

Law

Standards for Allocating the Burden of Proof in Medical Disputes

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Abstract. It is indisputable that medical disputes are distinguished by their specificity and represent a highly complex area of law. This field is particularly complex due to the nature of disputes arising in medical practice. The challenge in medical disputes is the proper distribution of the burden of proof and the ability of the parties to meet this burden. In many cases, it is not only difficult, but even impossible for the party to establish a causal link between the actions of the person providing medical services and the resulting damage. This difficulty is further compounded by the fact that obtaining evidence is very difficult for the patient, who is the weaker party in the relationship. Ultimately, all this leads to the burden of proof being so heavy for the plaintiff that it becomes virtually impossible to satisfy the claim. This article deals with the above-mentioned issues. Based on a comparative analysis, the paper reviews in detail the standards governing the distribution of the burden of proof in different countries. The article identifies the challenges in medical disputes and discusses possible solutions aimed at easing the burden of proof. In addition, the cases of reversal of the burden of proof in relation to gross medical error and fully controllable risks are discussed. It is worth noting that the literature on medical law in Georgia is quite scarce, and the issue raised in the article is truly complex and represents a challenge in contemporary legal practice. Therefore, it is undeniable that the topics discussed in this article are relatively new to Georgian legal scholarship and are very important in terms of enriching the literature on medical law. © 2026 Bull. Natl. Acad. Sci. Georg.

Keywords: medical disputes, burden of proof, medical law, causal link, fully controllable risks, gross medical error

Introduction

General and special rules for allocation of the burden of proof. The burden of proof constitutes a fundamental principle in civil procedure. In Georgia, this principle is expressly regulated by law. According to Article 102 of the Civil Procedure Code of Georgia, each party must prove the circumstances on which it bases its claims or

defenses (Bioling & Chanturia, 2003). As indicated by the Supreme Court of Georgia, in civil procedural law, the subject of proof consists of those circumstances that, within procedural legal relations, represent legal facts (Supreme Court of Georgia, NAS-860-860-2018). In contrast, the principles governing the burden of proof are not explicitly regulated by statute in the German legal

system. In German civil procedural law, it is established as a general principle that the burden of proof for facts giving rise to a right lies with the creditor or the person exercising the claim. Conversely, the burden of proof for facts that extinguish or impede a right, falls on the debtor (Stauch, 2008).

In Germany, the Doctrine on the Allocation of the Burden of Proof is regarded as a component of substantive law, not procedural law (Bundesgerichtshof [BGH], 1996). The German Code of Civil Procedure sets a high standard of proof for civil proceedings. Facts must be established with a standard of practical certainty; otherwise, the claim is regarded as unfounded (Bundesgerichtshof [BGH], 2014).

As a rule, the plaintiff must prove the facts upon which the claims are based. Conversely, the defendant must prove the circumstances that provide grounds for denying those claims. In civil cases, the basis for delivering a reasoned judgment lies in identifying the legal foundation from which the dispute between the parties arises. Therefore, the court's primary function in reviewing a dispute is to determine the material basis of the claim and the legal norm on which it is founded. Although a general rule for distributing the burden of proof exists in civil procedure, courts sometimes apply a specific rule regarding its allocation, which is directly regulated by law. A special rule for the distribution of the burden of proof applies in tort law, as well as in labor law and anti-discrimination law. This difference is dictated by the specific nature of the legal relationship, the difficulty of proving certain facts, and the objective ability or inability to present evidence (Meskhishvili, 2020). Therefore, in such cases, the burden of proof is reversed, meaning the obligation to prove facts presented by one party may be shifted to the other party (Arevadze, 2014).

The rule for distributing the burden of proof in medical law. In medical malpractice disputes, the

plaintiff is usually the patient or the patient's relative (Kvantaliani, 2014). This is directly provided by Article 1007 of the Civil Code of Georgia, which establishes that a claim for compensation for harm caused to a patient may be brought by the patient or by his or her relative (Supreme Court of Georgia, 2016, Case No. AS1102-1038-2015). The defendant, on the other hand, is typically the medical institution that provides medical services to the patient. Although in practice, it is usually an individual physician who treats the patient, the defendant in litigation is not the individual doctor but rather the medical institution itself.

As already noted, in medical disputes the courts apply special rules regarding the allocation of the burden of proof. As the Supreme Court has stated, there exists a presumption that the purpose of medical personnel is the recovery of the patient and that they act in good faith (Supreme Court of Georgia, 2016, Case No. AS-296-624-07). In cases of civil liability, medical personnel are considered negligent when they fail to use all available means to prevent risks. The Supreme Court developed the same reasoning in another decision, where it emphasized that the patient, as a consumer, places a particular trust in the contractual counterpart. This implies that the patient expects the medical institution to be staffed with qualified personnel (Supreme Court of Georgia, 2016, Case No. AS-111-111-2018). Regarding the burden of proof, the court has repeatedly noted that the patient bears the obligation to present the relevant facts comprehensively and to prove that a medical error occurred. Therefore, the patient must provide evidence demonstrating that the harm resulted from the medical institution's breach of duty (Stauch, 2008).

The responsibility of medical personnel, including physicians, implies that the physician bears the burden of proving that the treatment was carried out in accordance with the applicable standards. In other words, the physician must demonstrate that the procedure was conducted in

compliance with the established medical regulations, protocols, and contractual obligations. Based on the analysis of court practice, it can be concluded that the physician must prove that the treatment was performed without error and in accordance with established medical standards. As mentioned above, since the result of treatment is not guaranteed and the physician does not promise a specific outcome, the focus is on the process itself – namely, whether it was performed correctly and in compliance with medical and legal standards. Therefore, the physician is not liable for every adverse consequence, but only if the harm resulted from a deviation from established medical rules or standards (Kvantaliani & Rusiashvili, 2022).

As the above demonstrates, in Georgian judicial practice, the burden of proving the absence of fault in medical disputes lies with the medical institution. In such cases, the patient must demonstrate the fact of harm to health, which creates a presumption that the harm resulted from the medical institution's fault. Thereafter, the institution must prove that it acted in accordance with the relevant standard. In legal disputes initiated against a medical institution, it is therefore essential for the patient to establish that the physician's actions did not conform to generally accepted medical standards. Accordingly, in order for a claim for compensation to be granted, the patient must also establish the existence of a causal link.

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 often arises from the interaction of multiple factors or actions, each of which may independently or jointly serve as a necessary condition for the harm. 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, delay-

ed access to medical care, and other relevant circumstances (Kvantaliani, 2012).

Judicial determinations of causation rely heavily on expert medical opinions, yet establishing a direct causal link is often difficult or even impossible. Particularly noteworthy in this context is the possibility that evidence may be lost or disappear. Moreover, expert reports rarely provide categorical conclusions, often lacking thorough factual analysis and sufficient detail to fully clarify the case.

As mentioned, courts use a special rule for distributing the burden of proof in medical cases. In cases of civil liability, the issue is often the negligence of medical personnel, which occurs when they fail to use all available means to prevent risks. The established approaches to causation have gradually changed in European countries. It became clear that due to the heavy burden of proof, it was nearly impossible for patients to succeed in medical malpractice litigation. The Supreme Court of Canada in *Snell v. Farrell* (1990) addressed the allocation of the burden of proof and pointed out that a judge can shift the burden of proof based on the specific circumstances of a case. This trend toward easing the burden of proof is also supported by the Court of Justice of the European Union, which was approached by the French Supreme Court for an interpretation of the EU Product Liability Directive. In a specific case, the plaintiffs filed a lawsuit against the vaccine manufacturer Sanofi. The plaintiffs claimed that the vaccine caused multiple sclerosis in their relative, which led to their death in 2011. In its decision, the court discussed Article 4 of the EU Product Liability Directive, stating that under this directive, the plaintiff must prove the existence of causation. It should be emphasized that the court indicated that when scientific research does not allow for the definitive establishment of a causal link between the conduct and the result, the claimant must be granted the right to rely on other evidence to substantiate his or her position. For example, the short period of time between the administration of

the vaccine and the onset of the illness, the absence of the disease in the family medical history, and similar circumstances.

This judgment illustrates a relaxation of the burden of proof, allowing the claimant to establish causation with less effort by submitting alternative evidence when expert reports cannot confirm a direct link between the doctor's action and the injury. The court evaluates such evidence and weighs it in its decision. While certain facts may be inherently difficult or impossible to prove, this should not impose barriers on the plaintiff that undermine the principles of adversarial proceedings and equality (Hagenloch, 2024).

Reversal of the Burden of Proof in Cases of Gross Medical Error

In the process of establishing causation and, consequently, in the allocation of the burden of proof, particular significance is attached to the case of gross medical error as codified in paragraph 630h VI of the German Civil Code (Katzenmeier, 2024). In particular, according to judicial practice, when a physician commits a gross medical error which by its very nature entails the possibility of causing harm to life, body, or health, the burden is placed upon the physician to prove the absence of damage, that is, to demonstrate that the harm was not caused by the breach of duty and that it would have occurred even in the absence of the error (Bundesgerichtshof [BGH], 1994).

As the Federal Supreme Court notes, a medical error is regarded as gross when, based on the standards of the medical field and the doctor's level of education, the action is clearly wrong. In such a case, gross medical behavior can exist even without a showing of negligence. The key factor is the objectively wrong nature of the action itself, which runs contrary to universally accepted medical standards (Stauch, 2008).

According to Part V of Article 630 of the German Civil Code, if a healthcare provider makes a gross medical error, the burden of proof shifts to

them (Bergmann & Wever, 2014). Consequently, the patient no longer has to prove that the harm would not have occurred without the medical error (Wagner, 2020). From a medical perspective, the failure to implement necessary measures constitutes a gross medical error. This includes cases where a doctor fails to perform the required examination, does not conduct all tests specified by standard procedure, and so on. In accordance with the consistent practice of the German Federal Supreme Court, such gross medical errors lead to a reversal of the burden of proof (Bundesgerichtshof [BGH], 1994).

According to German case law, if a violation is gross, the burden of proof falls on the doctor (Oberlandesgericht Stuttgart [OLG Stuttgart], 1996). A gross error is a doctor failing to diagnose meningitis in a patient despite clearly expressed symptoms (Bundesgerichtshof [BGH], 1988). It would also be a case where a doctor did not perform a mandatory medical examination or treatment that was necessary in a specific situation (Oberlandesgericht München [OLG München], 2020).

On 23 January 2020, the Higher Regional Court of Munich delivered an important decision. The court based its review on Paragraph 630h (5) of the German Civil Code, which states that if a doctor's conduct constitutes gross medical error and endangers a patient's life or health, it is presumed that the harm was a result of the improper treatment. In this particular case, it was determined that a serious error during treatment caused paraplegia in a minor. Based on this finding, the burden of proof shifted to the medical facility. Ultimately, the clinic was ordered to pay €500,000 in pain suffering compensation, as well as fully reimburse all past and future expenses related to the medical error (Zhu et al. , 2021). The German Civil Code clearly states that in cases of a gross medical error, the burden of proof is reversed. Such an error is so significant and obvious that it creates a presumption of a professional duty breach by the doctor. As a result, it is presumed that the harm to the

patient was directly caused by this error. This presumption shifts the obligation to prove the absence of a causal link from the patient to the medical facility.

Fully Controllable Risk as a Basis for Reversing the Burden of Proof

German courts have repeatedly deliberated on standards for easing the burden of proof. The central question in these deliberations was whether a common risk inherent in treatment should be considered a "controllable risk" and thus be a basis for a presumption of medical error (Stauch, 2008). In response to this issue, German courts developed the "doctrine of fully controllable risks" for medical malpractice cases (Bussani et al., 2020). The goal of this doctrine is to ease the standard of proof or, in some cases, shift the burden to the medical facility (Stauch, 2010). The doctrine of fully controllable risks implies that if a problem arises entirely within the physician's sphere of responsibility, it is presumed to be caused by the physician's negligence. For instance, this could apply if a patient's brain damage is caused by a malfunction in the oxygen system during anesthesia (Wagner, 2020). This approach is also gaining recognition in German law, where the burden of proof is often reversed in favor of the patient to ensure a legal balance. This is why Paragraph 630h of the German Civil Code explicitly allows for the burden of proof to be shifted in the patient's favor (Stauch, 2008). Specifically, it is presumed that the risk was fully controllable for the healthcare provider, and therefore, the burden of proof is entirely shifted to the defendant (McGhee v. National Coal Board, 1973).

English courts share this view, noting that it is often very difficult for a patient to establish a causal link between the actions of a healthcare provider and the harm they suffered. When a part of the unlawfulness resulting from the physician's conduct remains unclear, the burden of proof must be shifted in such a way that the uncertainty is not used to the advantage of the defendant.

A notable example is *McGhee v. National Coal Board*, where the plaintiff, a workman employed by the National Coal Board, developed dermatitis after being required to cycle home covered in brick dust because his employer failed to provide adequate washing facilities. Medical experts could not prove with certainty whether the disease was caused by the initial exposure to dust during work or by the prolonged exposure while traveling home. The House of Lords held that although the traditional "but for" causation test was not satisfied, the employer's negligence had materially increased the risk of the harm occurring. Therefore, the creation of that risk was treated as sufficient causal connection. This reasoning marked a significant development in tort law, as it allowed the burden of proof to shift to the defendant to demonstrate that their negligence did not cause the injury (Katzenmeier, 2024).

A common ground for reversing the burden of proof is a medical facility's failure to properly maintain records. Physicians are obliged to document all essential measures in line with regulations, including the patient's history, treatment details, and related information (Hagenloch, 2024). According to Paragraph 630F of the German Civil Code, a medical facility is obligated to maintain complete medical records. Maintaining complete records means that the medical facility must include all procedures performed on the patient and attach all necessary documents (Lanzer, 2013). Courts in both Continental European and Anglo-American legal systems share a unified approach on this matter. When a medical facility breaches its duty to maintain medical records, the patient is completely relieved of the burden of proof, and this obligation shifts to the medical facility. Paragraph 630h(3) of the German Civil Code explicitly states that if a treating party has not maintained medical records containing information about necessary treatment measures and their results, it will be presumed that the party did not perform these measures or medical procedures (Lodge, 2025). The English courts take a similar approach, noting that the plaintiff is at a

disadvantage compared to the medical facility. The defendant has access to all the medical records and necessary expertise, which the patient does not. Therefore, the medical facility is strictly required to present all necessary documentation during the legal proceedings (Stauch, 2008).

In both German and English law, missing medical documentation significantly affects the burden of proof and judgment. German courts take a stricter stance, presuming a medical error when record-keeping duties are breached. By contrast, English courts adopt a more flexible approach, allowing facilities to rely on alternative evidence, such as witness testimony, to defend their position.

The Doctrine of Res Ipsa Loquitur

The doctrine of Res Ipsa Loquitur originated in England in 1863 and is now widely used in both English and American legal systems. It is somewhat similar to the German "fully controllable risks" doctrine, as well as the principle of reversing the burden of proof in cases of gross negligence. The essence of this doctrine is that a doctor's conduct is so far below the acceptable standard of care that it is regarded as negligence on its face (*prima facie*). (Byrne v. Boadle, 1863). Under Res Ipsa Loquitur, a plaintiff can create a presumption of negligence on the part of the defendant if they can prove the following circumstances: The injury would not have occurred without negligence; The cause of the injury was entirely under the defendant's control; There is no other logical, alternative explanation for the injury. This doctrine is also frequently used by courts in the United States. In such instances, the existence of harm implies that it was caused by negligence, creating a presumption of negligence (Supreme Court of California, 1944a). Consequently, the burden of proof to show the opposite shifts to the defendant. For this to apply, three preconditions must be met: 1) The incident is of a type that typically does not occur without negligence; 2) The incident was caused by something exclusively under the defendant's

control; 3) The plaintiff is not at fault for the harm. This doctrine was notably applied in the case of Byrne v. Boadle where a pedestrian was injured by a flour barrel that fell from a shop. In this case, the individuals responsible for securing the barrel were considered *prima facie* liable for the harm caused to the pedestrian (Byrne v. Boadle, 1863).

Conclusion

Civil liability of a medical service provider arises only in cases of culpable and unlawful conduct. For liability to be imposed, certain prerequisites must be satisfied – namely, an unlawful act, a causal link, and fault. Among these elements, causation is of particular importance, as it is both essential and one of the most difficult aspects to prove in medical malpractice cases. This difficulty arises from the very nature of healthcare: treatment often involves multiple providers, while patient-specific factors – such as physiological traits or psychological state – can significantly complicate, or even preclude, the establishment of a direct causal link.

It is important to note that the patient is inherently the weaker party in a medical relationship, especially when it comes to litigation. Patients often face substantial difficulties, or even impossibilities, in obtaining evidence and, consequently, to meet the burden of proof. Ultimately, this results in a failure to uphold the principle of equality of the parties in medical disputes. In such cases, the court plays a vital role in safeguarding the principles of adversarial proceedings and equality of arms. Medical disputes are inherently imbalanced: medical facilities hold the information and documentation, making proof considerably easier for them than for the injured patient. To address this disparity, courts must ensure a fair allocation of the burden of proof, which in some situations requires easing the patient's evidentiary burden to preserve equality and the integrity of the proceedings.

The research shows that both European countries and the United States are moving towards easing the burden of proof in medical malpractice

cases. The Anglo-American legal approach considers it an excessively heavy burden for patients to prove every element of liability. Therefore, it is held that if a wrongful act creates or increases the risk of harm, a causal link is presumed to exist, and the responsibility to rebut this presumption shifts to the medical facility. Specifically, when it is excessively burdensome for the patient to prove the existence of a particular element, courts may reduce the evidentiary threshold.

The Court of Justice of the European Union also leans toward easing the burden of proof. It allows

patients to use evidence other than expert opinions, which require less effort to obtain, to prove the existence of a causal link.

From the foregoing, it is evident that the problem lies in the specific nature of the issue itself. However, it is equally important that the courts, taking into account the particular circumstances of each case, properly allocate the burden of proof and balance the inequality between the parties through the correct standard of allocation.

სამართალი

მტკიცების ტვირთის განაწილების სტანდარტი სამედიცინო დავებში

მ. კვიციანი

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სამედიცინო დავებში გამოწვევას წარმოადგენს მტკიცების ტვირთის სწორად განაწილება და ამ ტვირთის დაძლევა მხარის მიერ. ხშირ შემთხვევაში, მხარისათვის არათუ რთული, არამედ შეუძლებელიც კი არის მიზეზობრივი კავშირის დადგენა სამედიცინო მომსახურების გამწევი პირის ქმედებასა და დამდგარ შედეგს შორის. ამასთანავე, მტკიცებულებების მოპოვება პაციენტისათვის, ამ შემთხვევაში კი ურთიერთობის სუსტი მხარისათვის, ძალიან რთულია. საბოლოოდ, ეს ყველაფერი იწვევს მტკიცების ტვირთის იმდენად დამძიმებას მოსარჩელისთვის, რომ მისი მოთხოვნის დაკმაყოფილება ფაქტობრივად შეუძლებელი ხდება. წინამდებარე ნაშრომში შედარებითი ანალიზის საფუძველზე, დეტალურად არის განხილული სხვადასხვა ქვეყანაში მტკიცების ტვირთის განაწილების სტანდარტი. ნაშრომში იდენტიფიცირებულია სამედიცინო დავებში არსებული გამოწვევები და მათი გადაჭრის გზები, მტკიცების ტვირთის შემსუბუქების მიმართულებით. ამასთან, განხილულია მტკიცების ტვირთის შემობრუნების შემთხვევები უხეშ სამედიცინო შეცდომასა და სრულად კონტროლირებად რისკებ-

თან მიმართებაში. აღსანიშნავია, რომ საქართველოში სამედიცინო სამართლის ლიტერატურა საკმაოდ მწირია, ხოლო ნაშრომში დასმული საკითხი ნამდვილად კომპლექსურია და გამოწვევას წარმოადგენს დღევანდელ რეალობაში. აქედან გამომდინარე, უდავოა, რომ აღნიშნული თემები იურიდიული ლიტერატურისთვის სიახლეს წარმოადგენს და ძალიან მნიშვნელოვანია სამედიცინო სამართლის ლიტერატურის გამდიდრების თვალსაზრისით.

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