

Ease of Proof Responsibility for Causal Relationship of Medical Injury Infringement

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Abstract: Medical injury infringement is usually allocated based on the principle of "who claims, who provides evidence". The result of the patient's infringement damage is more easily proven by the medical treatment behavior of the doctor. The focus of the conflict between the doctor and the patient usually focuses on the degree of participation in the causal relationship between the infringement damage result and the medical treatment behavior of the doctor. After analyzing the causal relationship proof content of different types of medical disputes, this article believes that the application of the burden of proof mitigation should be limited to medical technology damage disputes and informed consent damage disputes involving diagnosis and treatment behavior, and should only be used to demonstrate whether there is a causal relationship between medical behavior and patient damage. At the same time, when determining whether there is a causal relationship, judges also need to consider whether the medical institution's treatment has fulfilled its diagnostic and treatment obligations under existing objective technical conditions, whether the doctor has made mistakes in diagnosis and treatment, and ultimately determine whether the causal relationship between the medical behavior and patient's damage is established.

Keywords: Medical Damage; Causal Relationship; Mitigation of Proof of Responsibility.

1. Introduction

Medical care is one of the basic guarantees for people's daily lives. Due to the huge difference in medical knowledge levels between doctors and patients, conflicts in the doctor-patient relationship coexist for a long time. Proper handling of medical damage infringement is of great significance for balancing the rights and interests of both doctors and patients, adjusting and regulating the entire medical environment.

How to properly resolve medical disputes, harmonize doctor-patient relationships, and maintain medical order has always been the goal of continuous exploration in the academic community. There is still a lot of room for continuous improvement and discussion in the specific resolution measures of medical disputes.

The content of medical dispute proof is highly professional, and how to solve the problem of heavy burden of proof for the plaintiff has not been able to reach a unified view in the long discussion [1]. Therefore, it is necessary to analyze the allocation of burden of proof for medical injury infringement when studying medical injury infringement issues.

2. Legislative Evolution of Relevant Regulations and Proposal of Issues

From a legal perspective, China's legislation on the burden of proof for medical injury infringement is mainly divided into the following stages.

Since the implementation of the "Several Provisions of the Supreme People's Court on Evidence in Civil Litigation" in 2002, the burden of proof for medical injury disputes has been subject to Article 4 (8), which stipulates that "in disputes arising from medical acts, medical institutions shall bear the burden of proof for the absence of a causal relationship between medical acts and medical injuries.". In medical infringement cases, the burden of proof is reversed, i.e. the burden of proof is shouldered by the medical party to reduce

the burden of the patient.

After the implementation of the Tort Liability Law of the People's Republic of China (referred to as the Tort Liability Law) in 2010, the reasons for presuming that medical institutions are at fault were further clarified. However, the law adopts an avoidance attitude towards the issue of causality, one of the elements that constitute tort liability.

Article 4 of the Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Medical Injury Liability Disputes, promulgated in 2017, stipulates that "if a patient claims medical injury infringement liability, they shall submit evidence of medical treatment and injury to the medical institution." If a patient is unable to submit evidence of the fault of the medical institution and its medical staff, as well as the causal relationship between diagnosis and treatment behavior and damage, and submits an application for medical damage appraisal in accordance with the law, the people's court shall allow it. The patient bears the burden of proving the causal relationship between medical behavior and medical harm. From then on, the provision on the inversion of the burden of proof for causal relationships in the Civil Procedure Evidence Regulations is no longer cited in China's judicial judgments. In 2019, the Supreme People's Court also deleted the entire content of Article 4 of the 2002 Civil Procedure Evidence Regulations.

The Civil Code of the People's Republic of China (referred to as the Civil Code), which has been implemented since 2021, basically retains the provisions of the Tort Liability Law on the principle of fault attribution for medical torts, weakens the determination of causal relationships in medical torts, and directly uses "whether it violates the normative content of diagnosis and treatment activities" as the basis for the existence of fault by the medical party. If the medical party "cannot prove that it is not at fault, it should bear tort liability" [2]. At present, the burden of proof for medical infringement cases in China is fully borne by the patient.

In short, in the factual evidence of medical malpractice liability, the burden of proving the causal relationship between the patient's medical treatment behavior and the damage suffered from the medical institution, as well as the fault of the medical party, is borne by the patient, while the medical party has the responsibility to prove that they have fulfilled their treatment obligations. Due to the diagnosis and treatment behavior of the medical party, the patient's damage results are reflected more intuitively in the medical record data. The core issue of medical injury infringement ultimately focuses on "whether the medical party is at fault" and "whether there is a causal relationship between the diagnosis and treatment behavior and the damage".

Under the general principle of "who claims, who provides evidence", the objective burden of proof borne by the patient is relatively disadvantageous for the patient. Patients generally do not have medical knowledge, and the proof process mainly relies on materials provided by the medical party and third-party appraisal results. However, there are certain problems with the simple transfer of the objective burden of proof to hospitals in Article 8 of Article 4 of the Civil Litigation Evidence Regulations issued by the Supreme Law in 2002. Due to the uncertainty of medical diagnosis and treatment effectiveness, as well as the special circumstances of patients and limitations on medical technology, there are many situations in reality where medical authorities are unable to provide evidence. Therefore, this clause has been deleted. In summary, it can be seen that there are certain problems in simply and broadly dividing the objective burden of proof between the medical and patient sides.

The general classification of medical damages in China's academic community is based on infringement behavior, which is divided into four categories: medical technology, medical products, medical ethics, and medical management damages. [3] Among them, medical management damages are often included in other types of infringement situations in the Civil Code's tort liability section, and there are few specialized cases in practice. Therefore, this article will not talk about them. Medical product infringement is subject to the principle of "no fault liability" in substantive law, and patients only need to bear the burden of proving the existence of infringement behavior and damage in litigation law. The causal relationship between the two is proved by the production or user of medical products.

The existing controversial parts in the types of medical disputes are medical technology damage and medical ethics infringement damage. The author hopes to further classify and study the two types of medical disputes mentioned above, and discuss in detail the allocation and proof process of causal relationship proof responsibility, explore more perfect allocation methods in different situations, and alleviate the current situation of excessive patient causal relationship proof responsibility.

3. The Application of Mitigating the Burden of Proof for Causal Relationships

In addition to informing patients about their condition and causing damage to patient information confidentiality, medical ethics damage often includes some complex issues that combine medical behavior with patient informed consent, including violations of information disclosure, informed consent, and breach of confidentiality obligations [4].

Violation of information disclosure and breach of confidentiality obligations constitute medical ethical damages that do not affect diagnosis and treatment behavior, while violations of informed consent constitute medical ethical damages that affect diagnosis and treatment behavior. Therefore, the author divides medical ethics damage into medical ethics damage that affects diagnosis and treatment behavior and medical ethics damage that does not affect diagnosis and treatment behavior.

3.1. The Causal Relationship between Breach of Confidentiality Obligations and Breach of Information Disclosure Damages does not Apply to the Mitigation of Proof Responsibility

The liability for breach of confidentiality obligations generally only involves damage to the patient's mental state. According to the Civil Code, if a patient's privacy, personal information, or medical record data is leaked, regardless of whether it causes damage to the patient, medical institutions and their medical staff should bear the liability for infringement. Therefore, if the dispute only involves the patient's right to know and does not affect the patient's treatment results, it can be handled according to the general principle of proof in civil infringement, which states that "whoever claims, who provides evidence". For patients, it is necessary to prove that the patient's privacy and other information have been leaked, without the need to prove the causal relationship between the leaked information and their own damage. Therefore, there is no need to discuss the burden of proof of causal relationship in this situation.

Firstly, it should be clarified that the patient's informed consent is based on the doctor's full disclosure of information, which is the doctor's obligation. Medical institutions and staff, as the main body of notification, need to prioritize informing patients. Only when patients are in a state of unconsciousness or inability to make decisions independently, or when the condition is not suitable for patients to be explained, can close relatives be notified instead of patients. The form of communication is usually a combination of written and oral forms. Medical professionals tend to use professional terminology in written communication. However in oral communication they should adhere to the principles of simplicity and loyalty in order to make it easier for patients to understand their health status and treatment plans.

The obligation of information disclosure here can also be understood as the obligation of medical professionals to ensure that patients are fully aware of their condition and medical activities. The specific standards, the content and method for informing patients are determined by the doctor based on the individual patient's situation, taking into account factors such as the patient's education level, occupation, age, and special circumstances.

There are two types of information provided by doctors, one requires the patient's consent, and the other does not require the patient's consent, only a simple statement of the patient's condition. The time informed by the doctor should be timely and appropriate, so that the patient can correctly evaluate the situation, make a decision on whether to accept medical treatment, and fully protect the patient's right to informed consent. From another perspective, the difference between violating the obligation to disclose information and violating the right to informed consent is that respecting

informed consent requires the patient's consent, but the obligation to disclose information does not require the patient's consent. The violation of the obligation of medical authorities to disclose information may be more reflected in whether the patient is aware, often having little impact on the diagnosis and treatment results, and more often causing psychological damage to the patient. Therefore, in this case, patients need to provide evidence of the causal relationship.

3.2. The Difficulty of Proving the Causal Relationship of Medical Technology Damage should be Appropriately Reduced

Undoubtedly, patients do not have sufficient professional knowledge about whether a certain medical technology (or medical behavior) can cause harm to match their burden of objective proof.

In medical infringement cases, it is necessary to establish a causal relationship between the behavior of the medical party and the patient's injury as the prerequisite for infringement. However, due to the complexity and uncertainty of medical technology, there are also cases where damage occurs due to the special physical condition of patients, making it even more difficult to determine causal relationships. However, in medical technology cases, causal relationships are crucial in determining whether the medical party should bear tort liability, as well as the scope and amount of compensation provided by the medical party. Therefore, more careful consideration of causal relationships is necessary.

At present, the focus of controversy in medical technology damage disputes lies in the hospital proving whether there is a fault in the diagnosis and treatment process and bearing the corresponding burden of proof. However, the causal relationship between diagnosis and treatment behavior and damage results still lies with the patient's objective burden of proof. Patients often lack basic medical knowledge, so they can only rely on the judicial appraisal results of medical disputes to prove the causal relationship in the dispute.

In response to this type of medical technology damage, we can refer to the practice of the German practical community and propose the "theory of major medical defects" regarding the burden of proof in medical litigation. This theory suggests that when there is a significant medical flaw in the medical field, the burden of proof for the causal relationship between the patient's injury and the medical flaw will shift to the medical field, and the medical field should bear the corresponding burden of proof for the non causal relationship between the significant medical flaw and the patient's injury [5]. If the medical party cannot prove it, the causal relationship is presumed, and the principle of major medical defects applies to cases that include diagnostic defects and treatment defects, such as failure to conduct differential diagnosis, failure to undergo examination, or failure to promptly refer patients to large hospitals for necessary examinations [6].

The purpose of using the principle of major medical defects is to solve the problem of difficulties in providing evidence when there are defects in the medical process and the causal relationship between the defects and the damage suffered by the patient is difficult to clarify [7]. Therefore, patients should not be required to bear the burden of proof in this situation. In summary, the principle of major medical defects applies to situations where the medical treatment by the medical party has significant defects and can be attributed, and in such cases, the adverse consequences that cannot be proven by causal

relationships are borne by the medical party. The current provisions in the Civil Code of in China prove that the patient's damage occurred during the diagnosis and treatment process, and that the medical party violated laws, administrative regulations, rules, and other relevant diagnostic and treatment norms or illegally obstructed the patient's collection of medical record information. If the medical party is at fault, it proves that the medical party needs to bear corresponding tort liability. However, from the perspective of litigation law, this theory can also be used to further clarify the possible degree of participation in the causal relationship between medical defects and patient damage. In accordance with the six levels of "complete causal relationship (96% -100%), main causal relationship (56% - 95%), equal causal relationship (45% -55%), secondary causal relationship (16% -44%), minor causal relationship (5% -15%), and no causal relationship (0% -4%)" [8] that cooperate with the judicial department in determining the causal relationship between personal injury and disease, we will improve the evaluation criteria for the degree of participation of medical defects in personal injury so as to appropriately reduce the difficulty of proving the causal relationship between patients and medical technology damage.

3.3. The Difficulty of Proving the Causal Relationship of Medical Ethical Damage that Affects Diagnosis and Treatment Behavior should also be Reduced

The harm of informed consent often involves communication between doctors and patients, as well as the selection of treatment plans. The content of informed consent includes two aspects: "informed" and "consent" [9]. "Informed" includes the doctor's explanation and the patient's knowledge, while "consent" includes the patient's acceptance and rejection. In the issues related to the liability for damages caused by informed consent, if it involves diagnostic and therapeutic activities, especially invasive diagnostic and therapeutic activities, the patient's proof of damage includes whether the medical party has infringed on informed consent and whether there is any damage to patients caused by medical technology in the completed diagnostic and therapeutic actions.

At this point, referring to the analysis in the previous section, patients should adopt the theory of significant medical defects for the medical technology damage that has already ended. When it is difficult to clarify the causal relationship between the improper application of medical technology and the harm suffered by patients, the burden of proving whether there is a causal relationship is borne by patients is transformed into the burden of proving that the medical party bears the burden of proving that their diagnosis and treatment behavior is not flawed. For example, if a hospital only has the fault of non-standard medical record writing, but the medical appraisal results show that there is no significant delay in treatment, no damage to the patient's physiological structure and function, and no substantial adverse effects on the patient's recovery of health, the hospital's treatment has no medical defects, and existing evidence cannot prove that there is a direct causal relationship between the patient's subsequent medical expenses and the hospital's erroneous diagnosis and treatment behavior, the hospital shall not be liable for corresponding damages [10].

Sometimes the patient's own choice of different treatment

options has a significant impact on the final outcome. Considering the high degree of trust in the doctor-patient relationship, based on the patient's trust in the medical provider, in general, the information provided by the medical provider only needs to include an explanation of the patient's condition and medical measures. As long as the patient does not explicitly object, the medical provider can implement corresponding diagnosis and treatment activities. When performing surgery, special examinations, or special treatments, physicians should additionally inform patients of medical risks and alternative plans. In addition, the scope of medical notification should also include other situations where the patient's medical decision has a substantial impact, such as the expected effect of treatment, the consequences of not treating, etc. After understanding the specific situation, patients need to choose a treatment plan that they agree with for treatment, and the patient's decision is also one of the influencing factors of the diagnosis and treatment results.

If the patient's choice of different treatment plans may affect the effectiveness of the treatment, etc., the patient needs to prove whether they are aware of the consequences of their chosen treatment plan. The medical party first needs to prove that the treatment complies with relevant regulations and there are no diagnostic and therapeutic defects, while the patient needs to prove that if they know other treatment plans, they may make a judgment that is more conducive to the patient's treatment. The medical party needs to provide counter evidence to prove that the patient's choice of plan does not affect the treatment results or that the medical party has fully explained the different treatment plans and their possible consequences.

For example, in the (2023) Yue 01 Min Zhong 20705 Civil Judgment [11], the court provided a detailed explanation of the key issues in the doctor-patient dispute, citing appraisal reports and responses from appraisers. The final court held that due to insufficient risk disclosure and improper implementation of active medical behavior by the hospital, as well as varying degrees of violation of the obligation to explain during the prenatal and prenatal stages of diagnosis and treatment, the medical party bears the responsibility for damages due to diagnostic and treatment defects. In this case, it should be judged that there is a causal relationship between the hospital's fault and the damage result, referring to the Guidelines for Determining the Causal Relationship between Personal Injury and Disease to determine the specific compensation ratio.

4. Factors to Consider when Proving that Medical Treatment is not at Fault

At the same time as the patient bears the responsibility of proving the causal relationship, the medical party needs to prove that they have fulfilled their obligations, there is no negligence, and objective conditions limit their medical level. The inversion of the burden of proof for medical disputes only arises when the medical party provides proof of obstruction measures.

4.1. Inversion of Proof Responsibility Caused by Obstruction in Medical Proof

In medical disputes, medical records are an important basis for determining the responsibilities of both doctors and patients. Ensuring the objectivity, authenticity, and

completeness of medical records is of great significance for the resolution of medical disputes. The provisions on obstruction of medical proof in China are mainly reflected in Article 1222 of the Civil Code, which states that concealment, loss, forgery, tampering, or illegal destruction, as well as refusal to provide medical record materials related to disputes, can lead judges to assume that the medical party may have made mistakes. At this time, the objective burden of proof will be shifted to the medical party, so the medical party must provide standardized and complete medical records.

Article 14 of the Regulations on the Management of Medical Records in Medical Institutions (2013) also clearly stipulates that medical institutions should strictly manage medical records, and no one, including both doctors and patients, shall arbitrarily alter medical records. It is strictly prohibited to forge, conceal, destroy, seize, or steal medical records. It should be noted that forging or tampering with medical record information must be strictly distinguished from modifications caused by typos or other legitimate reasons during the writing process of medical records. Superior physicians can generally review and modify the medical records of subordinate physicians. When there is a typo or when the superior physician needs to modify the medical records, there are regulations to ensure that the original records are clear and identifiable [12]. Such compliant medical record modifications do not constitute proof obstruction behavior by the medical party, and therefore do not cause inversion of proof responsibility.

In addition, "If medical records are not filled out in a timely manner due to emergency rescue, medical personnel should make up the information truthfully within 6 hours after the rescue is completed, and indicate it." [13] Necessary and compliant medical record information supplementation and improvement should not be used as a basis for the fault of the medical party. The medical party can cooperate with relevant hospital regulations and other information to prove that they are not at fault.

The digitization of hospital information has not had a substantial impact on the relevant regulations in medical disputes. The "Regulations on the Application and Management of Electronic Medical Records (Trial)" (2017) stipulate the basic requirements, writing, storage, and use of electronic medical records. It requires that the creation, modification, and archiving of electronic medical records must have traceability, and retain the traces of previous operations, operation time, and information of operators. However, there are still many doubts about the authenticity and legality of electronic medical records, and it is difficult for courts and parties to determine whether medical institutions have "tampered, forged, concealed, or destroyed" electronic medical record data. At present, the main practice is to confirm the effectiveness of electronic medical records by jointly sealing the paper version of the medical records by both doctors and patients.

For the patient, it is relatively rare to tamper, forge, conceal, or destroy medical record information. A common occurrence is when the patient snatches medical record information. China has stipulated that if the patient considers it difficult to obtain evidence, they can obtain the necessary evidence through the method of applying to the court. If the medical party can provide evidence that the patient's seizure of medical records has led to the inability to conduct medical damage assessment, the patient must bear the consequences of the inability to provide evidence as a result [14]. In practice,

there are also cases where patients always have doubts about the continuity of medical records obtained through court applications [15], but this does not constitute an obstruction to medical proof by the medical party, and therefore does not constitute an inversion of the burden of proof. It is still necessary for patients to prove their doubts about the continuity of medical records.

4.2. Proof of Fulfillment of Medical Obligations and Absence of Negligence

According to the Civil Code and other regulations, medical institutions and their medical staff have the following seven obligations: medical disclosure obligation, emergency medical obligation, reasonable diagnosis and treatment obligation, privacy protection obligation, obligation to provide access to and storage of copied medical records, obligation not to use defective products, and obligation not to over-medicate [16]. Therefore, the medical party has an objective burden of proof to prove that they have fulfilled the above obligations.

The obligation of medical disclosure and the obligation to provide access, storage, and copying of medical records can be reflected through the patient's medical records and other information. The obligation of emergency medical care, privacy protection, and non use of defective products not only depends on the compliance of medical institutions with relevant laws and regulations, but also on the internal management of medical institutions. A sound internal management of hospitals can correct some of the deficiencies in medical behavior. Whether hospital regulations are sound and complete, and whether medical personnel comply with regulations are important factors in measuring whether medical institutions have diagnostic and treatment errors [17].

The author believes that the reasonable diagnosis and treatment obligation in China is similar to the "examination obligation" and "examination result assurance obligation" of the German Federal Court's medical party in dealing with patients, that is, when the medical party fails to fulfill its responsibility, the burden of proof on the patient should be reduced [18]. If there are necessary tests and treatment methods that can affect the patient's treatment or condition judgment, the medical party needs to provide evidence to prove that the medical party has fulfilled the examination obligation. If the medical party cannot prove that they have fulfilled the examination obligation, it is necessary to prove that there is no causal relationship between the diagnosis and treatment activity and the patient's damage [19], and the medical party shall bear the objective burden of proof because the obligation of examination is also an important part of ensuring flawless treatment for patients.

4.3. Proof of Objective Limitations on Medical Level

For individual patients, there are many uncertainties in the diagnosis and treatment behavior itself, which inevitably makes medical harm complex and also affects the consideration of whether the medical treatment is at fault in individual cases. The factor that objective medical level cannot treat patients should be an important reason to block the causal relationship between patient damage and diagnosis and treatment behavior.

The high risk of medical services may lead to medical disputes, but the medical treatment is not at fault. The medical industry is a high-risk industry, especially invasive treatments

that can cause external damage to the patient's body structure. Medical science is still constantly developing, with exploratory and experiential characteristics. Medicine is an empirical science, and there are still many problems that are difficult to solve in medical field. If the medical party can prove that the diagnosis and treatment have reached the current level of medical treatment, the medical party should not bear the responsibility for medical infringement. In addition, clinical decisions have a temporary nature, and in emergency situations, medical professionals can only seek best treatment at the minimum cost. Medical examinations and imaging observations may not fully reflect the true situation. The possible multi-factorial and dynamic variations of diseases, the uncontrollability of disease complications, the toxicity or side effects of drugs, the different constitutions of each patient and other factors may lead to certain risks in medical behavior itself [20]. Medical authorities should provide sufficient evidence for these factors.

The participation of diseases is also a key aspect that medicine practitioners need to focus on providing evidence in medical disputes. Most patients have already suffered from the invasion of diseases and have caused damage to their bodies. The damage caused by these diseases can suddenly endanger the patient's life safety in certain situations. Acute hemorrhagic shock, acute myocardial infarction, stroke, liver and spleen rupture, etc., can potentially cause the patient to die at any time. In addition, although there may be opportunities to cure some diseases, they are almost never successful. For example, in emergency rescue of injured patients in car accidents, medical staff are required to come up with the most effective solution in a short period of time to treat a patient. At the same time, it is also necessary to determine whether there is any injury that requires in-depth examination to further diagnose the patient. However, due to emergency situations, severe injuries, and other reasons, doctors sometimes find it difficult to further examine the patient in the shortest possible time. When medical staff discover problems with the patient's physical indicators, it is likely that the best rescue time has been lost, delaying the patient's condition.

The participation of basic diseases and the continuous development of the disease progression have increased the difficulty to analyze and judge medical damages in individual cases. Medical diagnosis and treatment should not hold responsible for these factors which cannot be solved at the current medical level. Therefore, if the medical party provides evidence for this, the judge needs to consider the above factors.

5. Summary

In recent years, with the gradual development of medical science and the transformation of people's concepts, the requirements of the entire social group for medical services have gradually increased, and the doctor-patient relationship has received more and more attention and importance. The interaction mode of doctor-patient relationship is also undergoing fundamental changes, and the traditional authority of doctors is constantly being challenged, leading to frequent doctor-patient disputes. Finding a feasible and acceptable burden of proof allocation model for both doctors and patients can help them further clarify their substantive legal responsibilities in medical infringement litigation.

At present, in practice, the issue of proving medical disputes is often judged through appraisal to determine the

proportion of responsibility borne by both parties, and substantive legal responsibilities such as fault presumption are used to reduce the difficulty of patients receiving compensation. Medical dispute appraisal has supported legal practitioners to further analyze the division of proof responsibility for causal relationships in medical disputes, in order to better achieve the effect of case closure. This article believes that the mitigation of the burden of proof of causality should be applied more cautiously to situations where diagnostic and therapeutic behavior may cause harm to patients, but the patient clearly lacks the ability to prove the harm and causality. A more appropriate approach is to prove whether there is a causal relationship between medical behavior and patient damage in medical technology damage disputes and informed consent damage disputes involving medical technology in order to fundamentally reduce the difficulty of patient proof. On the other hand, medical institutions demonstrate that there is no causal relationship between their diagnosis and treatment behavior and patient damage by proving that their treatment is faultless and flawless, ruling out the possibility of disputes involving medical institutions in the damage.

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