinion. Yet, even under expert scrutiny, establishing a direct causal link can prove highly challenging—and, in certain

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[29] *Zoidze, B.*, *Commentary on the Civil Code of Georgia* (ed. Lado Chanturia), Book III, Tbilisi, 2001, 366.

[30] *Kvantaliani, N.*, Patients' Rights and the Grounds for Civil Liability of Healthcare Personnel, Lawyers' World, Tbilisi, 173.

[31] *Dzlierishvili, Z.*, The Legal Nature of Contracts for the Transfer of Property Ownership, Tbilisi, 2010, 66.

[32] *Strauch M.*, The Law of Medical Negligence in England and Germany, A Comparative Analysis,Oxford and Portland, Oregon , 2008, 46.

[33] *Akhvlediani, Z.*, Law of Obligations, Tbilisi, 1999, 68.

[34] *Kvantaliani, N.*, *Patients' Rights and the Grounds for Civil Liability of Healthcare Personnel, Tbilisi: Lawyers' World Publishing*, 2014, 173.

cases, practically impossible. Some clinical scenarios are so medically intricate that even experienced experts struggle to determine which particular action gave rise to the harm. Particularly noteworthy in this context is the possibility that evidence may be lost or disappear.[35] Moreover, expert reports submitted during litigation rarely contain categorical conclusions. In practice, expert opinions submitted to the court rarely have a categorical character. These opinions frequently omit a thorough factual analysis and often lack the level of detail necessary to fully clarify the circumstances of the case.[36]

One particularly noteworthy decision of the Supreme Court[37] concerned a case in which the claimants argued that their father underwent a coronary angiography at a clinic, followed by stent placement, based on the same clinic's recommendation. According to the claimants, the procedure was not performed in accordance with established medical standards. Subsequently, the patient's condition deteriorated, and he suffered an acute myocardial infarction. He was then transferred to another medical facility, where he underwent emergency surgery. The claimants sought compensation from the medical institution 41,273 GEL in pecuniary damages and 100,000 GEL in non-pecuniary (moral) damages. The City Court dismissed the claim, citing two main grounds: the patient's family member had signed an informed consent form prior to the procedure, and expert testimony confirmed that the treatment had been provided in accordance with recognized medical standards and applicable legal norms. The claim was dismissed by the City Court, and this decision was subsequently appealed.

The Court of Appeals also rejected the claim, emphasizing that under Article 992 of the Civil Code, for the obligation to compensate damage to arise, the following prerequisites must be present: damage, an unlawful act, and a causal link between the act and the resulting harm. These elements constitute the legal framework necessary for imposing liability for damage, and the absence of any one of them excludes the possibility of holding a party responsible for the harm caused.

However, the Court of Appeals examined the standard for the distribution of the burden of proof in medical malpractice cases and also referred to Article 992. According to the Supreme Court's interpretation, the lower instance courts incorrectly allocated the burden of proof between the parties. Current judicial practice demonstrates that, in many cases, claims for compensation for harm caused by medical institutions are dismissed due to the failure to establish a causal link. As previously noted, establishing causality is further complicated by

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[35] *Stauch M.*, The Law of Medical Negligence in England and Germany, A Comparative Analysis, Oxford and Portland, Oregon, 2008,

[36] *Kvantaliani, N.*, Patients' Rights and the Grounds for Civil Liability of Healthcare Personnel, Lawyers' World Publishing, Tbilisi, 2014, 181.

[37] Civil Chamber of the Supreme Court of Georgia, Decision of 25 May 2010 (Case No. ას-1268-1526-09).

accompanying factors inherent in medical procedures. These may include, for instance, the patient's emotional condition, which can adversely affect the recovery process.[38]

As mentioned above, expert opinion plays a central role in medical malpractice litigation, and courts often base their decisions on the findings presented in expert reports. In one notable case,[39] the Supreme Court established the existence of a causal relationship on the basis of expert testimony. The forensic analysis was conducted by the Levan Samkharauli National Forensics Bureau, which concluded that during an abortion performed at LLC "D," the uterus had not been fully evacuated. As a result, embryonic tissue remained in the uterine cavity. Two months later, the patient required further medical intervention due to the development of a cyst and a significantly deteriorated health condition.

Cases involving multiple contributing factors to the outcome are particularly complex. In such scenarios, it is especially difficult to determine which act had the most decisive impact on the result, or to what extent each act contributed to the overall harm.

7.3. Establishment of Causality by the Court in Legal Disputes

As previously discussed, causation in legal disputes may be categorized as either simple or complex. Establishing simple causation typically does not present significant challenges, as it involves a clear and direct sequence of actions or omissions that together constitute an unlawful act. In contrast, complex causation arises when multiple interrelated actions are involved, making it difficult to determine which specific act—or combination of acts—was decisive in causing the harm to the patient.[40]

The Supreme Court of Georgia has addressed the issue of simple causation in a case[41] where it rejected a medical institution's argument that no causal connection existed between the intervention and the harm sustained. The Court found a causal relationship between the medical procedure and the patient's infection with hepatitis C, as well as the existence of damage resulting from that intervention. It was unequivocally established that prior to the patient's visit to the clinic and before the initiation of treatment for gastro-intensive bleeding, no liver function abnormalities had been recorded. The deterioration of the patient's health occurred after discharge from the clinic. The case included an expert opinion confirming that

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[38] *Kvantaliani, N.*, Problems of Establishing Causality Between the Unlawful Conduct of a Medical Personnel and the Harm Caused to the Patient, Justice and Law, No. 2 (33), 2012, p. 9.

[39] Civil Chamber of the Supreme Court of Georgia, Ruling of 26 April 2010 (Case No. ას-280-265-2010).

[40] *Kvantaliani, N.*, Patients' Rights and the Grounds for Civil Liability of Healthcare Personnel, Lawyers' World, Tbilisi, p. 174.

[41] Civil Chamber of the Supreme Court of Georgia, Ruling of 9 February 2012 (Case No. ას-1779-1757-2011).

the patient had no liver dysfunction prior to the start of treatment, whereas within one month after discharge, acute liver impairment had developed and the patient's condition had significantly worsened. During treatment, the patient received transfusions from seven blood donors, one of whom had been designated as a reserve donor. One of these donors was later classified as unsuitable due to the discovery of an infection.

In the case at hand, the complexity was compounded by the fact that the incubation period for the Hepatitis C virus ranges from approximately 1 to 24 weeks, rendering it practically impossible to determine the precise source of the infection. A critical issue that emerged during the proceedings was that the blood donors had not undergone the required annual clinical screening. Given the medical specificity of the case, it was impossible to establish the exact origin of the infection with certainty. Nevertheless, the court considered the broader context: the claimant was a socially vulnerable individual, whereas the respondent was a financially capable medical institution with substantially greater financial capacity to demonstrate the absence of fault. Despite this advantage, the respondent failed to adequately discharge its share of the burden of proof. In this case, the court assessed the submitted evidence based on its inner conviction and concluded that there was a high degree of probability that the patient had contracted hepatitis C during the visit to the clinic.

8. Standard of Proof in Medical Disputes

8.1. General and Specific Rules for the Allocation of the Burden of Proof

The Civil Procedure Code of Georgia does not provide a definition of the burden of proof. However, in foreign legal literature, the burden of proof is generally understood as the obligation of a party to establish the factual circumstances on which their claims or defenses are based, where uncertainty regarding those facts may result in an unfavorable outcome for that party.[42] The Civil Code stipulates that each party must prove the facts upon which their claims and counterclaims rely.[43] In civil proceedings, considering the principles of party autonomy and adversarial process, the final outcome of the dispute largely depends on how the burden of proof is allocated. Therefore, the proper distribution of the burden of proof between the parties is of particular importance.[44] Accordingly, the allocation of the burden of proof holds not only procedural significance but also substantial material-legal implications.

In civil procedural law, there are general and special rules governing the allocation of the burden of proof. Article 102 of the Civil Procedure Code of Georgia refers to the standard of

[42] *M. K. Treushnikov,* Judicial Evidence, Moscow, 1999, p. 54.
[43] Article 102(1) of the Civil Procedure Code of Georgia.
[44] *Gagua, I.*, Doctoral Thesis: "The Burden of Proof in Civil Procedural Law", Tbilisi State University, 2012, 6.

fair and objective distribution of the burden and provides that the burden of proof lies with the party who asserts a particular fact, rather than the party who denies it.[45] In civil litigation, the outcome of a dispute between the parties often depends on how effectively the burden of proof is exercised and the extent to which it is fulfilled.[46]

Furthermore, the Civil Code establishes a special standard for the allocation of the burden of proof, under which the burden may be reversed.

The standard for allocating the burden of proof varies across legal systems. For example, in the United States, the prevailing standard is the "preponderance of the evidence," which means that a party must prove that the facts supported by evidence are more likely to be true than not.[47]

8.2. Allocation of the Burden of Proof in Medical Disputes

According to Georgian civil legislation, a special rule on the allocation of the burden of proof also applies in medical malpractice cases. However, it is noteworthy that the courts demonstrate inconsistent approaches in this regard. This inconsistency may stem from the presumption that a physician acts in good faith, with the utmost diligence, and with the primary goal of restoring the patient's health. Based on this presumption, courts sometimes apply the general rules of burden of proof in medical disputes.[48]

Consequently, when a patient brings a medical malpractice claim before the court, the patient bears the burden of proving a causal link between the harm suffered and the conduct of the alleged wrongdoer. The defendant, in turn, must prove that their actions were neither unlawful nor negligent.[49]

According to the Supreme Court's interpretation, in medical malpractice cases the patient is responsible not only for presenting the facts in a clear and convincing manner but also for demonstrating that a medical error occurred.[50]

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[45] *Akhalaadze, M.*, The Burden of Proof: Analysis of the Case Law of the Civil Chamber of the Supreme Court of Georgia, 2018, 12.

[46] *Gagua, I.,* Doctoral Thesis: "The Burden of Proof in Civil Procedural Law", Tbilisi State University, 2012, p. 6, available at:< https://press.tsu.ge/data/image_db_innova/Disertaciebi/ilona_gagua.pdf> [accessed: 16 April 2022].

[47] https://bit.ly/38s3Xef [accessed: 16 April 2022].

[48] Civil Chamber of the Supreme Court of Georgia, Decision of 22 January 2016 (Case No. ას-1102-1038-2015).

[49] Civil, Entrepreneurial, and Bankruptcy Chamber of the Supreme Court of Georgia, Decision of 13 April 2005 (Case No. ას-33-406-05).

[50] Civil Chamber of the Supreme Court of Georgia, Decision of 11 May 2018 (Case No. ას-111-111-2018).

In one of its rulings,[51] the Supreme Court emphasized that if the medical professional's goal is the patient's recovery, the professional is presumed to be acting with due care. In civil liability cases, however, medical personnel may still be found negligent if they fail to use all available means to prevent foreseeable risks. The Supreme Court reaffirmed this reasoning in another decision,[52] noting that consumers place a particular degree of trust in their contractual counterpart. In the context of healthcare, this implies that patients reasonably expect medical institutions to be staffed by competent professionals.

In one such ruling,[53] the court held that the patient bears the burden of fully presenting the facts and proving the existence of a medical error. Therefore, the patient must present evidence demonstrating that the harm was a result of the medical provider's failure to fulfill their obligations.

As for the medical personnel, the physician bears the burden of proving that the treatment was carried out in accordance with established standards and that the procedure was performed as agreed under the terms of the contract. In other words, the physician is responsible for delivering the promised and error-free treatment, but not for every adverse outcome.[54] Thus, the medical institution bears the burden of proving the absence of fault, and the very fact of harm to the patient's health creates a presumption that the damage resulted from the institution's fault.[55]

Article 1007 of the Civil Code of Georgia provides that in disputes related to harm to health, the burden of proof lies not with the patient, but with the service provider—in this case, the medical institution. Based on the analysis of court practice, it can be concluded that it is the physician who must prove that the treatment provided was free of error. As previously discussed, since physicians are not expected to guarantee outcomes, but rather to follow proper procedures, the focus shifts to whether the treatment was administered correctly and in compliance with established medical and legal standards. Therefore, a physician is held liable only for improper treatment and for damage caused as a result of such treatment. The basis for the physician's liability is not the adverse outcome itself, but the deviation from accepted medical standards.[56]

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[51] Civil Chamber of the Supreme Court of Georgia, Decision of 22 January 2016 (Case No. ას-1102-1038-2015).
[52] Civil, Entrepreneurial, and Bankruptcy Chamber of the Supreme Court of Georgia, Decision of 25 September 2007 (Case No. ას-296-624-07).
[53] Civil Chamber of the Supreme Court of Georgia, Decision of 11 May 2018 (Case No. ას-111-111-2018).
[54] Civil Chamber of the Supreme Court of Georgia, Decision of 25 May 2010 (Case No. 1268-1526-09).
[55] *Kvantaliani, N., and Rusiashvili, G.*, The General System of Civil Liability of Physicians and the Significance of Fault, Georgian-German Law Journal, 2022, . 9.
[56] Civil Chamber of the Supreme Court of Georgia, *Decision of 25 May 2010* (Case No. ას-1268-1526-09).

The German approach to this issue is also of particular interest. According to Section 630h of the German Civil Code, a medical error is presumed when there is a controllable risk and harm is caused to the patient's body or health. Thus, if harm results from an action that was entirely controllable, the burden of proof shifts fully to the medical institution. This approach is consistent with the jurisprudence of the Federal Supreme Court of Germany, which holds that in medical service contracts, the burden of proof regarding a breach of obligation is not automatically reversed, as the physician is not responsible for the treatment's outcome, but rather for providing proper medical care.[57]

German courts similarly apply this approach in cases involving fully controllable risks—specifically, in situations where harm is caused due to violations related to infrastructure or hygiene standards in the medical facility.[58] Unlike standard cases, in such instances, the patient's individual physiological characteristics or other subjective factors are not relevant, as the risk is entirely within the control of the medical provider.[59] Therefore, under Section 630h, if a patient suffers harm due to an organizational error within the medical institution, the burden falls on the provider to prove that no fault occurred.[60]

8.3. Reversal of the Burden of Proof

In the context of medical malpractice litigation, the first step is to establish the fact of injury or deterioration of the patient's health. Accordingly, the patient bears the obligation to present the relevant facts and carries the burden of proving the existence of a causal link between the conduct and the resulting harm. If the patient fails to discharge this burden, a medical error will not be considered established.

In one medical malpractice case,[61] the court noted that the evidence submitted by the patient did not confirm that the post-operative complications were the result of treatment conducted in violation of established medical standards. In that specific case, the patient was unable to prove the existence of a causal relationship between the improper conduct of the healthcare provider and the harm suffered.

This problem is not unique to Georgian court practice; similar challenges have also been observed in German jurisprudence. As a result, German courts developed a practice whereby,

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[57] *Wagner*, MüKo/BGB, 8. Aufl., 2020, BGB § 630h, Rn. 21.

[58] Weidenkaff, in: Palandt, BGB, 77. Aufl. 2018, § 630h Rn. 3; Wagner, in: MüKo-BGB, 8. Aufl. 2020, § 630h Rn. 25

[59] BGHZ 171, 358, Rn. 11 = NJW 2007, 1682. (Urt. v. 06.12.2006 - XII ZR 164/04

[60] Wagner, in: MüKo-BGB, 8. Aufl. 2020, § 630h Rn. 22

[61] Supreme Court of Georgia, *Decision of 27 November 2007* (Case No. ას-537-879-07).

in certain cases, a reversal of the burden of proof is deemed justified. For instance, if the damage is characteristic of a known medical risk and is objectively controllable by the physician, the presumption of a medical error may arise. In this regard, German courts have reasoned that, since courts are obligated to ensure the equality of arms between the parties, in some circumstances, the reversal of the burden of proof may be necessary to uphold procedural fairness.[62]

It is also important to note that the proper maintenance of medical records by the physician may serve as a means to ease the burden of proof on their part. Under Georgian legislation, physicians and other healthcare professionals are required to keep medical documentation in accordance with established rules. It is on the basis of this documentation that a physician must prove that they acted in accordance with medical standards.[63] According to prevailing views in legal scholarship, failure to fulfill this obligation may justify easing the patient's burden of proving a causal link between the treatment error and the harm caused to their health or life.[64]

In one case where the medical institution failed to fulfill this documentation obligation, the court emphasized that proving the proper administration of treatment falls within the scope of the medical provider's evidentiary obligations.[65] In the case at hand, the claimant failed to establish which specific actions caused the worsening of the patient's condition. While the court acknowledged the medical institution's failure to properly maintain the required documentation, it also held that this fact alone could not constitute a sufficient basis for assigning liability to the physician.

Conclusion

As explored throughout this article, the definition of medical error varies across legislative frameworks. However, based on the interpretations provided, a medical error may be understood as a deviation by the physician from established and recognized medical standards during the provision of healthcare services, which results in harm to the patient's health or leads to death. A medical error may also be present in situations where the physician possesses knowledge exceeding the required standard but fails to apply it in practice.

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[62] BVerfG, Urt. v. 25.7.1979, NJW 1979, 1925 .

[63] Civil Chamber of the Supreme Court of Georgia, *Decision of 27 June 2011* (Case No. ას-260-244-11).

[64] *Gagua, I.*, Doctoral Thesis: "The Burden of Proof in Civil Procedural Law", Tbilisi State University, 2012, p.. 55, available at: <https://press.tsu.ge/data/image_db_innova/Disertaciebi/ilona_gagua.pdf> [accessed: 21 May 2022].

[65] Tbilisi Court of Appeals, *Ruling of 9 March 2018* (Case No. 2ბ/1843-17).

Civil liability of a medical service provider arises only in cases of culpable and unlawful conduct. For liability to be imposed, the presence of certain prerequisites is required—namely, an unlawful act, a causal link, and fault. Among these elements, the establishment of causation holds particular significance, as it is both a mandatory condition and one of the most challenging aspects to prove in medical malpractice cases. This difficulty largely stems from the specific nature of the healthcare sector itself. Medical services are often provided by multiple institutions, and individual factors—such as the patient's physiological characteristics or emotional state—can substantially complicate, or at times render impossible, the determination of a direct causal connection.

In this context, particular attention must be given to the standard for the allocation of the burden of proof. It has a substantial impact on the outcome of claims and, given that civil procedure is adversarial in nature, the distribution of the burden of proof between the parties often proves decisive. In Georgian judicial practice, it has become evident that courts adopt differing approaches to the allocation of the burden of proof in medical malpractice cases, stemming from two fundamentally opposing perspectives. In some cases, courts emphasize the presumed good faith of medical professionals, requiring the claimant to prove all elements of liability; in others, the burden of establishing causation is shifted to the defendant.

The approach of other countries—such as that of the German courts—is particularly noteworthy, as they have developed a consistent judicial practice and established the principle of easing the burden of proof in certain cases. Specifically, when it is excessively burdensome for the patient to prove the existence of a particular element, courts may reduce the evidentiary threshold. This is grounded in the principle that claimants should not be subjected to an unreasonably heavy burden of proof, which could otherwise lead to the dismissal of claims.

In Georgia, one of the critical issues is that claims for compensation related to harm caused by medical treatment are often dismissed on the grounds of insufficient evidence to establish a causal link. The challenge does not lie solely in the allocation of the burden of proof; One of the major challenges lies in the often formulaic and insufficiently detailed expert opinions, which tend to lack evidentiary effectiveness. In addition, patients frequently face difficulties in obtaining relevant information and supporting evidence in a timely manner. Due to the specific nature of the medical field, there may also be instances where evidence disappears or becomes unobtainable, particularly given the complex and specific nature of the harm involved.

The European Court of Human Rights has also addressed this issue, holding that when an expert report fails to establish a causal link between the conduct and the harm suffered by the

patient, the respondent must be given the opportunity to submit alternative evidence, and such evidence must be duly considered by the court alongside the expert's findings.

In conclusion, it is beyond dispute that the establishment of a causal link plays a critical role in determining the civil liability of a medical service provider, and the inability to establish such a link precludes the imposition of liability.

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