YARU LI*

*The evolution of the allocation system of burden of proof for medical malpractice in China***

Summary: 1. Introduction. – 2. Three stages of development of the burden of proof allocation system for medical malpractice in China. – 3 The stage of inversion of the burden of proof. – 4 The stage of diversified burden of proof allocation. – 5. Conclusions.

1. *Introduction*

With the improvement of medical technology, people's legal awareness, rights protection awareness and health awareness have been enhanced, and they have paid more attention to the protection of their own rights and interests. When medical disputes occur, the proportion of patients resorting to legal remedies through legal channels is increasing, resulting in a continuous increase in the number of medical damage disputes in recent years. There were even "medical dispute profiteers"[1]. The settlement of medical disputes is related to the construction of a harmonious society, and although medical damage liability is only one of the ways to resolve medical disputes, it is related to the response and evaluation of the civil

* *Ph.D. Student in Civil Law, School for Advanced Studies, UNICAM.*
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1 Z. LI, Y. LIU, X. NI, *On the improvement of litigation settlement mechanism of medical disputes in China*, in *Journal of Chongqing University of Science and Technology: Social Sciences Edition*, 2013, pp. 43-45.

legal system to the social reality, and its importance is no less than that of other dispute resolution mechanisms. The Lancet, a world-renowned medical journal, even thinks that Chinese medical institutions has become a "dangerous place", "battlefield" or "fortress", and the doctor would become a "high-risk profession"[2]. In the framework of the system of Medical Liability, particular emphasis is placed on the criteria of burden of proof and their articulation, which play a fundamental role in judgements of medical liability.

In a civil lawsuit, the burden of proof includes two parts: the responsibility for behavior and the responsibility for results. The distribution of the burden of proof is the core of the burden of proof, that is, according to the established procedural norms, the legal elements that appear in the litigation process are pre-allocated to the patient and the doctor who are the plaintiff and the defendant, so that they can respectively prove their own responsibilities. Then the distribution of the burden of proof for medical tort can be interpreted as the division of the burden of proof borne by the patient and the doctor as the plaintiff and the defendant.

As an important part of civil tort litigation in China, the determination of medical tort litigation is more complicated and difficult than general tort liability litigation. Due to the high degree of professionalism and complexity of medical behavior, the biased evidence, the individual differences of patients' conditions, and the uncontrollability of the living body often leads to the uncertainty and uncontrollability of medical behavior, so the patient often faces more difficulties when proving evidence[3]. Therefore, the allocation of the burden of proof for medical damage has always been a difficult problem in legislation, and it is also the most controversial focus issue, which directly affects the relevant rights and obligations of both doctors and patients in medical damage cases. Whether the parties can provide evidence

[2] T. YIN, Z. LIU, Y. XU, *Analysis of Crisis Management of Medical Disputes in China and Australia: A Narrative Review Article*, in *Iran J Public Health*, 2019, p. 2116 ss.
[3] S. JIANG, *Reduction of the burden of proof in physicians' civil liability procedures*, in W. WANG (editor), *Reform of Civil Procedure Law*, Beijing, 2005, p. 3.

to prove their claims or defend the claims of the other party has become the key to affecting the judgment result and whether the parties can win the case.

2. *Three stages of development of the burden of proof allocation system for medical malpractice in China*

There is a proverb in ancient Rome: The proof, the losing. How to balance the proving capabilities of both doctors and patients, protect the interests of vulnerable parties, and distribute the burden of proof in a fair and reasonable manner are issues that China has been exploring in recent years. Throughout the historical process of the development and evolution of China's medical malpractice burden of proof allocation system, it can be roughly divided into three stages. At different stages, both doctors and patients need to bear different burdens of proof.

Before and at the beginning of the reform and opening up in 1978, medical damage disputes were not common, and the only cases of medical damage disputes were adjusted by criminal law and administrative law through criminal and administrative means, and very few disputes were resolved through civil litigation procedures[4]. With the development of the market economy and the improvement of people's living standards, there have been many types of illegal and tortious acts that are not specifically stipulated by the law. Therefore, it is necessary to formulate a more complete legal system to adapt to the development of the country. However, medical torts in this period were only regarded as a category of common torts and were not classified as special tort cases, which were mainly adjusted by the General Principles of Civil Law (hereinafter also referred to as the GPCL) and Civil Procedure Law[5]. According to Art. 106, para. 2 of the GPCL[6], the resolution of medical damage liability

[4] L. YANG, *On the System of Imputation Principle of medical Damage Liability*, in *Journal of CUPL*, 2009, p. 63.
[5] D.GAO, *Research on the burden of proof mitigation system for medical injury in China*, in *Inner Mongolia University of Science & Technology*, p. 9.
[6] Art. 106, par. 2 of the *GPCL:* Citizens and legal persons who infringe upon the property of the state or the collective, or the property or person of others due to their fault, shall bear civil liability.

disputes shall be based on the principle of fault liability as a method of accountability, and the principle of "who claims, who proves" shall be applied accordingly to the allocation of the burden of proof. The patient shall bear the full burden of proof for the four elements of medical tort (i.e., illegal act, the fact of damage, causation and medical negligence)[7]. However, due to the influence of the Soviet trial model in China's judicial trial system at this stage, it was in a super-authoritarian model, with judges in a dominant position and more involvement in cases. Whether it is the collection of evidence or the investigation, the court is in charge of it, and the parties' proof becomes an empty talk.

On January 1, 1987, the State Council promulgated and implemented the Measures for Handling Medical Accidents (hereinafter referred to as the Measures), which implements the principle of strictly limited fault liability. Even if the damaged patient can prove that the medical institution has medical errors, the medical institution shall not be liable for compensation. Only when a medical liability accident or medical technical accident has been identified, the patient can apply for compensation, and the compensation must be limited according to the accident level, circumstances and patient's conditions[8]. Due to the implementation of the welfare policy of public funded medical care in China during this period, the medical behavior of medical institutions is of a welfare nature[9], so the legislation focuses more on the protection of the interests of medical institutions and medical staffs. And with the transformation of China's litigation model to a party-based litigation model, the status of the

[7] There are mainly two theories of "three elements theory" and "four elements theory" for the constitutive elements of medical tort liability. The "Three Elements Theory" is represented by Liming Wang, who believes that the constituent elements should include the fact of damage, causation and medical negligence, while the "Four Elements Theory" is represented by Lixin Yang, compared with the "Three Elements", there is one more "illegal act" element.

[8] Art. 3 of the *Measures*: During the diagnosis and treatment, any of the following circumstances is not a medical accident: (1) Although there are errors in diagnosis and treatment, it does not cause the death, disability or functional impairment of the patient; (2) Unforeseeable and preventable adverse consequences occur due to the illness or the special constitution of the patient; (3) The occurrence of unavoidable complications; (4) The patients and their family members do not cooperate with the diagnosis and treatment as the main reason to cause adverse consequences.

[9] L. YANG, *China's Medical Damage Liability System Reform*, in *Legal Research*, 2009, p. 81.

parties' litigation subject has been strengthened, and the burden of proof has been confirmed. The patient should bear all the burden of proof, which leads to an excessive burden of proof on the patient, and the doctor only needs to prove that he or she has a disclaimer and provide counter-evidence based on the patient's proof. Many medical dispute cases cannot be well resolved due to the inability of the parties to provide evidence, which seriously damages the civil rights and interests of the patients. Therefore, the effect brought about by the implementation of the Measures is not satisfactory.

In view of the highly specialized issues involved in medical disputes, and the unequal access of information and medical knowledge between doctors and patients, in the practice of medical tort litigation, the application of the "who claims, who proves" rule is not very ideal. This is because, on the one hand, patients have no way to know whether the diagnosis and treatment of medical institutions are in compliance with regulations and professional procedures. Compared with medical institutions and medical staff, patients have obvious disadvantages. On the other hand, medical institutions and medical staffs have more control over the information in the process of diagnosis and treatment than patients and their families, and patients are unable to record the behavior of doctors when receiving treatment. For example, under anesthesia, it is impossible to know the specific situation of the operation, and it is difficult to know the meaning or harm of certain medical behaviors. Compared with patients, medical institutions and medical staffs can directly grasp the comprehensive and specific information in the process of diagnosis and treatment activities. Evidence such as medical records, diagnosis and treatment records, laboratory test sheets, etc. to prove whether the medical behavior of medical institutions is at fault is kept by the hospital, which is generally difficult for patients to access. Therefore, if the two parties cause a conflict and then sue to the court, it often happens that the patient is unable to provide evidence or the evidence provided is insufficient to prove his claim and gets an unfavorable judgment. The allocation standard of the burden of proof lacks the inclined protection for patients, which

makes the burden of proof on patients too heavy. When the legitimate rights and interests of patients cannot be relieved through legal channels, they will choose other ways to protect their own rights and interests. Therefore, at this stage, the phenomenon of "Yinao"（医闹）[10]occurred frequently, and the contradiction between doctors and patients continued to intensify, which led to a tense situation in the relationship between doctors and patients.

3. *The stage of inversion of the burden of proof*

Art. 4, par. 8 of the Several Provisions of the Supreme People's Court on Evidence in Civil Procedures (hereinafter referred to as PECP)[11], which came into effect on April 1, 2002, inverted the burden of proof of the elements of fault and causation in medical tort disputes to medical institutions, and implemented the principle of presumed responsibility for fault. But this does not mean that the patient does not need to bear any burden of proof, according to the regulations, it still requires the patient to bear the burden of proof for the diagnosis and treatment of medical institutions or medical staffs and the fact of physical damage. After the patient has fulfilled the obligation of proof, the remaining two elements of the burden of proof is that there is no causal relationship between the diagnosis and treatment and the fact of the damage suffered by the patient, and the diagnosis and treatment is not at fault by the doctor to bear. The Supreme People's Court explained why the inversion of the burden of proof should be applied in medical tort litigation: Given that the patients being treated lack the appropriate medical expertise, and has insufficient ability to obtain evidence relevant to the determination of the facts of the case, and are at a disadvantage compared with medical institutions and medical staffs. Due to insufficient evidence, patients often have no way

[10] B. L. LIEBMAN, *Law in the Shadow of Violence: Can Law Help to Improve Doctor-Patient Trust in China?*, in *Columbia Journal of Asian Law*, 2016, pp. 113-115 (explaining "Yinao" literally means "medical chaos," and is "the term most commonly used to describe patient protest").

[11] Art. 4, para. 8 of the *PECP*: In a tort lawsuit caused by medical behavior, the medical institution shall bear the burden of proof that there is no causal relationship between the medical behavior and the result of the damage and that there is no medical fault.

to receive compensation commensurate with the losses they have suffered. In order to balance the interests of both doctors and patients who have a direct interest in the case, the PECP clearly stipulates that the inversion of the burden of proof should be applied to the litigation of medical disputes[12]. This is similar to the "dangerous field theory" advocated by some scholars. The "field" of the diagnosis and treatment process is under the control of the doctor, and the patient is subject to information asymmetry. For balance considerations, the field controller should assume greater responsibility[13].

In 2002, the State Council revised the Measures and promulgated the Regulations on the Handling of Medical Accidents (hereinafter referred to as the Regulations) on September 1, implementing the principle of fault liability. If a medical institution has medical damage caused by medical negligence, it should bear the responsibility for medical damage. Although there are many improvements in the Regulations compared with the Measures, for example, the definition of medical accident is relaxed[14], and the fourth-level medical accident is added[15], that is, other consequences that cause obvious physical damage to the patient (but only limited to physical damage, not including mental damage, property damage, etc.); abolished one-time financial compensation and formulated specific compensation standards and calculation methods, etc. However, these measures did not fundamentally change the principle of restricting compensation for medical accident damages, and the balance of the law is obviously tilted towards medical institutions[16].

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12 Y. SHI, *Medical Tort Law*, Beijing, 2011, p. 188.

13 X. LIU, J. XIAO, *Research on the typification of causality and the balance of burden of proof in medical disputes - taking 224 civil judgments as analysis samples*, in *Medicine and Law*, 2022, p. 30.

14 Art. 2 of the *Regulations* provides, The term "medical malpractice" as mentioned in these Regulations refers to an accident in which a medical institution and its medical staff violate the laws, administrative regulations, departmental rules, diagnosis and treatment and nursing norms and routines in the course of medical activities, and cause personal injury to the patient through negligence.

15 Medical accident is classified into four grades based on the level of physical harm caused to the patient, with grade 1 being the most severe and grade 4 being the least severe, however, to be classified as grade 4, the medical accident must have caused the claimant "substantial" damage. C. XI and L. YANG, *Medical liability laws in China: The tale of two regimes*, in *Tort Law Review*, 2011, p. 66. Thus, a "non-substantial" injury, even it meets all definitional requirements, will not constitute a medical accident. Y. YI, *Disputes over Medical Injury Compensation*, Beijing, 2010, p. 106.

16 At this time, the contradiction between administrative regulations and judicial interpretations began to

Subsequently, on January 6, 2003, the Supreme People's Court promulgated the Notice on Trial of Civil Cases of Medical Disputes with Reference to the Regulations on the Handling of Medical Accidents, clarified its attitude towards handling medical damage liability disputes. It is stipulated that "Disputes over medical compensation due to medical accident shall be handled with reference to the relevant provisions of the Regulations; other medical compensation disputes arising from reasons other than medical accident shall be governed by the provisions of the GPCL". Different laws are applied according to whether it constitutes a medical accident, forming a duality of legal application[17].

However, in the Interpretation of the Supreme People's Court of Some Issues concerning the Application of Law for the Trial of Cases on Compensation for Personal Injury (hereinafter referred to as the Judicial Interpretation on Compensation for Personal Injury), which was published on December 26, 2003 and implemented on May 1, 2004, the items and standards of personal damage compensation determined by the Supreme People's Court are far higher than the compensation standards stipulated in the Regulations, and put forward the opinion that medical malpractice liability and state compensation liability do not apply to the compensation standards stipulated in the Judicial Interpretation on Compensation for Personal Injury[18], and the Regulations does not provide for death compensation. According

emerge. One stipulated that the principle of fault liability was implemented to reduce the responsibility of medical institutions, while the other stipulated that the principle of presumed fault liability was implemented to strengthen the protection of the rights of victimized patients. However, in the face of challenges and requests for instructions on the application of the law, the Supreme People's Court adopted an attitude of not conflicting with administrative regulations. For details, can refer to the Notice on Trial of Civil Cases of Medical Disputes with Reference to the Regulations on the Handling of Medical Malpractice promulgated by the Supreme People's Court below. L. YANG, *China's Medical Damage Liability System Reform*, cit, pp. 81- 85.

17 C. MA and G. ZHANG, *Regulations logic and application path of medical damage liability---From the perspective of the coordination between the civil code and the "medical law"*, in *Hebei Law Science*, 2022, p. 46. Objectively speaking, the system design of "medical malpractice" leads to a structural dislocation of "dual system" in the handling of doctor-patient disputes, which in turn leads to disordered consequences in the judicial practice of medical damage compensation. As mentioned below, patients often choose to sue medical institutions in court on the grounds of medical negligence rather than medical accident, in order to avoid the application of the Regulations.

18 On the surface, this opinion seems to maintain the authority of administrative regulations and protect the rights of medical institutions, but in the field of tort law, medical institutions are positioned as a special subject of tort liability and a special institution, and they do not accept unified legal adjustments. , resulting in a chaotic situation in the application of the law. L. YANG, *Research on the Concept of Medical Damage Liability*, in *Politics and Law*, 2009, p. 76.

to the definition of medical accident in the Regulations and Measures, medical accident is constituted only when the consequences of medical damage are more serious. At this time, the loss suffered by the patient is bound to be greater, but the compensation received is less, which is obviously unreasonable. Therefore, patients often prefer to choose to sue medical institutions in court on the grounds of medical negligence (i.e., non-medical accident) rather than medical accident, in order to avoid the application of the Regulations. In practice, the judiciary often adopts an attitude of acquiescence or even encouragement to support the patient in filing a lawsuit on the grounds of medical negligence. However, due to the application of the rule of inversion of the burden of proof, the medical institution needs to bear the burden of proof for the elements of fault and causation, and is in a disadvantageous position in the litigation, and if in the unfortunate event of losing the case, the medical institution will also have to bear high compensation costs. But at the same time, we should also see that the high compensation behind the right to claim compensation for medical fault damages to some of the damaged patients is a substantial increase in the cost of medical treatment. The different provisions of the Judicial Interpretation on Compensation for Personal Injury and the Regulations on damage compensation have formed a duality of compensation standards.

The implementation of the inversion of the burden of proof, by distributing the burden of proof between the doctor and the patient, reduces the difficulty and the burden of the patient's proof, and the status of the doctor and the patient tends to be equal. While helping the patient to sue and claim easily, it also gradually revealed its drawbacks and defects. The main problems are the number of tort cases caused by medical disputes increases rapidly due to the random litigation of patients. The inversion of the burden of proof has greatly lowered the threshold for the patient to file tort lawsuits, and people's awareness of rights protection has been continuously improved, as long as the patient or his close relatives are dissatisfied with the doctor's diagnosis and treatment, it is possible to push the hospital into

court. It even causes some patients to arbitrarily exercise their right to sue in order to obtain illegitimate benefits, because even if the patient loses the lawsuit, they only need to bear a small part of the litigation costs, and will not pay other costs and legal liabilities for this. This will lead to a considerable number of medical disputes becoming indiscriminate cases, which is not conducive to the optimal allocation of China's judicial resources, and destroys and disrupts the normal judicial, medical and social order.

The increase of "defensive medical treatment" and over-medical treatment. "Defensive medical treatment" refers to preventive medical measures taken by doctors in the process of diagnosis and treatment in order to reduce medical risks and reduce the probability of medical litigation[19]. It can take two forms: "positive" and "negative" defensive medicine[20]. On the one hand, doctors must treat diseases and save people, on the other hand, they must preserve and collect no-fault evidence. As a result, some diseases that can be judged based on years of experience and detailed consultation, the doctor also requires patients to do some unnecessary instrumental examinations to obtain objective results to determine the type and cause of the disease. In order to avoid the uncertainty and high risk of the disease, doctors often choose the program or conservative treatment with a relatively low risk factor rather than the most suitable treatment for the patient. For the same reason, many hospitals refuse to accept even high-risk patients. On the one hand, it leads to an increase in the cost of medical treatment for patients, waste of medical resources, and leads to various social problems. On the other hand, the contradiction between doctors and patients has been intensified, making it more difficult to trust each other.

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[19] L. WANG, *On Several Issues on Inversion of the Burden of Proof*, in *Guangdong Social Sciences*, 2003, p. 154.

[20] A. ANTOCI, A. FIORI MACCIONI, P. RUSSU and PL. SACCO, *Curing is caring? Liability reforms, defensive medicine and malpractice litigation in a post-pandemic world*, in *Socio-Economic Planning Sciences*, Volume 80, 2022, 101164. "Positive" defensive medicine entails performing unnecessary tests or procedures so that physicians attempt to legally protect themselves by being over-cautious, while "negative" defensive medicine entails avoidance of risky treatments, or denial of appropriate care to patients deemed too risky, to reduce the exposure to malpractice litigation.

The research of medical science is stagnant and its development is hindered. Medicine is a discipline closely related to theoretical knowledge and practical experience. When a new treatment method is proposed, it needs not only to pass theoretical and medical experiments, but also to undergo clinical tests. If a new treatment is used in the course of diagnosis and it does not work, the doctor is likely to face the risk of being sued by the patient and most likely to lose the case. This will make doctors too conservative and dare not conduct break-through research and treatment, restrict the innovation of medical technology, and hinder the progress and development of medical technology. Legislation should not disregard the legitimate rights and interests of the other party in order to protect the interests of the weaker party. This is not fairness in the substantive sense, but a violation of the principle of fairness and justice.

4. *The stage of diversified burden of proof allocation*

On July 1, 2010, the implementation of the Tort Liability Law(hereinafter referred to as the TLL) marked the entry of a new process in the allocation system of the burden of proof in China. On the basis of drawing lessons from the French classification method on medical science negligence and medical ethics negligence[21], it is groundbreaking based on the causes and characteristics of medical damage, and determines the principles of attribution and the distribution of the burden of proof for medical technical damage, medical ethics damage and medical product damage[22]. The provisions of Art. 54 are the principle of fault liability[23], which implements the distribution method of the burden of proof of "who claims, who proves". The patient shall bear the burden of proof that the medical institution is at fault in the diagnosis and treatment, and there is a causal relationship between the fault and

21 Z. CHEN, *The burden of proof of medical malpractice in French law*, Taipei, 2008, p. 139.
22 L. YANG, *Research on Medical Damage Liability*, Beijing, 2009, p. 120.
23 Art. 54 of the *Tort Liability Law*: If a patient suffers damage in the course of diagnosis and treatment, and the medical institution and medical staff are at fault, the medical institution shall be liable for compensation.

the damage suffered by the patient. Considering that it is difficult for the patient to bear all the burden of proof, in order to balance the interests of both parties, Art. 58 stipulates three situations in which the principle of fault presumption applies[24]. When the situation stipulated by law occurs, it is presumed that the medical institution is at fault. According to the inversion of the burden of proof, the medical institution shall bear the burden of proof that there is no fault in its medical behavior, but the patient should also first prove the premise facts, if it cannot be proved, it is considered that the patient has not fulfilled the obligation of proof, failed to meet the standard of proof, and the appeal cannot be supported by the judge, thus the medical institution does not need to bear the tort liability. The provisions of Art. 59[25] determine the application of the principle of no-fault liability in medical product damage, as long as the patient suffers damage due to the medical product and the medical product is defective, the doctor needs to bear the corresponding tort liability[26]. Due to the emergence of the presumption of fault, the law stipulates the corresponding exemptions in Art. 60[27], which provides a remedy for the medical party under certain circumstances.

In response to the confusion caused by the duality of legal application and compensation standards before the promulgation of the TLL, the TLL has devoted a special chapter on medical malpractice liability. And abandoned the relevant legal concepts such as medical

[24] Art. 58 of the *Tort Liability Law*: If a patient suffers damage due to any of the following circumstances, it is presumed that the medical institution is at fault: (1) Violating the provisions of laws, administrative regulations, rules and other relevant regulations on diagnosis and treatment; (2) Concealing or refusing to provide medical records related to disputes; (3) Forging, tampering or destroying medical records.

[25] Art. 59 of the *Tort Liability Law*: If a patient suffers damage due to defects in medicines, disinfectants, or medical devices, or transfusion of unqualified blood, the patient can claim compensation from the producer or blood provider, or from the medical institution. Where a patient requests compensation from a medical institution, the medical institution shall have the right to seek compensation from the responsible producer or blood supply institution after making compensation.

[26] X. YU, *Preventing Medical Malpractice and Compensating Victimised Patients in China: A Law and Economics Perspective*, London, 2017, p. 133. «Art. 59... provides a basis for medical products liability, which is based on strict liability».

[27] Art. 60 of the *Tort Liability Law*: If the patient suffers damage due to any of the following circumstances, the medical institution shall not be liable for compensation: (1) The patient or his close relatives do not cooperate with the medical institution to conduct diagnosis and treatment that conforms to the diagnosis and treatment standards; (2) Medical staff have fulfilled their reasonable duty of diagnosis and treatment in emergency situations such as rescuing critically ill patients; (3) It is difficult to diagnose and treat due to the medical level at that time. In the case of item 1 of the preceding paragraph, if the medical institution and its medical staff are also at fault, they shall bear the corresponding liability for compensation.

accidents, and unified the medical malpractice liability to summarize. The composition of tort liability is no longer necessary for medical accidents, which has cut off the relationship between TLL and regulations, and ended the situation of duality[28]. The death compensation that is not stipulated in the Regulations has been increased, and the scope and standard of compensation are also fairer and more reasonable. It also stipulates the obligation of medical institutions to inform, and prohibits excessive medical behavior, which not only regulates the behavior of medical institutions, but also protects their legitimate rights and interests.

Although the TLL, which was passed after four deliberations, and the provisions on medical torts that have been negotiated and revised for many times, have had a positive impact on balancing the interests of both doctors and patients and alleviating the conflicts. However, there are still some problems and deficiencies, and even failures[29]. It can be said that China's regulations on the allocation of the burden of proof are not the most ideal model, but the result of legislative compromise. For example, there are only three cases for the application of the principle of presumption of fault, and lacks miscellaneous provisions; the fault in the liability for medical technology damage is defined as "failure to fulfill the duty of diagnosis and treatment corresponding to the medical level at that time". However, there is no specific explanation for the standard of reasonable duty of care[30]; the patient's right to

28 L. YANG, *Research on Medical Damage Liability*, cit, p. 10.

29 V. L. RAPOSO, *How can Asian countries deal with medical liability and patient compensation*, in *PEOPLE: International Journal of Social Sciences*, Vol.1, Issue 1, pp. 942-956. She argues that the failure of tort liability law can be explained, on the one hand, by inadequacy of tort law to deal with the specificities of medicine; on the other hand, by the absence of an expert evaluation, since court judges are not suited to evaluate complex medical cases.

30 The third review draft of the Tort Liability Law stipulated that "when judging the duty of care of medical personnel, factors such as the region, the qualifications of medical institutions, and the qualifications of medical personnel should be properly considered", but it was later deleted when it was passed. H. LIAO, *On the Determination of Medical Negligence: From the Perspective of Understanding and Application of Medical Damage Tort Liability*, in *Politics and Law*, 2010, p. 21. The reason is that in the process of soliciting opinions, some scholars pointed out that this clause is suspected of discriminating the right to life and health of individuals, and it is impossible to specifically measure whether factors such as regions and qualifications can be considered in the application of these regulations, and should be analyzed based on individual circumstances. Laws, administrative regulations, rules, and diagnosis and treatment regulations stipulate specific requirements for diagnosis and treatment behaviors, medical institutions and medical personnel should generally abide by them, and should not vary according to regions and qualifications. S. WANG, *Interpretation of the Tort Liability Law of the People's Republic of*

informed consent is stipulated, but there is a lack of specific regulations and standards for operations such as who to inform, who is to be informed, what to inform, when to inform, what information should be informed, and under what circumstances; and Art. 58 only expressly stipulates the inversion of the burden of proof for medical negligence, and does not involve the distribution of the burden of proof for causation[31]. Since the PECP was not repealed at that time, it is still valid, therefore, whether to continue to apply the inversion of the burden of proof or let the patient bear the burden of proof has caused great controversy in judicial practice and academia. Which legal norm a judge applies when making a judgment depends entirely on the judge's value orientation. It can be said that judges play a decisive role in allocating the burden of proof at this time, which will have a direct impact on the judgment results of the case, and the phenomenon of "different judgments in the same type of case" occurs, which not only affects the authority of the judiciary, but also weakens the credibility of the judiciary.

The TLL has only 11 provisions on medical damage liability, which focuses on regulating it in a general way, so it cannot provide detailed provisions in every aspect. Some details still need to be clarified by relevant laws, regulations and medical norms. Otherwise, it will

China, Beijing, 2010, p. 283. Xinbao Zhang advocates that "reasonable expert standards" or "reasonable physician standards" should be used as the standard for the reasonable duty of care that medical institutions and medical personnel should perform in diagnosis and treatment activities. X. ZHANG, *Negligence Determination in Medical Damage Compensation Cases in China*, Taipei, 2008, p. 93. Lixin Yang advocates that different factors such as regions, medical institution qualifications, and medical personnel qualifications should be properly considered, and national standards and the principle of differentiation should be adhered to. L. YANG, *The Reform Of Liability For Damages Caused By Medical Treatment In The Tort Liability Law: its success and shortages*, in *Journal of Renmin University of China*, 2010, p. 15.

[31] In fact, in the draft Tort Liability Law, the rules for the burden of proof for causation have been stipulated, that is, Art. 59 of the Second Review Draft: The patient's injury may be caused by the medical staff's diagnosis and treatment behavior, unless the medical staff provides contrary evidence, it is presumed that there is a causal relationship between the diagnosis and treatment behavior and the patient's personal injury. However, it was deleted during the deliberation of the National People's Congress Standing Committee. S. WANG, *Interpretation of the Tort Liability Law of China*, Beijing, 2010, pp. 483-484. L. YANG, *The Reform Of Liability For Damages Caused By Medical Treatment In The Tort Liability Law: its success and shortages*, cit, p. 13. When the Tort Liability Law was officially promulgated, it adopted an evasive attitude towards issues related to causality. Not only did it not set up an independent clause on causality, but it also avoided talking about the rules for proof of causation.
The Civil Code promulgated in 2020 also follows the provisions of the Tort Liability Law. H. FENG, *Research on the identification of causal relationship and responsibility distribution for medical damage*, in *Jiangsu Social Sciences*, 2021, p. 131.

lead to the lack of corresponding specific standards in the process of medical damage liability determination, and then there will be some difficulties in judicial practice. Some scholars have proposed to formulate a special departmental law to deal with medical damage compensation cases. However, it will take a lot of time and energy for a legal provision to be promulgated and implemented. Even if the departmental law is formulated and promulgated, there may be a lag problem, which still cannot fundamentally solve the problem. Therefore, the Supreme People's Court can issue relevant judicial interpretations, make corresponding supplements and explanations for the unclear legal provisions, and provide a more specific, effective and operable basis for judges to try cases. Specifically, the basic functions of judicial interpretation mainly include: Explain the problems that the legal provisions are not specific enough to make understanding and implementation difficult, and give specific content to the general and principled provisions; Adapting to the changed new social situation through legal interpretation; When the understanding of specific legal provisions is inconsistent in the process of applying the law, through interpretation, unified understanding, or for a certain type of case, problem or a specific case, unified standards on how to understand and implement legal provisions; Explain how courts at all levels should cooperate with each other to hear cases, determine jurisdiction and related operational norms in accordance with legal provisions; Make up for the deficiencies of legislation through interpretation activities. The functions of the judicial interpretations mentioned below are nothing more than these.

Until February 4, 2015, the implementation of the Interpretation of the Supreme People's Court on the Application of the Civil Procedure Law of the People's Republic of China, Art. 91 stipulates the burden of proof[32], the court should determine the burden of proof in

[32] Art. 91 of the *Interpretation of the Supreme People's Court on the Application of the Civil Procedure Law of the People's Republic of China*: The people's court shall determine the burden of proof in accordance with the following principles, unless otherwise provided by law: (1) The party claiming the existence of a legal relationship shall bear the burden of proof for the basic facts that gave rise to the legal relationship; (2) The party who claims that the legal relationship is changed or eliminated or the rights are hindered shall bear the burden of proof to prove the basic facts that the legal relationship is changed or eliminated or the rights are hindered.

accordance with the principle of "who claims, who proves", unless otherwise provided by law. That is, in medical malpractice liability disputes, if a patient claims that there is a legal relationship of medical tort, he should bear the burden of proof for the fault of the medical institution, the damage result, and the causal relationship between the diagnosis and treatment and the damage result. However, there is still a legal conflict with Art. 4, para. 8 of the Provisions on Evidence in Civil Procedures on the allocation of the burden of proof.

Art. 4 of the Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Medical Damage Liability Disputes (hereinafter referred to as the Judicial Interpretation of Medical Damage), which came into effect on December 14, 2017, assigns the burden of proof of medical negligence and causality in medical malpractice cases to the patient, and the patient can apply for medical injury appraisal according to law when the proof cannot be provided[33]. Accordingly, the inversion of the burden of proof in Art. 4, para. 8 of the PECP is no longer applicable to cases of medical malpractice liability disputes, and the application of the law is thus unified.

The Civil Code of the People's Republic of China passed on May 28, 2020 stipulates the liability for medical malpractice in Chapter 6 of the book seven on tort liability. On the basis of revising individual words of the TLL, and inheriting most of its provisions and spirit. In addition, it is stipulated in the Supplementary Provisions that the GPCL and the TLL shall be abolished at the same time from the date of implementation of the Civil Code[34]. Its provisions on the burden of proof and the principles of attribution for medical torts are mainly

[33] Art. 4 of the *Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Medical Damage Liability Disputes*: If a patient claims that a medical institution bears compensation liability in accordance with Art. 54 of the Tort Liability Law, he shall submit evidence of damage to the medical institution for treatment. If a patient is unable to submit evidence that the medical institution and its medical staff are at fault, and that there is a causal relationship between the diagnosis and treatment behavior and the damage, the people's court shall approve the application for medical damage appraisal in accordance with the law.

[34] Art. 1260 of the *Civil Code*: This Code shall come into force on January 1, 2021. The Marriage Law, the Succession Law, the General Principles of the Civil Law, the Adoption Law, the Security Law, the Contract Law, the Property Law, the Tort Liability Law, and the General Provisions of the Civil Law of the People's Republic of China shall be repealed at the same time.

reflected in: For general medical tort disputes, also known as medical technology damage, the principle of fault liability applies according to the provisions of Art.1218[35], the patient shall bear the burden of proving the elements of medical infringement; for medical ethical damage, Art.1221 stipulates the principle of presumption of fault[36] and stipulates three presumption situations in Art.1222[37]to balance the probative capacity of both parties[38]; for medical product damages the principle of no-fault liability applies in accordance with the provisions of Art. 1223[39]. The Civil Code further improves the medical malpractice liability dispute system on the basis of the TLL, for example, for the expression of the subject of the fault, Art. 54 of the TLL is revised to "the fault of a medical institution and its medical staff" as "the fault of a medical institution or its medical staff", the coexistence relationship is modified to an alternative relationship, and the expression is more accurate. Second, the substantive notification requirement of informed consent in Art. 55 of the TLL is that medical personnel should obtain the written consent of the patient or his close relatives. However, this will lead to the provision of the obligation to explain in a mere formality and deviate

35 Art. 1218 of the *Civil Code*: Where a patient suffers damage during diagnosis and treatment, and the medical institution or its medical staff is at fault, the medical institution shall assume the liability for compensation.

36 Art. 1221 of the *Civil Code*: Where the medical staff fail to fulfill the duty of diagnosing and treating the patient up to the then current appropriate medical level, and thus causes harm to the patient, the medical institution shall assume the liability for compensation.

37 Art. 1222 of the *Civil Code*: A medical institution shall be presumed to be at fault where damages is caused to a patient during diagnosis and treatment under any of the following circumstances: (1) there is a violation of the provisions of laws, administrative regulations, rules, or other relevant guidelines for diagnosis and treatment; (2) the medical records are concealed or the request for provision thereof is refused;or (3) the medical records are lost, forged, tempered with or illegally destroyed.

38 However, some scholars believe that the three situations listed in Art. 1222 are often used as the standard for proving medical fault in judicial decisions. This kind of domination in the judicial field will not only lead to inconsistencies in the results of judicial decisions, but will also seriously damage the majesty and stability of the judicial system. G. JI, *Proof of Fault in Medical Tort Cases*, in *Journal of National Prosecutors College*, 2019, pp. 159-176.

39 Art. 1223 of the *Civil Code*: When damage is caused to a patient due to a defect in a drug, disinfection product, or medical instrument, or due to the transfusion of substandard blood, the patient may claim compensation against the drug marketing license holder or the manufacturer of the drug, or the blood supply institution, or against the medical institution. Where the patient claims compensation against a medical institution, the medical institution, after paying compensation, has the right to indemnification against the responsible drug marketing license holder or manufacturer of the drug, or the blood supplier.

from the original legislative purpose[40]. Therefore, Art. 1219[41] of the Civil Code revised "written consent" to "explicit consent", paying more attention to substance rather than form. Third, compared with Art. 58 of the TLL, Art. 1222 revised "patients suffered damages" to "patients suffered damages in the course of diagnosis and treatment activities", and added the case of "lost" medical records. The "destruction" of medical records was revised to "illegal destruction", so the act of legal destruction was excluded[42]. By limiting the damage to the patient in the diagnosis and treatment activities, the scope of application of the presumption of fault of the medical institution is better limited. Fourth, for medical product liability, in order to avoid the absence of relevant responsible subjects when damage caused by drugs occurs, the Civil Code added "drug marketing authorization holders" as the subject of responsibility, not just medical institutions and producers (blood supply institutions), and changed "disinfectant" to "disinfectant product", etc.

However, the Civil Code still has certain defects in some aspects, which needs further discussion and improvement. For example, the above-mentioned clauses on causation are not set up, but are only implicitly reflected in some articles, such as Art. 1165[43] and Art. 1175[44]. Due to the lack of legislative provisions on causality, the criteria for identifying cau-

40 ERKEN ABDULLAH, *On the Modification and Improvement of China's Medical Damage Liability System: From the Perspective of the Provisions of the Civil Code - Tort Liability (Third Review Draft)*, in *Hebei Law Science*, 2020.

41 Art. 1219 of the *Civil Code*: Medical personnel shall explain the condition and medical measures to patients during diagnosis and treatment activities. If surgery, special examination, or special treatment is required, medical personnel shall promptly explain the medical risks, alternative medical plans, etc. to the patient, and obtain their explicit consent; If it is impossible or inappropriate to explain to the patient, it should be explained to the patient's close relatives and their explicit consent should be obtained.

42 C. MA and G. ZHANG, *Regulations logic and application path of medical damage liability---From the perspective of the coordination between the civil code and the "medical law"*, cit, p. 46.

43 Art. 1165 of the *Civil Code*: Where an actor infringes upon the civil rights and interests of others by fault and causes damage, he shall bear tort liability.

44 Art. 1175 of the *Civil Code*: If the damage is caused by a third party, the third party shall bear the tort liability.

sality and the principle of distribution of responsibilities related to causation cannot be discussed, and it is even more unfavorable for the settlement of doctor-patient disputes[45]. Second, although Art.1227[46] provides for excessive medical treatment, it lacks specific provisions on the responsibility. Third, Art. 1222 stipulates three situations in which the medical party is presumed to be at fault, but whether a medical institution can overturn the presumption of fault by "proving that it is not at fault" in accordance with the provisions of para. 2 of Art. 1165, there is theoretical disagreement[47]. Fourth, according to Art.1221, the standard of medical staff's duty of diagnosing and treating is that they should meet the current appropriate medical level. If the duty of diagnosing and treating is not fulfilled, there is medical negligence. However, there is no unified measurement standard for medical level[48], and the regulations are too abstract. As scholars put it, in tort law, this phenomenon is due to the systematic reason that «the factual circumstances leading to potential liability for accidental

45 H. FENG, *Research on the identification of causal relationship and responsibility distribution for medical damage*, cit., p. 131.

46 Art. 1227 of the *Civil Code*: Medical institutions and their medical staff shall not conduct unnecessary inspections in violation of the diagnosis and treatment norms.

47 The representative viewpoints in the academic circles mainly include the "irrebuttable fault determination theory" proposed by Prof. Huixing Liang and Lixin Yang and the "rebuttable fault presumption theory" proposed by Prof. Liming Wang. The former asserts that the presumption of this clause is equivalent to a legal determination, which does not allow medical institutions to present evidence to overturn it. H. LIANG, *Medical Damage Liability in Tort Liability Law*, in *Law and Business Research*, 2010, p. 38; L. YANG, *Tort Liability Law*, Shanghai, 2010, p. 411; X. Cheng, *Tort Liability Law*, Beijing, 2015, p. 565. The latter claims that the presumption of this article can be overturned, that is, even if a medical institution has relevant acts, it can still prove that there is no medical fault. L. WANG, *Tort Liability Law*, Beijing, 2016, pp. 334-336; C. CHEN, *The Formation and Development of Medical Responsibility*, Taipei, 2019, p. 263; S. CHEN, *Research on Legal Issues of Medical Injury*, Beijing, 2019, p. 213; J. XIONG, *The Central Theory of Diagnosis and Treatment and the Determination of Medical Negligence*, in *Zhejiang Social Sciences*, 2019, p. 41.

48 Dongdong Sun advocated that the standards for diagnosis and treatment formulated by the Chinese Medical Association were to judge whether medical personnel fulfilled the technical standards of medical care duty equivalent to the medical level at that time. D. SUN, *Study and application of legislative changes on liability for medical damage in the Civil Code*, in *National Medical Journal of China*, 2021, p.1397. Hongjie Man advocated that this standard is similar to the "a reasonable physician standard", which makes a comparison between the healthcare provided by the defendant, with that which could have been provided by a reasonable, hypothetical healthcare practitioner, under the same circumstances. V. L. RAPOSO and R. G. BERAN, *Medical Liability in Asia and Australasia*, Singapore, 2022, p. 17. Tao Xue, Huicong Lv and others believe that due to economic development level, medical development level, medical institution level, medical personnel qualifications, geographical environment and education level, there will be some differences in medical level. Therefore, it is necessary to add discrimination clauses in the Civil Code, and consider various factors to define the medical level objectively. T. XUE, H. LV, *Discussion on Medical Damage Liability from the Perspective of Civil Code*, in *China's Health Legal System*, 2022, p. 33.

damage are too complex and diverse to be regulated by detailed ex ante rules»[49]. However, abstract standards cannot meet the needs of judicial practice, and judges still need to interpret and apply them concretely when trialing cases.

5. *Conclusions*

Medical tort disputes have always been regarded as a complex social issue related to people's livelihood[50], which is not only related to the rights and interests of both doctors and patients, but also related to fairness and justice and the harmonious development of society and long-term stability. For this reason, China has been constantly adjusting and reforming the distribution system of the burden of proof for medical damage to make it more suitable for the country's rule of law construction. However, there is no perfect law, only constantly revised and more perfect laws. In order to make China's medical damage burden of proof distribution system more perfect, it is necessary to learn from the world's advanced excellent theories, such as the principle of "self-evidence of facts" in the common law system[51], the principle of "evidence by appearance" in Germany[52], and the principle of "rough presumption" in Japan, etc.[53], strive to balance the legitimate rights and interests of both doctors and patients to the greatest extent, promote the development of medical care, and ensure the fair

[49] M. STAUCH, *The Law of Medical Negligence in England and Germany: A Comparative Analysis*, translated by C. TANG, Beijing, 2012, p. 13.

[50] «Medical malpractice is both a legal issue and a health system issue, since it involves governments, health providers, insurance companies, legal systems and patients». Z. WANG, N. LI, M. JIANG, K. DEAR and CR. HSIEH, *Records of Medical Malpractice Litigation: A Potential Indicator of Healthcare Quality in China*, in *Bull World Health Organ*, 2017, p. 434.

[51] C. CHEN, *Research on the burden of proof for medical negligence in the United States*, in B. ZHU et al. *Comparison of the burden of proof for medical negligence*, Wuhan, 2010, pp. 136-140; H. ZHANG, *Research on Medical Tort Litigation from the Perspective of Substantive Equality of Parties*, in *Journal of Theory*, 2013; S.GONG, *Research on the Legislation of Medical Damage Compensation*, Beijing, 2001, p. 280.

[52] S.JIANG, *The New Civil Evidence Law*, Xiamen, 2017, p. 141; Q. WEI, *Application of Appearance Proof in Medical Tort Disputes*, in *Journal of Chifeng University*, 2013, pp. 63-65; S. ZHAN, *Research on the burden of proof for medical negligence in Germany*, in B. ZHU et al., *Comparison of the burden of proof for medical negligence*, Wuhan, 2010, pp. 43-60.

[53] X. ZHANG, *Research on the Legislation of Tort Liability Law*, Beijing, 2009, pp. 286-295; L. YANG, *On the System of Imputation Principle of medical Damage Liability*, cit, pp. 64-69; B. ZHU, *On the Burden of Proof of Medical Negligence in Japan*, in B. ZHU et al. *Comparison of the burden of proof for medical negligence*, Wuhan, 2010, pp. 1-31; D. HONG, *On the burden of proof in medical tort litigation*, in *Politics and Law*, 2012, p. 101.

realization of substantive law by realizing procedural fairness.

Abstract

The distribution of the burden of proof for medical damage, as a key factor in deciding whether a case will win or lose, has a great impact on the liability of both doctors and patients, and directly affects the outcome of the lawsuit. Throughout the historical process of the development and evolution of China's medical malpractice burden of proof allocation system, it can be roughly divided into three stages. From the stage of "who claims, who proves", the patient bears the complete burden of proof, to the stage of inversion of the burden of proof, where the burden of proof and the causal relationship elements are inverted to the medical institution, and the responsibility for presuming fault is implemented, and then to today's diversified burden of proof allocation stage, according to the causes and characteristics of medical damage, the attribution principles and burden of proof distribution of medical technology damage, medical ethics damage and medical product damage are determined. The provisions on the distribution of the burden of proof for medical damages at each stage have both reasonableness and space for improvement. The advanced theoretical designs of other countries can provide valuable experience for this, which is worth thinking and learning in the following research.

Abstract

La ripartizione dell'onere della prova per i danni medici, in quanto fattore chiave per decidere se una causa sarà vinta o persa, ha un grande impatto sulla responsabilità sia dei medici che dei pazienti, ed influisce direttamente sull'esito della causa. Il processo storico di sviluppo ed evoluzione del sistema di attribuzione dell'onere della prova per i danni medici in Cina può essere suddiviso in tre fasi. Dalla fase dell'*onus probandi ei qui dicit,* in cui il paziente

ha l'onere della prova completo, alla fase dell'inversione dell'onere della prova, in cui questo e gli elementi del rapporto di causalità sono invertiti a favore dell'istituzione medica e viene attuata la responsabilità per presunzione di colpa, fino all'odierna fase di ripartizione diversificata dell'onere della prova, in cui, in base alle cause e alle caratteristiche del danno medico, vengono determinati i principi d'attribuzione e la ripartizione dell'onere della prova del danno da tecnologia medica, del danno da etica medica e del danno da prodotto medico. Le disposizioni sulla ripartizione dell'onere della prova per il danno medico in ciascuna fase sono ragionevoli, ma migliorabili. I progetti teorici avanzati di altri Paesi possono fornire una preziosa esperienza in tal senso, su cui vale la pena di riflettere ed approfondire in ricerche successive.

Camerino, dicembre 2022.