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Scientific article

Research on Tort Liability in the Context of Medical Artificial Intelligence

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Abstract. The rapid integration of artificial intelligence (AI) into healthcare has substantially improved diagnostic accuracy and treatment efficiency while simultaneously creating complex challenges for determining tort liability. The autonomous decision-making capacity of medical AI systems and the opacity of algorithmic processes ("black box" effect) complicate the identification of fault, the establishment of causation, and the allocation of liability within traditional tort law frameworks. This article argues that existing legal mechanisms are insufficient to address harms caused by highly autonomous medical technologies and proposes a comprehensive liability regime adapted to the specific risks of medical AI.

The proposed framework is based on three key dimensions. First, specialized legislation should introduce classification and risk-grading standards for medical AI and clear criteria for identifying algorithmic defects, thereby clarifying responsible parties. Second, a coordinated system of imputation combining fault-based, strict (no-fault), and equitable liability is necessary to balance technological innovation with effective protection of patients' rights. Third, a diversified remedial mechanism should include reversal or mitigation of the burden of proof, compulsory liability insurance, and compensation funds to ensure prompt and adequate compensation.

Such a risk-oriented legal framework is essential for safeguarding patient safety and supporting the sustainable development of medical AI.

Keywords: Medical Artificial Intelligence, tort Liability, imputation principles, algorithmic defects, allocation of the burden of proof

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Introduction

In recent years, China's medical artificial intelligence technology has demonstrated a rapid development trend, with the market size growing from 1.136 billion RMB in 2019 to 11.137 billion RMB in 2023, representing a compound annual growth rate as high as 53.37% [1].

The "State Council Opinions on Deepening the Implementation of the 'AI Plus' Action" issued in 2025 further emphasized exploring and promoting high-level, accessible resident health assistants, and orderly advancing the application of AI in scenarios such as assisted diagnosis and treatment, health management, and medical insurance services, significantly improving the capacity and efficiency of primary healthcare services [2].

However, with the widespread application of medical AI in scenarios like clinical diagnosis, surgical operations, and health management, the tort liability issues it triggers have become increasingly prominent. For instance, the Da Vinci surgical robot has been reported in numerous injury-causing cases globally, resulting in 144 patient deaths and 1,391 injuries between 2000 and 2013 [3].

Currently, Chinese judicial practice primarily relies on the rules of medical malpractice liability and product liability in the "Civil Code" when handling medical AI tort disputes, but both face significant issues in application. On the one hand, the "black box" nature of algorithms and the autonomous decision-making capability of medical AI complicate the determination of fault and the assessment of causation [3]. On the other hand, its ambiguous legal status leads to controversies regarding liability attribution, with academic circles holding divergent views such as the "affirmative theory," "negative theory," and "compromise theory"[4]. Furthermore, the current system lacks targeted supporting relief mechanisms such as compensation funds and compulsory insurance, making it difficult to fully protect patients' rights and interests when liability cannot be attributed to traditional liable subjects like natural persons [5].

At the theoretical level, existing research predominantly focuses on areas like autonomous vehicles and general artificial intelligence, while systematic discussion on tort liability for medical AI remains insufficient. In practice, courts commonly adopt the medical malpractice liability approach when adjudicating such cases, yet this fails to effectively address the imputation challenges posed by technological autonomy [6].

How to construct a system of liability rules that balances technical characteristics, patient rights, and medical innovation has become an urgent legal issue. Therefore, it is necessary to provide a systematic solution for the medical AI tort liability regime by clarifying the subject status, refining the imputation pathways, and improving the relief mechanism.

Materials and Methods

This paper employs literature analysis, normative analysis, and comparative analysis to systematically examine the theoretical foundations, existing institutional problems, and pathways for improvement regarding tort liability for medical artificial intelligence.

Literature Analysis – Through a systematic review of domestic and international academic monographs, journal articles, and research reports concerning medical AI tort liability, this study focuses on core controversies such as legal subject status, imputation principles, and the determination of causation. It summarizes representative academic viewpoints, analyzes theoretical divergences, and provides scholarly support for constructing a liability determination framework.

Normative Analysis – Centering on Article 1218 (Medical Malpractice Liability) and Article 1223 (Liability for Medical Products) of the "Civil Code," and incorporating normative documents such as the "Product Quality Law" and the "Guiding Principles for the Classification and Definition of Artificial Intelligence Medical Software Products," this study analyzes the logical conflicts and regulatory gaps within existing rules as applied to medical AI tort scenarios. It clarifies the necessity and direction for further legal regulation and adjustment.

Comparative Analysis – Selecting extraterritorial legislative practices such as the EU's "Artificial Intelligence Act," this study compares their institutional designs concerning AI categorization and tiered supervision, compulsory insurance systems, and the allocation of the burden of proof. It extracts transferable regulatory experiences to provide references for improving China's medical AI tort liability system.

Literature Review

Intelligent healthcare is no longer a novel topic in Chinese academia. To propose a rigorous path for improving legal safeguards, it is necessary to review scholarly research on how to advance the construction of China's medical AI tort liability system. Existing research primarily encompasses the following aspects:

First, the issue of the legal status of medical AI. Wang Yihan and Wang Zhu argue that while current AI possesses intelligence, it lacks human disposition and consciousness. Its autonomy is purely technical, and it remains an instrumental medical device; thus, should not be granted legal subject status [7]. Liu Huiming and Zhang Shengnan propose that at the weak AI stage, medical robots do not possess legal subject status; whereas at the strong AI stage, due to their high degree of autonomy, they could be accorded legal subject status, but this requires legislation to establish a specialized liability system [8]. Zheng Zhifeng contends that diagnostic and therapeutic AI does not alter the existing doctor-patient relationship structure, remains in an auxiliary role, with medical institutions still being the liable subjects; as a tool, AI should not enjoy legal personality [9]. Xu Weikun advocates adhering to the principle of anthropocentrism, emphasizing that medical AI is essentially a medical device designed by humans, and thus liability should be attributed to developers, producers, or users [10]. Zhao Min also argues for defining medical robots as medical devices, clarifying their object attribute through national standards [11]. Wang Qingsong presents the view that medical AI serves only as an auxiliary tool, and its decision-making process requires supervision by medical personnel, thereby implying that it lacks independent legal personality [11]. Li Ya'nan believes that although algorithmic decision-making possesses autonomy, it is essentially a product of human design and should therefore fall under the product liability framework, denying it independent legal personality [12]. Qin Weijia observes that most scholars tend towards the negative theory, but future consideration could be given to limited personality based on technological development [13].

Second, the application of imputation principles for medical AI. Lü Shujie, from the perspective of causation, suggests balancing imputation principles through the "adequacy" standard [14]. Zheng Zhifeng points out that liability for medical malpractice should apply the fault principle, judging negligence by the "reasonable physician standard"; liability for medical products applies the no-fault principle, while safeguarding the discretionary power of medical staff in human-machine collaboration [15]. Wang Yihan and Wang Zhu argue for minimal adaptation within the existing legal framework to accommodate new changes. Specifically, imputation rules

should be applied based on the scenario: product liability applies the no-fault principle, medical malpractice liability applies the fault principle, and liability for ultra-hazardous activities applies the no-fault principle in specific cases [16]. From a comparative law perspective, Ding Xiaodong proposes that China's AI legislation should follow the principle of "scenario-based regulation," requiring differentiated regulation based on risk levels. Strict liability should apply to major public risks; for general risks, the fault principle should apply, relying on industry self-regulation and ex post tort remedies [17]. Furthermore, Bi Xiaole emphasizes that imputation principles should match the level of technical autonomy, proposing a "tiered imputation system" based on the autonomy level of diagnostic and therapeutic robots [18]. Wei Zixin also advocates for improving imputation principles based on scenarios, but suggests appropriately introducing other liable subjects like producers [19].

Last, the allocation of the burden of proof in medical AI cases. Tan Zaixiang and Jiang Yatong propose utilizing black box recordings of medical AI operation data, establishing regulatory mechanisms and compulsory insurance systems to reduce the difficulty of proof; they also recommend implementing a registration and publicity system for AI products [20]. Li Runsheng suggests alleviating proof difficulties by strengthening the specific informed consent obligations of medical personnel and incorporating AI use into the informed consent process [21]. Dong Chunhua believes that the approach in multi-cause medical injury cases, where judges reduce the patient's burden of proof based on expert opinions, can be extended to medical AI tort scenarios [22]. Based on the "sphere of danger" theory, Lü Yan argues that the burden of proof should shift towards the party controlling the dangerous sphere. In cases involving algorithmic defects, a reversal of the burden of proof should apply; in medical negligence cases, causation should be presumed, while courts' power to investigate evidence ex officio can compensate for patients' lack of capacity to adduce evidence [23]. From a technical standpoint, Liu Mengmeng suggests that technical means like blockchain evidence preservation can reduce the difficulty of proof [24]. Jin Xianting points out that in medical product liability, producers should bear the burden of proving the absence of product defects to reflect the substance of the no-fault principle [25]. Additionally, Guo Gaowei emphasizes that algorithm transparency can reduce the difficulty of proof [26]. Chen Lili recommends applying a reversal of the burden of proof in medical malpractice liability, shifting the obligation to prove absence of fault to the medical institution, particularly addressing the proof difficulties caused by the "algorithmic black box" [27].

Western developed countries have paid earlier attention to AI tort liability issues. Regarding the dilemmas faced by medical AI tort, foreign scholars have also proposed various solutions. The German scholar Thomas Hoeren presents a forward-looking view. He believes the high autonomy of AI makes its behavior patterns infinitely close to human autonomous consciousness. Simply categorizing it as a "thing" no longer aligns with technological reality. He argues that the law should evolve, considering creating new types of legal subjects or treating intelligent agents meeting specific criteria as legal "persons," making them directly responsible for their actions [28]. Scholar Xavier suggests the necessity to move beyond existing frameworks and consider creating new types of liability specifically for AI torts, to more precisely define and allocate risks. John Frank Weaver proposes a solution from a regulatory perspective, emphasizing that natural persons should be the primary regulators of AI. Their liability should be based on whether they have adequately fulfilled reasonable supervisory duties, while AI itself should bear liability for damages caused by its algorithmic defects or technical failures. Regarding risk-bearing mechanisms, scholars like Marcelo Corrales advocate establishing compensation funds

or compulsory insurance systems specifically for AI, transforming individual risk into socially shared risk.

In summary, constructing a tort liability system for medical AI requires breaking through traditional legal frameworks, applying categorized regulation based on technical autonomy, and achieving a balance between protecting patient rights and fostering technological innovation through pluralistic imputation principles and risk-sharing mechanisms.

Dilemmas in the Legal Regulation of Tort Liability for Medical Artificial Intelligence

Based on a systematic study of tort liability for medical artificial intelligence, this paper identifies the following core dilemmas facing the current legal regulatory framework, which urgently need to be addressed through legislative refinement, technical adaptation, and mechanism innovation.

1. Lagging Legislation and Regulatory Gaps Concerning Medical AI Tort Liability

Although China has established a legal framework for medical malpractice liability centered on the Civil Code, the Product Quality Law, and the Regulations on the Supervision and Administration of Medical Devices, it has not yet enacted specific provisions for the emerging field of medical AI. Existing rules struggle to encompass novel tort scenarios such as damages caused by algorithmic defects or autonomous decision-making. From a jurisprudential perspective, traditional tort law is predicated on the predictability and imputability of human conduct, whereas the autonomy and unpredictability of AI systems pose a fundamental challenge to this anthropocentric liability framework. The "black box" nature of algorithmic decision-making renders basic elements like fault determination and causality assessment difficult to adjudicate using traditional standards. The practical consequence of legislative lag is manifested not only in normative gaps but also in a failure to promptly address the ethical dilemmas and rights conflicts arising from technological advancement within the underlying value system. Traditional tort law defines "product defect" primarily around quality flaws in tangible products, whereas the core risk of AI products stems from their intangible algorithms and decision logic. This fundamental discrepancy causes the defect identification standards stipulated in the Product Quality Law to be problematic or inapplicable when applied to algorithms. Furthermore, Article 1223 of the Civil Code, which governs liability for medical products, contains ambiguity regarding liability attribution because it does not clearly define the legal status of AI designers and developers. This legislative vacuum reflects a serious disconnect between the normative system and technological reality. When the algorithm itself becomes the core value and source of risk of the "product," traditional product liability law, which regulates tangible objects, proves inadequate. This also leads to inconsistent application of law in judicial practice; judges lack clear legal guidance when confronted with technical complexity and must rely heavily on discretionary power, thereby undermining the predictability and fairness of the law.

2. Complex and Ambiguous Identification of Liable Subjects

Medical artificial intelligence involves multiple parties, including developers, manufacturers, healthcare institutions, and medical practitioners, presenting significant challenges in liability allocation. This reflects the limitations of traditional legal subject theory in addressing AI technologies. The ambiguity in identifying liable subjects stems from the complex "human-machine collaboration" network formed by medical AI applications, where human decision-making and machine autonomous behavior are intertwined, making it difficult to clearly delineate their respective shares of responsibility. Taking fully autonomous surgical robots as an example,

their actions cannot be directly attributed to any natural or legal person behind them, posing a fundamental challenge to the current liability system in determining accountable entities. This raises a profound jurisprudential question: whether and when to recognize the legal subjectivity of non-human entities. Recognition would subvert the traditional subject system, while non-recognition would make it difficult to address damages caused by highly autonomous systems. When auxiliary diagnostic AI causes misdiagnosis due to algorithmic black box issues, there are also no clear standards for apportioning responsibility between developers and healthcare institutions. In such cases, the developer's liability is based on product design defects, while the healthcare institution's liability may arise from two aspects: negligence in selection (such as choosing an inappropriate system) and negligence in supervision (such as failing to properly oversee the system's use). However, there is a lack of standards for connecting and distributing these two types of liability. If healthcare institutions are forcibly held liable through theories like "vicarious liability" or "negligence in selection," practical problems of inconsistent value standards and judicial discretion will arise.

3. There are significant divergences in the application of imputation principles.

Traditional fault liability, no-fault liability, and equitable liability all face application difficulties in the context of medical artificial intelligence, reflecting the conflicts and balances between underlying values. Fault liability emphasizes moral culpability but is difficult to apply to unconscious AI, as fault essentially assesses a subjective mental state, while AI lacks free will and subjective intent – its decision-making behavior is merely the result of algorithmic operation. Applying fault liability to AI is like subjecting a scalpel to moral judgment; it is difficult to justify jurisprudentially. No-fault liability focuses on risk distribution and loss compensation but may unduly stifle technological innovation. Equitable liability, meanwhile, lacks clear application standards, which can easily lead to arbitrary outcomes.

4. Imbalance in the Allocation of the Burden of Proof and Technical Barriers

Issues such as the algorithmic black box create a triple challenge for patients: difficulty in meeting the burden of proof, difficulty in obtaining evidence, and difficulty in obtaining expert evaluation. The autonomous decision-making behavior of fully autonomous AI is difficult to incorporate into the fault assessment system. The opacity of the algorithmic decision-making process in medical AI, coupled with the fact that key data is often controlled by developers or healthcare institutions, makes it extremely difficult for patients to obtain evidence, rendering the chance of successfully discharging their burden of proof minimal. This creates a serious problem of "imbalance of evidence," undermining the principle of equality of arms in traditional litigation. Patients are not only technologically disadvantaged but also face structural obstacles within the legal process, leading to a substantive inequality in litigation capacity. Patients losing lawsuits due to an inability to provide evidence of algorithmic defects not only means that individual justice is denied but also creates a chilling effect, deterring potential victims from seeking redress, ultimately causing the liability mechanism to lose its deterrent and compensatory functions.

Although Article 22 of the "Supreme People's Court Interpretation on Several Issues Concerning the Application of Law in the Trial of Medical Damage Liability Dispute Cases" provides for joint tort liability concerning medical products, it does not make special arrangements for a reversal of the burden of proof in the context of AI. The current regulations fail to adequately consider the particularities of AI technology. In AI medical scenarios, it may be necessary not only to apply a reversal of the burden of proof in the sense of product liability but also to create special

evidentiary rules addressing novel issues such as algorithmic transparency and data quality, in order to restore a balance in litigation.

The difficulty in proving causation is not merely a problem of evidence law, but fundamentally an epistemological problem. When even experts cannot fully comprehend the algorithmic decision-making process, requiring ordinary patients to prove causation becomes nearly impossible. This effectively deprives patients of their right to obtain redress, constituting a profoundly inequitable situation.

5. Absence of Systemic Governance Mechanisms

There is currently a lack of a full-cycle regulatory system for medical AI risks. Issues such as biases in algorithm training data, insufficient clinical validation, and the absence of monitoring during usage frequently occur. This reflects the fact that the current regulatory model is fragmented and reactive, rather than a risk-based, full-cycle governance approach. Effective governance requires a closed-loop management system extending from front-end design and development, through mid-end clinical application, to back-end incident monitoring and recall. The risk-based tiered regulatory model proposed in the EU's Artificial Intelligence Act and the FDA's "Algorithm Change Protocol" mechanism in the United States offer valuable references for China. Comparative legal experience shows that advanced regulatory models share common characteristics: emphasizing risk-based differentiated regulation, stressing algorithm transparency and explainability, establishing update and supervision mechanisms for continuous learning systems, and constructing collaborative governance frameworks involving multiple stakeholders. Meanwhile, socialized relief mechanisms such as compulsory liability insurance and compensation funds have yet to be established. Sole reliance on the tort liability system is already insufficient to address systemic risks. Socialized relief mechanisms can not only ensure timely compensation for victims but also disperse innovation risks, preventing the entire industry from bearing excessive burdens due to occasional accidents, thereby achieving a balance between rights protection and industrial development.

Discussion: Systematic Improvement Pathways for Medical AI Tort Liability

Against the backdrop of the profound transformation driven by AI technology in the medical field, the determination of tort liability for medical artificial intelligence has become a frontier and a challenging issue in legal research. The traditional tort law framework, built on an anthropocentric basis, demonstrates significant incompatibility when confronted with medical AI characterized by autonomy and algorithmic black box features. Its imputation logic, identification of liable subjects, and rules of evidence often lead to regulatory incapacity in the face of many tortious acts. This discussion aims to systematically dissect the core legal dilemmas confronting medical AI tort liability. From a comparative law perspective, it explores systematic regulatory pathways and liability allocation schemes to balance technological innovation with the protection of patients' rights and interests, thereby providing jurisprudential support for building an inclusive, safe, and trustworthy governance ecosystem for medical AI.

1. Unifying the Legal Identification Standards for Tort Liability of Medical Artificial Intelligence

Currently, China's legal framework for regulating medical liability, centered on the Civil Code, the Product Quality Law, and the Regulations on the Supervision and Administration of Medical Devices, lacks targeted provisions addressing medical AI as an emerging entity. This gap results in significant regulatory voids and ambiguous standards when applying the framework to AI-related tort scenarios.

1.1Establishing the Basic Principles for Constructing a Medical AI Tort Liability System

Before formulating specific rules for medical artificial intelligence, it is essential to first clarify, at the jurisprudential level, the basic principles for constructing its tort liability system. This will provide top-level design and value guidance for technological research and development, clinical application, and judicial adjudication.

First, the Risk Control Principle. Medical AI possesses inherent technical risks and unpredictability, making risk control a core principle. Drawing on the risk-based tiered regulatory approach of the EU's Artificial Intelligence Act, differentiated duties of care and liability standards can be established based on indicators describing the system's autonomy level (such as assisted diagnosis, surgical execution, or fully autonomous decision-making) and indicators distinguishing the risk level of its application scenarios (such as life support, intensive care, or health management). Stricter liability rules should apply to high-risk applications.

Second, the Balancing of Interests Principle. Legal regulation must precisely balance the tension between patients' rights to life, health, and privacy on one hand, and technological innovation and industrial development on the other. Excessively heavy liability will stifle innovation, while excessively light liability condones risks and harms patients' rights. Policymaking should, through scientific assessment, find an equilibrium that effectively provides redress for patients without substantially hindering technological development.

Last, the Transparency and Explainability Principle. Addressing the "black box" nature of algorithms, legal requirements for algorithm transparency and decision explainability should be established. Developers and users have an obligation to explain the logical basis of AI decisions to patients and relevant parties in an understandable manner. This is not only pertinent to informed consent but also a prerequisite for determining fault and causation.

1.2 Constructing a Systematic Legal and Standardization Framework

The regulation of tort liability for medical AI is a systematic project that requires establishing a multi-level, interconnected system of laws and regulations, technical standards, and ethical norms. Firstly, specialized legislation should be initiated by researching and formulating specific administrative regulations for medical AI applications. These should clarify the legal definition, classification, and grading of medical AI, the basic rights and obligations of various parties, and core imputation principles, thereby addressing the gaps in general laws like the Civil Code.

Secondly, the technical standardization system needs enhancement. Led by authorities such as the National Medical Products Administration (NMPA) and the National Health Commission (NHC), and collaborating with industry associations and technical experts, technical standards covering the entire lifecycle of medical AI should be developed. These must specifically include standards for algorithm security, data quality, clinical validation, and accessibility/age-friendly design. The standards should be concrete and quantifiable—for instance, stipulating maximum misdiagnosis rates for AI-assisted diagnostics, precision error ranges for surgical robot arms, and requirements for font size and voice interaction in user interfaces. Standard development can draw lessons from the U.S. FDA's "Pre-Cert Program" and the EU's "conformity assessment" requirements, making compliance a prerequisite for product market entry and serving as crucial evidence in judicial proceedings for determining whether a product has "defects" or presents "unreasonable risks."

Finally, ethical guidelines should be strengthened by promoting the establishment of Medical AI Ethics Review Committees. These committees would conduct ethical assessments for high-risk AI applications to ensure compliance with fairness, non-discrimination, privacy protection,

and other ethical requirements. Furthermore, ethical norms should be integrated into the considerations of legal liability.

2. Clarifying the Subjects and Boundaries of Tort Liability for Medical AI

The application of medical AI involves multiple parties, including designers, developers, manufacturers, sellers, healthcare institutions, and medical practitioners, forming a complex "human-machine collaboration" network. This complexity makes identifying the liable subject exceptionally difficult, presenting the greatest challenge in judicial practice.

2.1 Product Liability of Designers and Manufacturers

When harm originates from defects in the medical AI product itself – whether in design, manufacture, or inadequate warnings – product liability rules should apply. According to Article 1203 of the Civil Code, patients can claim compensation from the manufacturer or the seller. The core difficulty lies in defining a "defect," particularly an algorithmic defect. Traditional views on product defects focus on hardware flaws, whereas the core value and risk of medical AI stem from its software and algorithms. Therefore, algorithmic defects must be included within the scope of product defects. The author argues that scenarios such as significantly reduced diagnostic accuracy for specific populations (e.g., the elderly, patients with rare diseases) due to biased training data, or erroneous surgical path planning caused by flawed algorithm logic, should be recognized as design defects. Manufacturers must be responsible for the safety, efficacy, and fairness of their algorithms. The burden of proving the absence of defects lies with the manufacturer, which aligns with the jurisprudential basis of no-fault liability in product liability and thereby compels manufacturers to enhance product quality.

2.2 User and Supervisory Liability of Healthcare Institutions

When healthcare institutions introduce and use medical AI systems, especially when providing fee-based AI services to patients, their legal status combines that of a "seller" and a "user." Their liability primarily stems from negligence in selection, negligence in supervision, and negligence in management. Negligence in selection refers to the institution's failure to exercise a reasonable duty of care by procuring AI products that lack regulatory approval, do not meet standards, or are known to have high-risk defects. Negligence in supervision occurs when medical personnel, while using AI for assisted diagnosis or surgery, fail to maintain necessary professional vigilance, blindly rely on AI outputs, or neglect to identify and correct obvious errors made by the AI. Negligence in management refers to the institution's failure to establish robust systems for AI operation training, routine maintenance, emergency response protocols for adverse events, and data security management. When determining the liability of a healthcare institution, courts should comprehensively consider the autonomy level of the AI. For low-autonomy systems, such as software providing only diagnostic assistance, the supervisory responsibility of medical personnel is greater. For high-autonomy systems with a significant degree of independent decision-making power, such as autonomous surgical robots, the institution's responsibilities regarding selection and system maintenance become more critical.

2.3 Prospective View on the Legal Status and Liability Attribution of Fully Autonomous AI

For a fully autonomous medical AI that may emerge in the future, whose actions exceed pre-programmed boundaries and can learn independently and make decisions, the current legal framework faces the problem of a missing liable subject. Jurisprudentially, theories like "electronic personality" have been discussed. The European Parliament once proposed creating an "electronic person" legal status for intelligent robots, allowing them to bear limited liability independently with their own assets, supported by dedicated funds or insurance. Although

highly controversial, this offers one approach to addressing the liability challenges posed by highly autonomous systems. A more pragmatic alternative is to adhere to the "instrumentalist" view but mandate through legislation that its developers, manufacturers, or user institutions obtain compulsory liability insurance or establish compensation funds. This ensures adequate redress for victims while ultimately tracing responsibility back to the control exercised by traditional legal subjects, such as natural persons.

3. Improving the System of Imputation Principles for Medical AI Torts

Imputation principles form the core of tort law. The complexity of medical AI makes it difficult for a single principle, be it fault-based or no-fault liability, to fairly and effectively resolve all tort disputes. Therefore, it is necessary to construct a diverse and flexible system of imputation principles.

3.1 Application and Challenges of the Fault Liability Principle

Fault liability remains the foundational principle, particularly applicable to the negligent acts of healthcare institutions and medical personnel in supervision and management. The challenge in applying different imputation principles lies in the objectification of the fault standard and the difficulty of proof. Judges need to determine the presence of fault based on the duty of care expected of a "reasonable medical professional" under the same circumstances. However, due to the novelty and complexity of AI technology, there is no consensus on what constitutes "reasonable care." The solution lies in, on one hand, relying on clinical guidelines, technical standards, and industry norms as concrete benchmarks for determining fault. On the other hand, when medical personnel have followed all standard operating procedures, but damage occurs due to an unforeseeable error from the AI "black box," their fault liability should be considered exempt; otherwise, it would impose excessive blame on medical personnel, making them hesitant to use new technologies.

3.2 Expanded Application of No-Fault Liability

The principle of no-fault liability should be expansively applied to the special risks inherent to medical AI itself that are difficult to avoid completely. This applies mainly to product liability borne by the manufacturer and certain highly hazardous clinical applications of AI, such as fully autonomous surgery. The jurisprudential basis is that developers and manufacturers profit from the application of AI technology and should therefore bear the special risks it brings; they are also best positioned to disperse these risks through technological improvements and price mechanisms like insurance. Applying no-fault liability can significantly reduce the patient's burden of proof, requiring only demonstration of causation between the damage and the AI's action to obtain redress, aligning with substantive fairness.

3.3 The Supplementary Role of the Equitable Liability Principle

In extremely rare individual cases where damage indeed occurs, but the patient cannot prove fault on the part of any party, and there is no clear legal basis for applying no-fault liability, consideration can be given to applying the equitable liability principle pursuant to Article 1186 of the Civil Code. This would apply to scenarios like accidental damage caused by exploratory applications of cutting-edge AI technology that cannot be explained or prevented by the current state of science. The court may, based on the actual circumstances, order the beneficiaries, such as the developer or healthcare institution, to provide appropriate compensation to the patient. This measure aims to fill legal gaps and reflect humanitarian concern, but its application conditions should be strictly limited to prevent abuse.

4. Addressing the Difficulties in Proving Medical AI Tort Cases

The "difficulty of proof" is the primary obstacle for patients seeking redress, stemming fundamentally from extreme information asymmetry and the "black box" nature of algorithms. Innovation beyond the traditional "he who asserts must prove" rule is necessary.

4.1 Introducing Mitigation and Reversal of the Burden of Proof

Rules for mitigating or reversing the burden of proof should be widely introduced in cases involving proof of algorithmic defects or causation. When a patient has provided preliminary evidence indicating that the harm was likely caused by the AI system, the burden of proof should shift to the defendant, who must then prove that the AI system had no defect or that there was no causal link between its action and the harm. For instance, if a patient has proven that the AI provided an erroneous diagnostic suggestion and a doctor acted upon it, the manufacturer or healthcare institution should bear the burden of proving the absence of a defect in the AI system or the absence of causation. This essentially allocates the "behavioral burden" of producing evidence and the "consequential burden" of failing to prove to the party that is more capable and closer to the source of the evidence, which is key to restoring equality of arms in litigation.

4.2 Strengthening Evidence Preservation and Information Disclosure Obligations

To ensure that the reversal of the burden of proof rule functions effectively, it is essential to concurrently strengthen the evidence preservation and information disclosure obligations of developers and healthcare institutions. Legislation should mandatorily require: First, Data Recording and Retention. AI systems must be equipped with tamper-proof "black box" devices that continuously record key data, parameters, and logs from the decision-making process, with a mandatory retention period. Second, the Right to an Explanation. In the event of a dispute, patients have the right to request an understandable explanation for the individualized decision made by the AI. Last, Limited Source Code Disclosure. When extremely necessary and meeting confidentiality requirements in judicial proceedings, the court may rule to compel the developer to disclose part of the source code for judicial expertise, thereby addressing the "black box" challenge.

4.3 Developing Specialized Judicial Expertise and Technical Assessment

Confronted with highly specialized technical issues, the development of a third-party judicial expertise and technical support system should be prioritized. Expert pools comprising medical experts, computer scientists, and jurists should be established to provide courts with authoritative and neutral professional opinions on determining algorithmic defects, standards of fault, causation, etc. This serves as the technical safeguard to help judges overcome knowledge barriers and render just decisions.

5. Constructing a Diversified Relief Mechanism for Medical AI Tort Liability

Sole reliance on litigation and tort compensation is no longer sufficient to address the systemic risks that medical AI may bring. It is imperative to establish a diversified mechanism encompassing pre-incident prevention, in-process control, and post-incident relief.

5.1 Establishing a Compulsory Liability Insurance System

Learning from the mature experience of compulsory traffic accident liability insurance, a compulsory liability insurance system for medical AI should be promoted. Producers and sellers of AI products, as well as healthcare institutions, should be required to purchase insurance, thereby transforming individual risks into socially shared risks. This can not only ensure that victims receive timely compensation but also provide the AI industry with a stable risk expectation, promoting its healthy development.

5.2 Setting up a Special Compensation Fund

A medical AI damage compensation fund, jointly established by the industry and the government, should be set up to address situations not covered by insurance or where a liable party cannot be identified, such as unforeseen, rare side effects caused by technological limitations. Sources of funding for the fund could include industry levies, government appropriations, and social donations. This measure constitutes the final safety net of the relief system, demonstrating the law's humanistic care and social responsibility, while also effectively ensuring the development of AI technology and maintaining a balance between technological advancement and the protection of rights and interests.

5.3 Improving Administrative Supervision and Industry Self-Discipline

Pre-incident and in-process risk prevention and control are equally important. Powerful administrative supervision and effective industry self-discipline can reduce the occurrence of tort incidents at the source. Strong administrative supervision methods, such as pre-market approval and post-market monitoring led by the medical products administration, can be adopted, supplemented by effective industry self-discipline mechanisms like formulating industry ethical guidelines and establishing safety standards. Regulatory agencies should have the power to demand product recalls, system takedowns, and revocation of registration certificates, creating an effective deterrent for enterprises.

Conclusion

This paper takes the tort liability system for medical artificial intelligence as its research object and employs comprehensive methods such as literature analysis, normative analysis, and comparative research to conduct a systematic study of its theoretical foundations, practical problems, and institutional construction. Through in-depth analysis of domestic and foreign legislative examples and judicial practice, combined with the realistic background of the deep application of AI technology in the medical field, it reveals the systemic deficiencies of the current legal framework in addressing new challenges such as autonomous decision-making and algorithmic black boxes. Furthermore, it proposes targeted improvement paths from the three levels of theoretical innovation, institutional construction, and implementation mechanisms.

This research has primarily yielded the following conclusions and innovative results:

First, it systematically constructs a "Layered-Categorized" regulatory theory for medical AI tort liability. Breaking through the traditional jurisprudential framework of the "subject-object" dichotomy, this paper innovatively proposes a regulatory approach that stratifies AI systems based on their degree of autonomy and categorizes them according to the risk level of their application scenarios. This theoretical framework resolves the controversy surrounding the legal status of highly autonomous AI systems and provides a solid jurisprudential basis for establishing a differentiated imputation system. This theoretical innovation not only addresses fundamental difficulties in the study of medical AI tort liability but also provides clear theoretical guidance for subsequent relevant legislation.

Second, it innovatively proposes a "Tripartite Imputation System" for medical AI torts. Based on an in-depth analysis of the application difficulties of existing rules in the Civil Code, and drawing on the risk-based tiering approach of the EU's Artificial Intelligence Act and the evolving regulatory experience of the United States with medical AI, this paper constructs a tripartite imputation system coordinating fault liability, no-fault liability, and equitable liability. This

system specifies that: the fault liability principle applies to low-autonomy AI, strengthening the professional supervisory duties of medical personnel; the no-fault liability principle is introduced for high-autonomy AI, safeguarding patient rights through risk distribution mechanisms; and equitable liability applies limitedly to damages caused by technological limitations, reflecting the law's humanistic concern. This institutional design effectively balances the dual value objectives of rights protection and technological innovation.

Finally, it creatively designs a scheme for allocating the burden of proof in medical AI tort cases. Addressing the difficulty of proof caused by the "algorithmic black box," this paper proposes rules centered on the presumption of causation, combined with mitigating the burden of proof and supporting obligations for technical information disclosure. Specifically, after the patient provides preliminary proof, the burden of proving the absence of algorithmic defects or causation shifts to the developer/user, while mandating that relevant parties undertake obligations for data recording, preservation, and algorithm explanation. This design protects the litigation rights of patients while providing clear and practical adjudication rules for judicial practice.

This study has certain limitations. Firstly, regarding the attribution of liability for fully autonomous medical AI, although a solution combining electronic personality with compulsory insurance is proposed, its specific implementation awaits further clarification in future legislation. Secondly, the research primarily focuses on the domain of civil liability, leaving room for deeper exploration of its connection with administrative supervision and criminal liability. These unresolved issues also point the way for subsequent studies.

In summary, through systematic research, this paper not only reveals the inherent defects in the medical AI tort liability system but also constructs improvement proposals possessing both theoretical coherence and practical feasibility. The research findings hold significant theoretical value and practical importance for promoting the formulation of regulations governing medical AI application management, guiding judicial practice in properly handling related disputes, and fostering the deep integration and healthy development of AI in healthcare.

The legal regulation of tort liability for medical AI is a complex subject requiring deep interdisciplinary integration of law, medicine, ethics, and computer science. We can neither seek to halt the advance of technology nor should we, but we must pave a fair and safe developmental path for it through the wisdom and innovation of the law. The future path of regulation should be dedicated to constructing a systematic governance framework: one that is led by specialized legislation, based on clear classification, grading, and liability allocation, centered on pluralistic imputation principles and the distribution of the burden of proof, and safeguarded by compulsory insurance and compensation funds. Only in this way can we fully unleash the immense potential of AI to empower healthcare while steadfastly protecting the legitimate rights and interests of every patient, especially digitally disadvantaged groups, ultimately realizing the positive vision of technology for good, safeguarded by the rule of law.

Contribution of the authors

Liu Chunhao – developed the research concept, formulated the main scientific problem, and prepared the key theoretical conclusions of the study.

Hou Ruixue – conducted the literature review and legal analysis, drafted the main sections of the article, and coordinated the final editing of the manuscript.

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Гражданско-правовая ответственность в условиях применения медицинского искусственного интеллекта

Аннотация. Стремительная интеграция искусственного интеллекта (ИИ) в сферу здравоохранения существенно повысила точность диагностики и эффективность лечения, одновременно породив сложные проблемы определения деликтной ответственности. Способность медицинских систем ИИ к автономному принятию решений и непрозрачность алгоритмических процессов («эффект чёрного ящика») усложняют установление вины, причинно-следственной связи и распределение ответственности в рамках традиционных моделей деликтного права. В статье обосновывается, что существующие правовые механизмы недостаточны для урегулирования вреда, причинённого высокоавтономными медицинскими технологиями, и предлагается комплексный режим ответственности, адаптированный к специфическим рискам медицинского ИИ.

Предлагаемая модель основывается на трёх ключевых направлениях. Во-первых, специальное законодательство должно предусматривать классификацию и градацию рисков медицинского ИИ, а также чёткие критерии выявления алгоритмических дефектов, что позволит определить круг ответственных лиц. Во-вторых, необходима согласованная система вменения ответственности, сочетающая ответственность по вине, строгую (безвиновную) ответственность и ответственность, по справедливости, чтобы обеспечить баланс между технологическими инновациями и эффективной защитой прав пациентов. В-третьих, диверсифицированный механизм возмещения должен включать перераспределение или смягчение бремени доказывания, обязательное страхование ответственности и компенсационные фонды для обеспечения своевременного и достаточного возмещения ущерба.

Такая риск-ориентированная правовая модель является необходимым условием обеспечения безопасности пациентов и устойчивого развития медицинского ИИ.

Ключевые слова: медицинский искусственный интеллект, деликтная ответственность, принципы вменения ответственности, алгоритмические недостатки, распределение бремени доказывания.

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Медициналық жасанды интеллектіні қолдану жағдайындағы азаматтық-құқықтық жауапкершілік

Аңдатпа. Жасанды интеллектінің (ЖИ) денсаулық сақтау саласына жедел енгізілуі диагностика дәлдігін және емдеу тиімділігін едәуір арттырды, сонымен қатар деликттік жауапкершілікті айқындауда күрделі мәселелер туындатты. Медициналық ЖИ жүйелерінің автономды шешім қабылдау қабілеті және алгоритмдік процестердің ашық еместігі («қара жәшік» әсері) дәстүрлі деликттік құқық шеңберінде кінәні анықтауды, себеп-салдарлық байланысты белгілеуді және жауапкершілікті бөлуді қиындатады. Мақалада қолданыстағы құқықтық тетіктер жоғары автономды медициналық технологиялар келтіретін зиянды реттеу үшін жеткіліксіз екендігі негізделіп, медициналық ЖИ-дің ерекше тәуекелдеріне бейімделген кешенді жауапкершілік режимі ұсынылады.

Ұсынылған модель үш негізгі бағытқа негізделеді. Біріншіден, арнайы заңнама медициналық ЖИ-ді жіктеу мен тәуекел деңгейлері бойынша саралауды, сондай-ақ алгоритмдік ақауларды анықтаудың нақты өлшемдерін енгізуі тиіс, бұл жауапты субъектілерді айқындауға мүмкіндік береді. Екіншіден, технологиялық инновация мен пациенттердің құқықтарын тиімді қорғау арасындағы тепе-теңдікті қамтамасыз ету үшін кінәлі жауапкершілікті, қатаң (кінәсіз) жауапкершілікті және әділеттілік қағидатына негізделген жауапкершілікті үйлестіретін келісілген жүйе қажет. Үшіншіден, залалды өтеудің әртараптандырылған тетігі дәлелдеу ауыртпалығын ауыстыру немесе жеңілдету, міндетті жауапкершілік сақтандыруы және өтемақы қорларын қамтуы тиіс, бұл жәбірленушілерге уақтылы әрі жеткілікті өтемақы төлеуді қамтамасыз етеді.

Мұндай тәуекелге бағдарланған құқықтық модель пациенттердің қауіпсіздігін қамтамасыз ету және медициналық ЖИ-дің тұрақты дамуын қолдау үшін аса маңызды.

Түйін сөздер: медициналық жасанды интеллект, деликт бойынша жауапкершілік, жауапкершілік қағидаттары, алгоритмдік ақаулар, дәлелдеу ауыртпалығын бөлу

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