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The Judgment of Legal Liability in AI Medical Malpractice

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Abstract: AI medical uses modern technologies such as deep learning and computer algorithms to realize auxiliary therapy, medical imaging, medicine development and other functions. It is one of the fields with the most promising development prospects in the application of AI. With the development and extensive application of AI in the field of medicine, how to define the legal civil status of AI medical devices and how to assign the legal liability of medical workers and artificial intelligence for causing harm have become tough problems to be solved urgently. In this article, we will discuss the non-autonomous surgical robots and the semi-autonomous surgical robots, in which the former is fully controlled by the surgeon and the latter completes most of the operation independently. This essay mainly focuses on China's application of AI in the field of surgery and the liability judgment according to Chinese law. We will review the existing cases, point out the disputes in the treatment results, and then analyze the liability of each responsible party in the general situation, and finally give the universal solutions to helping judge legal liabilities clearer.

Keywords: artificial intelligence (AI), medical malpractice, legal liability

1. Introduction

"It can be called artificial intelligence to make machines behave the same as human beings" (John McCarthy, 1956). This opinion marked the birth of the subject of artificial intelligence. It is generally believed that artificial intelligence is a new technical science to research and develop theories, methods, technologies, and application systems for simulating and extending human intelligence. In the 1970s, people realized the huge potential value of artificial intelligence in the medical field and began to apply it to the medical field on a large scale in 2011. At present, artificial intelligence is mainly concentrated in the fields of the virtual assistant, auxiliary treatment, and medical robots. However, although AI medical has a broad application prospect, it also faces many urgent problems such as data utilization, lack of standards, and risk accountability. Among them, the occurrence of medical errors such as medical AI's diagnosis errors and surgical injury has caused the public opinion to think about the risk liability regulation of AI medical. This paper will take the judgment of legal liability in AI medical malpractice as the topic, conduct case analysis, then make a more reasonable assessment of the liabilities to be borne by all parties, and finally propose feasible solutions, aiming to provide references for liability allocation for the occurrence of a similar situation.

2. Case review and data analysis

With the rapid development of technology, some surgical robots are designed and already applied in the medical field. As the previous study (HAO Ye et al.,2020) shows,

by the end of 2017, a total of 69 machines had been installed in mainland China, 68 for clinical applications and 1 for training. In addition, 26,765 surgeries had been completed in China throughout the year, with an average of 393.5 surgeries per Da Vinci surgical robot per year and 7.6 surgeries per week. As a representative of these AI medical devices, the DaVinci robot has shown its high precision, flexible operation, and elimination of physical tremors on certain clinical occasions. Despite the high precision and operability of AI medical devices, there remain risks in the application field. Therefore, we will make a case analysis of major medical negligence, Britain's first robotic heart valve operation, in the following part.

Primarily, it's necessary to review the overall process of this medical accident. The operation was carried out in February 2015. Subsequently, problems occurred: the robot console transmits signals with a faint sound and poor quality, communication between surgeon Sukumaran Nair and assistant surgeon Thasse Pillay became so difficult that doctors had to shout to each other. What's worse, the robot punched an assistant's arm, and the patient's heart was stitched in the wrong place and way. The stitches had to be removed and restitched. The patient's aortic valve was damaged and blood spilled onto the surgical robot's camera, which made Nair unable to see clearly. Eventually, the patient died of the erroneous operations on March 3rd, 2015.

At the hearing, Nair acknowledged the lack of a complete grasp of how to operate the machine, also he didn't inform Pettit, the patient, that he would be the first patient to undergo robotic mitral valve surgery. What's more, the proctors were present for only some of the procedure on Mr. Pettit but left part-way through. It seemed more like a man-made calamity. The horrible medical accident would have brought panic to the public, not only due to the concerns of becoming the victims of technological development of AI medical devices, but also the risk accountability behind the accident. The lack of transparency can be one main part. According to YANG Luojia et al.(2020), in the clinical application of Da Vinci's surgical robot, the doctor must explain clearly to the patient the patient's condition, operation plan, operation risk, prognosis, cost, etc., so that the patient can understand and therefore obtain the consent of the patient. Also, the negligence highlights the problem of the imperfect management system, for the current AI medical devices don't possess autonomous consciousness, and therefore depends on their operators. Apparently, as the first robotic heart valve operation, the criteria of access and special training are not clear enough. Relevant policies should be improved and the responsible person should be clarified.

Nevertheless, it's not always due to doctors' misoperation during the surgeries. According to a survey, surgical robots caused at least 1391 injuries and 144 deaths in the US between 2000 and 2013. The following table (HAO Ye et al.,2020) shows the main causes of operation failure from 2000 to 2013.

Table 1: Main causes of operation failure from 2000 to 2013

causes	cases	proportion
Software problems (restart, system halted)	787	7.4%

Equipment problem	1557	14.7%
Thermal burn	1111	10.5%
Accidental operation	1078	10.1%
Cable and power problems	5092	57.3%

From the table, it's shown that the causes are various. According to Homa (2016), they could be roughly classified into the following categories: inherent risks of surgery, underlying diseases of patients, technological problems of the devices, and the operation problems of the team. And through this case, we are alarmed that the same risk can also happen in China, relevant policies are needed to regularize the application of AI medical devices. For instance, it's crucial to trace the whole process from production to operation, and responsibilities should be made to the people to ensure the accountability chain is intact. Therefore, we will discuss the problem of accountability in the next part.

3. The judgment of legal liability

If an operation performed with artificial intelligence medical devices causes medical malpractice, the judgment of legal liability should be considered. This part will mainly discuss the judgment of legal liability in medical malpractice from three aspects.

3.1 Legal liability of developers

It is universally acknowledged that only if the subject has the ability to take legal liability, he or she should bear legal liability. Legal liability ability is composed of recognition ability and control ability, among which recognition ability refers to the ability to recognize the content, social significance, and results of one's own behavior, while control ability implies the ability to control oneself to implement or not implement a specific behavior (Chen Xingliang, 2010). However, AI medical devices which employ current technology fail to qualify the ability, because they do not possess autonomous consciousness, and can merely implement behavior within the scope of their developer's preset programs (Liu Jianli, 2019). Consequently, according to Chinese law, it is unreasonable to condemn AI medical devices themselves. In that case, the developer of artificial intelligence medical devices may be legally accountable.

Actually, the Catalogue of Medical Devices Classification in China has not established definite approval standards for artificial intelligence medical devices (Lv You, 2020). Hence most semi-autonomous AI medical devices are in the stage of detection and clinical trial. Even if certain AI medical devices have obtained certification from China Food and Drug Administration (CFDA), whether there is hidden peril in them is still suspicious. All these circumstances make it difficult for judiciary authorities to judge the legal liability of developers.

Therefore, when medical malpractice occurred, two aspects should be considered

to judge the developer’s legal liability. For one thing, judiciary authorities shall interrogate everybody present in the malpractice to determine whether AI medical devices have performed obvious negligence, just like the case of Leonardo's robot in 2015. Meanwhile, the investigation of available videos about the operation process can be a complementary method of exploring the primary cause of malpractice. For another, it is essential that the retrieval and analysis of relevant data during AI medical devices’ operation be examined immediately. If technicians can verify that algorithm loopholes do exist in the preset programs, no matter whether the developers know them or not, the developers will inevitably bear legal liability. If technicians cannot, then developers may be free of legal liability according to article 41 of Product Quality Law.

Furthermore, if compelling evidence shows that developers’ preset programs have significant risks while manufacturers, sellers, and doctors have indeed fulfilled their obligations, it is suggested that developers be condemned as liability subject though all of them are liable for negligence.

3.2 Legal liability of manufacturers and sellers

According to article 41 of Tort Liability Law, “Where any defect in a product causes damage to another person, the producer shall be liable for the tort.” As stated by article 46 of the Product Quality Law, the term "defect" means the product does not conform to national or trade standards for safeguarding human health and safety of human life and property. Allowing for the unique features of AI medical devices, the “producer” above should be understood as a combination of two terms: the developer and the manufacturer. Therefore, the manufacturer of artificial intelligence medical devices may also bear legal liability. That is to say, if AI medical devices fail to reach the precise accuracy required by the developer during the manufacturing process, it is the manufacturer rather than both “producers” who is legally accountable.

What’s more, article 42 of Tort Liability Law stipulates that “If the defect of the product is caused by the seller's fault and causes damage to others, the seller shall be liable for the tort.” For instance, when one medical institution purchases AI medical devices from the seller, the seller neither illustrates how to maintain their hardware nor informs the hospital of indispensable regular update of the AI system, which ultimately causes the medical malpractice, the seller shall take legal liability.

3.3 Legal liability of medical institutions

3.3.1 Legal liability of equipment departments

According to the Regulations for the Supervision and Administration of Medical Devices(2017 Amendment), medical institutions have the obligation to purchase qualified medical devices. Due to medical devices related to artificial intelligence serving as high-tech medical equipment, the equipment department is supposed to be more cautious while purchasing them. If it ensures that the purchases are made through

strict procedures, though patients claim compensation from the hospital once malpractice happened, the hospital shall, after compensation, have the right to recover compensation from the producer who should be to blame (Tort Liability Law of the People's Republic of China, Article 59). However, if the equipment department purchased the AI medical equipment via non-standard procurement procedures for lower prices or something else, or purchase them with a casual attitude, it would violate the obligation stated above. Once malpractice happened, the equipment department of the medical institution must assume the corresponding legal liability.

3.3.2 Legal liability of chief surgeons

Although the operations employing AI medical devices are rather different from conventional operations, the obligations of the chief surgeon still exist, including the duty of informing and care. If the chief surgeon does not fulfill the obligations, he/she is also legally accountable.

3.3.2.1 Violating duty of informing

In terms of the duty of informing, the chief surgeon must inform patients and their families of the risk of this high-tech operation and must get permission to use AI medical devices during the operation. Because operating with AI medical devices is a risky venture itself, no one can guarantee its absolute safety. As is known, the relatives of patients will be asked to sign a consent form before an operation, which lists the possible risks of the operation. This preoperative signature is an important measure to protect the informed consent of patients and their families, and it is also an authorization for surgeons to operate. If a surgeon uses the AI medical devices during the operation without getting the patients' family's consent, he has already violated the duty of informing whether the operation is successful or not. There will be a risk of civil and even criminal liability for him/her to assume except for some special circumstances(Xv Xiaojun, 2018)

Moreover, there is a common phenomenon that while signing the consent form in case of emergency, some patient's family may be pressed for time so they sign the consent without carefully reading it. If a surgeon catch hold of the loophole and then cut corners or add other clauses for his own sake in the consent form, he not only deviates from the professional ethics of doctors but also violates the informed consent right of families and the notification obligation of medical institutions. Once a medical malpractice dispute happened, he himself and the medical institution would be impossible to escape legal liability.

Besides, it should be noted that the patient's family's signature on the consent form does not mean that the surgeon and hospital can assume no liability when malpractice happens. According to article 53 of the Contract Law of the People's Republic of China, in case of personal injury to the other party, the exemption clause of the contract shall be invalid. Preoperative signature is just an authorization for doctors, but it does not have the effect of exemption.

3.3.2.2 Violating duty of care

In the case of using non-autonomous or semi-autonomous surgical robots discussed in this essay, the AI medical devices do not have complete consciousness to plan and finish an operation. In consequence, the chief surgeon still works as an important role in an operation to guide and do some auxiliary operations, contributing to the success of the operation. Therefore, the duty of care is particularly important in this process. AI operation is a rather risky task, which is also a test of the surgeon's mental endurance, caution, professional skills, and familiarity with the composition and operation methods of devices such as the operating console and 3D HD probe imaging, etc. If an AI operation results in malpractice due to improper operation or neglect of attention by the chief surgeon, the chief surgeon cannot be exempted from liability even if he/she uses the equipment with the patient's consent before the operation, because he/she did not perform the duty of care that he/she should have performed. Though the behavior of doctors should be regarded as duty behavior, and the legal consequences of their behavior should be borne by medical institutions(Chen Shaohui, 2019), in terms of morality and professional quality, the chief surgeon is supposed to shoulder some liability as well.

Liu Yuming(2014) once claimed that :

> "Only when a medical institution has clearly informed the patient of the risks before the operation, and the patient has signed the voluntary letter of operation, agreeing that the medical institution operates on him/her, and the medical institution has no fault during the operation and produces the adverse results listed in the risks after the operation, the medical institution shall not bear tort liability."

As a result, whether the chief surgeon and the medical institution should assume the legal liability cannot be decided only by the happening of malpractice or a one-sided account of the patient's family. The degree of the fulfillment of obligations is the final judgment for the allocation of legal liability.

4. Solutions to helping judge legal liability clearer

Since China's current medical damage liability and product liability system is not consummate to determine legal liability, some solutions are proposed based on Chinese current legislation and researches conducted by scholars.

4.1 About the developers

Article 64 of the Civil Procedure Law stipulates that "the parties shall have the duty to provide evidence for their claims". In other words, the aggrieved person must provide solid evidence to demonstrate there is a causal relationship between defects in AI medical devices and the fact of damage to claim the developer (Zhang Jie, 2019). However, due to the professionalism and complexity of AI medical devices as well as the absence of national and industry standards, the aggrieved person who may know nothing about artificial intelligence has difficulty in proving the developer's legal

liability. To overcome the difficulty, it is recommended that a data collector be installed in AI medical devices so that the intermediate process in the AI system during the input and output of instructions can be supervised. Moreover, if the data reaction system (DRC) is pre-arranged at the stage of development, how to judge the developers' legal liability will be significantly helped.

4.2 About the medical institutions

To judge a medical institution's legal liability, for one thing, as for the equipment department, it is supposed to establish a complete and effective supervision mechanism, such as choosing professional bid invitation person to purchase AI medical devices and arranging specialized people who follow the bid invitation person to supervise and record every step of the procurement process in detail fairly. And the record should be preserved carefully, which can be regarded as proof of judgment of legal liability once medical malpractice happened. For another, the legal department of the medical institution should be widely established. "Due to the lack of professional legal knowledge and awareness of relevant functional departments, the contract provisions, potential legal risks, the protection of the interests of the hospital and other aspects cannot be professionally reviewed during the review process, resulting in great legal risks."(Wang Chaojun, 2016) Therefore, establishing the legal department is of great importance at present. Every consent form should be reviewed by the legal department before the operation and needs to be filed in the legal department. This will make the investigation and judgment more convenient and reduce some disputes over objective issues like the validity of the contract and the performance of duty of informing. Moreover, each operation should be equipped with a real-time monitoring system without interfering with the operation to determine whether the chief surgeon performs the duty of care during the operation, which can help judge the chief surgeon's legal liability.

4.3 About legislation and insurance

So far, countries around the world have not issued a tort law about malpractice caused by artificial intelligence, which signifies that the judgment of legal liability may be controversial and take numerous money and time. Therefore, the current tort law needs to be improved and laws defining the legal liability of AI medical malpractice should be introduced as soon as possible. Allowing for the long time required to amend the law, another resultful approach can be applied as a supplement.

The establishment of a compulsory insurance and compensation fund system is also essential, which can play an important role in addition to clarifying the subject through legal approaches (Zhou duo, 2020). To some extent, the measure can not only reduce the financial burden on the aggrieved person during the recovery stage but also effectively disperse the responsibility risk of producers. Drawing on the Eu civil Law Rules on Robots, if the AI medical devices possess high service danger, the possibility of infringement, and intelligent autonomy of behavior, they should be equipped with

compulsory insurance. For example, producers of AI medical devices can compulsively insure them when they are put on the market, while compensation funds may be donated by the community or initiated by a designated person (Zhang Jie, 2019).

5. Conclusion

The frequent accidents in the application of surgical robots in the medical field show the necessity of establishing a completely relevant accountability mechanism. Taking the producers, sellers, and medical institutions as the main research objects, by analyzing the possible risks and abnormalities in the operation and according to the existing legal literature, the responsibilities that each party should undertake can be roughly defined. But the uncertainties that may exist in reality are much greater than expected. In the face of specific cases, the distribution of responsibilities should be further refined. Therefore, although our solutions have a wide range of coverage, they also suffer from a lack of accuracy. In addition to liability determination, measures such as improving data monitoring techniques and adding relevant legal provisions also help to fill the gaps in this field. With the iterative updating of AI medical technology and the improvement of laws, the liability identification of surgical robots in medical accidents will no longer be an obstacle to the development of China's health cause.

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Contributions to the completion of this article

Zhang Yuanhang: Legal liability of medical institutions, solutions about the medical institutions, integration of the article

Li Qifan: Abstract, introduction, conclusion

Lou Jiayi: Case review and data analysis

Dai Qiulu: Legal liability of developers && manufacturers and sellers, solutions about the developers && legislation and insurance