# The Latest Development and Enlightenment of the Research on Social Risk and Regulation of Artificial Intelligence in Medicine in China

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**Keywords:** Artificial intelligence in medicine, CNKI, Risk, Legal regulation.

**Abstract:** In recent years, as artificial intelligence develops rapidly, its application in the medical field increase a lot. While in its application, there exists many arguments about the social risks and regulations of artificial intelligence in medicine. Under the influence of China's macro policies, industrial development and other factors, the research focus is constantly changing. In this paper, the analysis function and knowledge graph visualization technology of CNKI are used to analyze the document quantity characteristics, journal and discipline distribution, network characteristics of research institutions of the research on social risks and regulations of AI medical and AI medical. The hot spots and hot spots evolution are analyzed to draw the knowledge graph. Based on 901 documents collected by CNKI, it is found that the research focus in different ages is closely related to China's macro policies, industrial development and application scenarios of artificial intelligence. Since 2015, AI medical policy focuses on the application of wearable devices in health management, medical robots, intelligent image recognition, intelligent diagnosis and treatment, intelligent rehabilitation, etc. Therefore, the research on social risk and regulation mainly includes three aspects: artificial intelligence medical ethics, personal information security and medical damage liability. In the future, with the expansion of application scenarios, researches will focus on "formulating market access rules of artificial intelligence medical products, defining the nature of medical activity, interpreting the decision-making process in black box of algorithm".

## 1. Introduction

Taking the document system and document and metrological characteristics as the research subject, the paper uses mathematical, statistical and other metrological methods to study the distribution structure, quantitative relation and change rule of documents related to "social risk and regulation of domestic artificial intelligence + medical application". Then it discusses the latest developments of researches on the social risk and regulation of AI medicine, the frontier and the evolution of hot spots in the research field, and analyzes the characteristic and trend of the development of "social risk and regulation of domestic artificial intelligence + medical application" based on articles from some key journals.

Artificial intelligence (AI) is inseparable from medical treatment since its first day. After 60 years of evolution and development, it has made its mark in various walks of life. Now it can play a role in many aspects of the medical industry, mainly in intelligent diagnosis and treatment, intelligent image recognition, intelligent health management, intelligent drug development and medical robot. The application of AI in the medical field has become a hot spot of modern science, for its algorithm based on a large number of data can provide convenient and optimized way for medical services and promote the transformation of medical service mode. However, there are also huge social risks, which brings an unprecedented challenge to the current legal rules and order. Data, algorithm and application scenario are the three elements of the development of artificial intelligence, and the medical application field is composed of numerous specific application scenarios. Therefore, how to make legal guidance on the application of artificial intelligence in the

medical field and even specific application scenarios, and how to form a systematic and legal social governance system with the development and regulation of artificial intelligence in medicine as the theme, are theoretical and practical problems that experts and scholars in the legal field and related fields need to face and solve together.

## 2. Data Sources and Research Methods

### 2.1 Data Collection and Processing

In this paper, CNKI database is used as the source, which includes "Basic Science, Engineering Science and Technology Series I, Engineering Science and Technology Series II, Agricultural Science and Technology, Medical and Health Science and Technology, Philosophy and Humanities Science, Social Science Series I, Social Science Series II, Information Technology, Economy and Management Science" and other databases universally acknowledged in China. Retrieval strategy: make TS as AI medical, document type as full text, time range as 2000-2019 and date as December 10, 2019, and 901 AI medicine related documents are retrieved. Then make TS as risk and legal regulation and document type as full text to carry out the second level retrieval, 26 AI in medicine + risk, legal regulation related documents are retrieved.

### 2.2 Research Methods

The paper uses CNKI' s own analyze software to analyze key words, theme, publication year, research level, author, organization, fund, cited contribution, cited journal and other information, mining its implicit information and presenting the relation between relevant information and information entity directly with the help of visual Atlas. Through the aggregation of relevant information, it shows the development trend of "AI in medicine + risk, legal regulation" in a certain period, and understands and forecasts the research hot spot and frontier.

## 3. Research Result and Analysis

### 3.1 Analysis on the Trend of Document Quantity

Based on the statistical analysis function of CNKI database, there were 897 "artificial intelligence in medicine" related documents between 2000 and 2019, among which the number of documents surged in 2016, and then continued to increase in 2017, 2018 and 2019 for three consecutive years (Figure 1). Among the 897 documents, 26 are related to "artificial intelligence in medicine + risk, legal regulation". From 2000 to 2016, there were no relevant document published, while 1 in 2017, 7 in 2018 and 18 in 2019 (Figure 2).
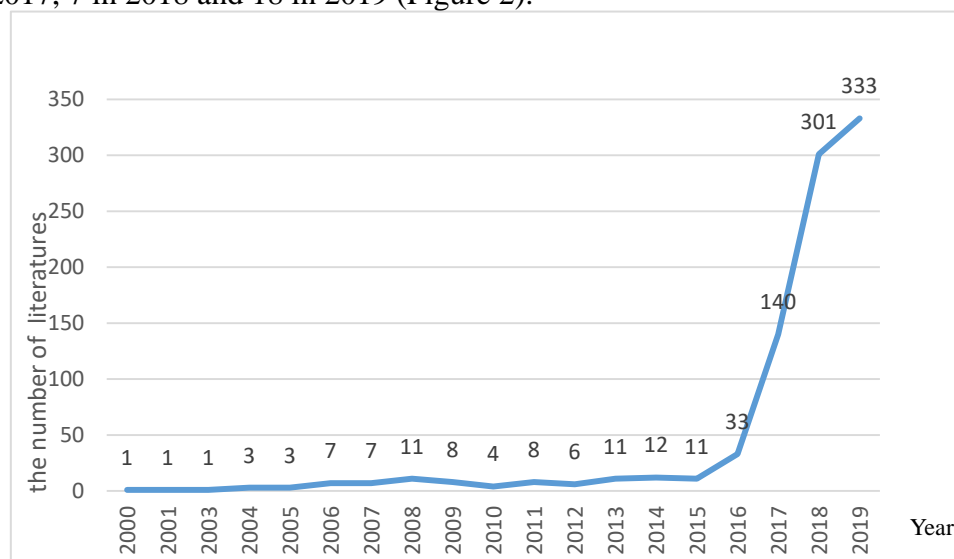


Figure 1 The number of "artificial intelligence in medicine" literatures published annually from 2000 to 2019
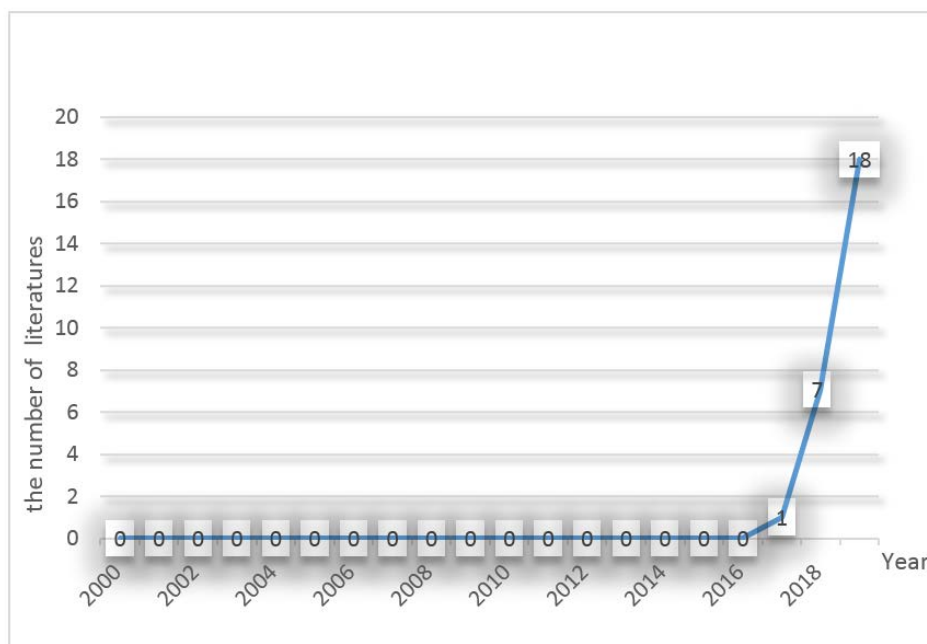
Figure 2 The number of literatures published annually on "artificial intelligence in medicine + risk and legal regulation" from 2000 to 2019

From the above-mentioned quantity of annual published documents and change trend, from 2000 to 2015, China's research document quantity in the field of "artificial intelligence in medicine" had ups and downs, and the document quantity doubled in 2006 (as shown in Figure 1), increasing sharply in 2016 and doubling in 2017, 2018 and 2019. However, no attention has been paid to "AI in medicine + risk, legal regulation" and there is no relevant document (as shown in Figure 2). Until 2017, only one document related to "AI in medicine + risk, legal regulation" appeared, and then the quantity of documents increased rapidly in 2018 and 2019.

From the perspective of national policies, since 2015, China's relevant government departments have successively issued nearly 20 relevant policies, providing guidance in personnel training, technological innovation, standard supervision, industry integration, etc. For example, "Made in China 2025", "The State Council's Guiding Opinions on Actively Promoting the 'Internet plus' Action", "Development Plan for New Generation AI" and other national strategic plans were issued successively. Among them, "The State Council's Guiding Opinions on Actively Promoting the 'Internet plus' Action" is directly related to artificial intelligence. Local governments have also actively issued policies to support the development of artificial intelligence, which has gradually formed a boom in the development of artificial intelligence in China. In May 2016, National Development and Reform Commission, Ministry of Science and Technology, Ministry of Industry and Information Technology and Office of the Central Cyberspace Affairs Commission issued the " 'Internet Plus' Three Year Action Plan for Artificial Intelligence"; in June, the general office of the State Council issued the "Guidance of the general office of the State Council on the promotion and regulation of the development of medical big data"; in July, Ministry of Industry and Information Technology and National Development and Reform Commission issued the "Special Action for Innovation and Development of Intelligent Hardware Industry (2016-2018)" ; in November, the State Council issued the "Development Plan for the 13th Five-year Plan National Strategic Emerging Industry" and other relevant documents, all of which contain the application of artificial intelligence in the field of health care. In 2017, artificial intelligence was first written into China's government work report, which strongly supports the development of artificial intelligence from national strategic perspective, among which the application of AI in medicine is also one of the key contents of the national policy. In July of the same year, the State Council issued the "Notice of the State Council on Printing and Distributing the Development Plan for the New Generation of Artificial Intelligence", and provinces and cities successively issued the local development plan for artificial intelligence, setting off the upsurge of artificial intelligence research and application. In

December of the same year, the Ministry of Industry and Information Technology issued the "Three-year Action Plan for Promoting the Development of the New Generation of Artificial Intelligence Industry (2018-2020)". In April 2018, the "Opinion of the General Office of the State Council on Promoting the Development of Internet Plus Medical Health" has been released, which put the overall investment of artificial intelligence in medicine in the acceleration linkage stage. In October of the same year, general secretary Xi Jinping pointed out when members of the CPC Central Committee studied the current development situation and trend of artificial intelligence that artificial intelligence is a strategic technology leading this round of scientific and technological revolution and industrial transformation, which has a strong "head goose" effect. In response to the call of national policy, provinces across the country have released a number of policy documents related to the application of artificial intelligence in medicine.

Based on the development of China's AI medical industry, at present, companies engaged in AI in medicine related businesses in China can be roughly divided into three categories: start-ups, internet platforms, traditional medical enterprises. Since the State Council issued the "Development Plan for New Generation of Artificial Intelligence" on July 20, 2017, National Institute for Food and Drug Control, China National Drug Administration (CNDA) and other relevant institutions have been actively contacting with professions, and relevant policies and regulatory programs are in the process of being worked out. However, no relevant policies have been issued yet. Due to the lack of standards, at present, most of the AI medical products applied for the third type of medical devices in China are still in the stage before registration and application, and no products have passed the examination and approval. However, in 2019, the scale of China's big data industry will reach 789.1 billion yuan, and it is expected to exceed trillion yuan by 2020(as shown in Figure 3). Big data is the core and foundation of artificial intelligence, and massive data lays a good foundation for the development of artificial intelligence in medicine.
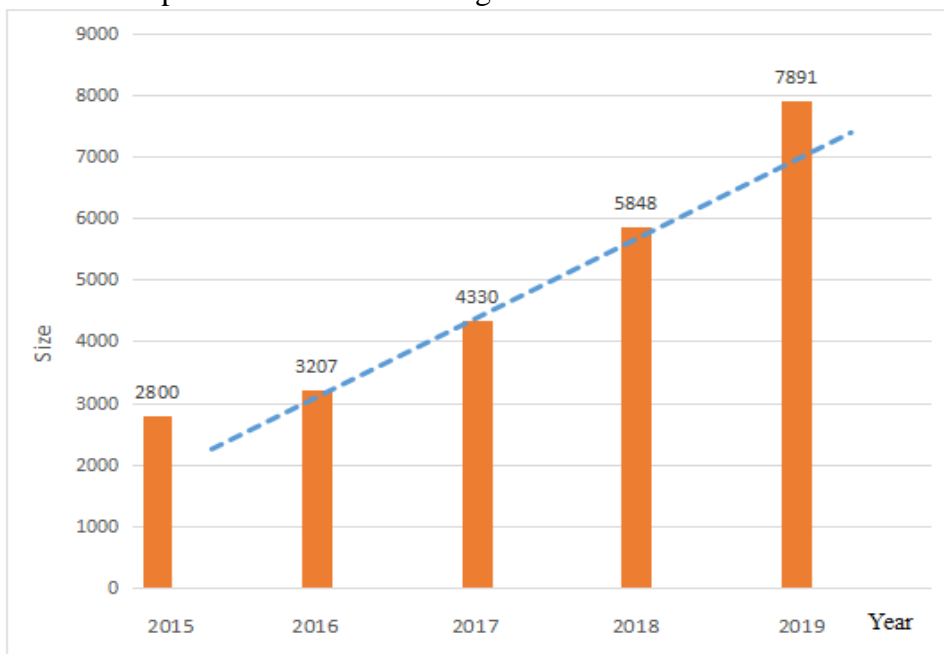


Figure 3 Scale of China's big data industry in 2015-2019 (100 million yuan)

From the event of China's AI in medicine, in August 2016, "Watson" Health Care entered 21 hospitals in China. In February 2017, the world's first "artificial intelligence (AI) in ophthalmic diagnosis and treatment" which can make a diagnosis and develop a treatment plan in a few minutes launched by Guangzhou Zhongshan Eye Center was officially open to the public, taking the first step in exploring the clinical application of artificial intelligence. In March of the same year, the "DE ultrasonic robot" jointly developed by the school of mathematics and physics of Zhejiang University and Zhejiang Demetics Medical Technology Co., Ltd. was applied in the staff hospital of the 55th Research Institute of Nanjing China Electronics Technology Group Co., Ltd., and was clinically applied in the First Affiliated Hospital of Zhejiang University. On May 19 of the same

year, Xiangya Second Hospital of Central South University, together with Ding Xiangyuan and Danale, held a press conference, announcing that major breakthroughs have been made in China's first "Artificial Intelligence Aided Diagnosis System for skin diseases", which can accurately distinguish various subtypes of lupus erythematosus and its similar diseases. According to incomplete statistics of iyiou think tank, as of July 2019, there were 126 active AI medical enterprises in the Chinese market, basically the same as the statistics in 2017 (131).

To sum up, after 2016, the number of documents increased gradually, and increased sharply in 2017, 2018 and 2019, which is consistent with the national policy orientation and industrial development trend.

### 3.2 Distribution of Resource Type

In terms of the number of documents, industrial guidance (Social Sciences) contributed the most, with 107 documents, accounting for 25% of the total. Secondly, the number of basic research (Social Sciences) documents reached 83, accounting for 19% of the total, the number of industry technical guidance (Natural Sciences) documents reached 76, accounting for 18% of the total, and the number of advanced science popularization (Natural Sciences) documents accounted for 11% of the total. Policy research (Natural Sciences) and policy research (Social Sciences) accounted for 9% and 3% of the total respectively (see Figure 4).
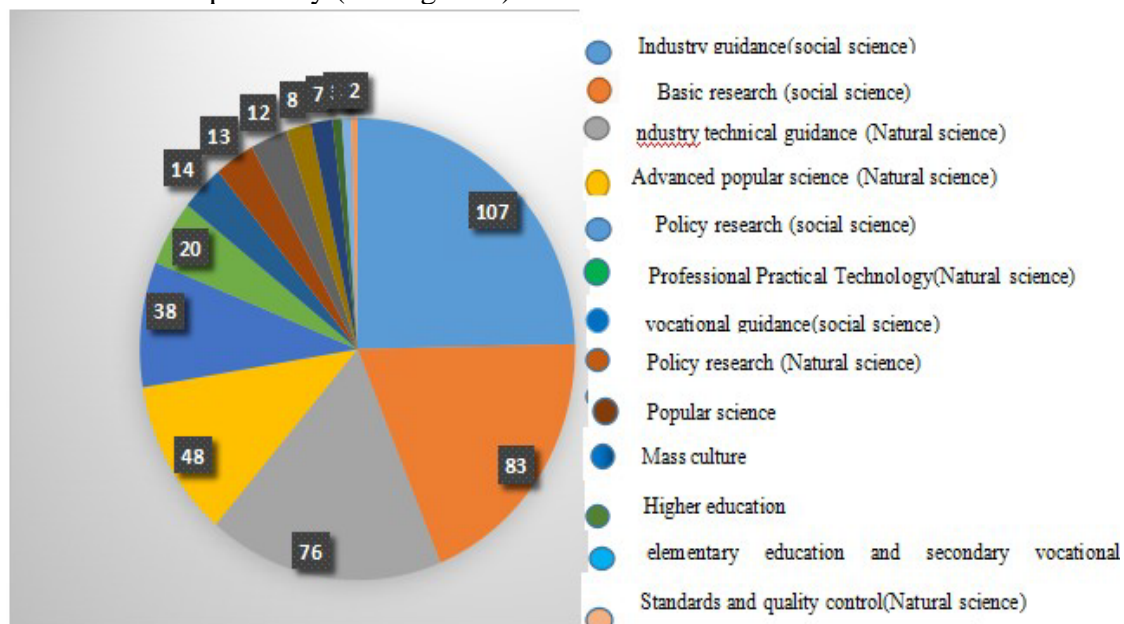


Figure 4 "Artificial intelligence in medicine" Literature research hierarchical distribution from 2000 to 2019

### 3.3 Analysis of Document Sources

Among the 901 documents searched, 101 documents with more than or equal to 5 cited times are selected. It can be seen that the number of documents from other sources is the most, 79, accounting for 78.2% of the total, and few from colleges and universities, accounting for only 1% of the total (see Figure 5). In April 2018, the Ministry of Education issued the notice on printing the "Action Plan for Artificial Intelligence Innovation in Colleges and Universities". In May, the School of artificial intelligence, the Institute of artificial intelligence, the Institute of intelligent manufacturing, and the research center of intelligent medical treatment of Jilin University were established successively, with a relatively large number of documents.
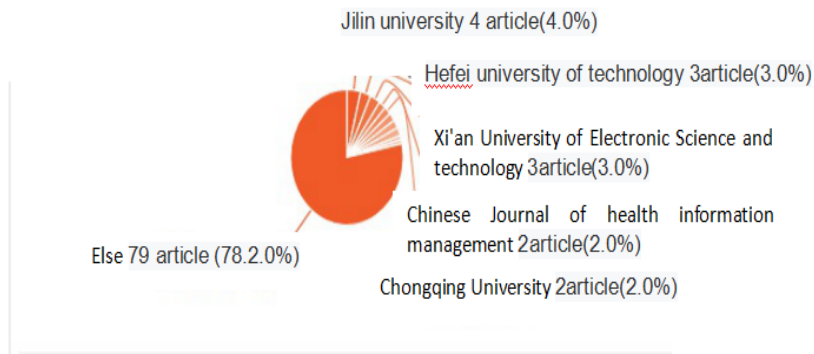
Figure 5 Source distribution of literature institutions cited more than 5 times

## 4. Evolution of Research Hot Spots

### 4.1 The Evolution of Artificial Intelligence Research Hot Spots from the Perspective of Keyword Contribution Analysis

Keywords are the core generalization of a paper. There must be some relationship among several keywords given in a paper, which can be expressed by the frequency of co-occurrence. It is generally believed that the more frequently lexical pairs appear in the same document, the closer the relationship between the two themes. By counting the frequency of the two subject words in a group in the same document, a coinage network composed of these word pairs can be formed. Among the 901 documents searched, 101 documents with more than or equal to 5 cited times are selected. Using CNKI's own analysis software, choose "ball distance = 3.2, node frequency = 2, cluster analysis = 3". The circle size in the figure represents the frequency of keywords. The higher the frequency is, the larger the circle is. From 2000 to 2019, The key words with high frequency (more than 2 times) in artificial intelligence medical research are: artificial intelligence (28 times), artificial intelligence technology, medical image (6 times), feature extraction, data set, network parameter (5 times), deep learning, machine learning, intelligent machine, homogeneous clustering (4 times), intelligent decision-making, intelligent medical treatment, computer vision, medical health, voice recognition , auxiliary diagnosis, fuzzy clustering, genetic algorithm, pixel point (3 times), medical robot, surgical robot (2 times).

Among the 901 retrieved documents related to AI in medicine, the second level retrieval was conducted with TS = risk and legal regulation, document type = full text, and 26 documents related to AI in medicine + risk and legal regulation were retrieved. Using CNKI's own analysis software, select "ball distance = 3.3, node frequency = 2, cluster analysis = 3". From 2000 to 2019, the key words of "AI in medicine + risk, legal regulation" are: AI (13 times), tort liability law (5 times), product liability, medical damage, medical damage liability (4 times), personal information protection (3 times), legal regulation, privacy protection, information protection, medical robot, personal health, patient information, medical devices , legal subject (twice).

From 2000 to 2016, China's research on AI in medicine mainly focused on the application and development of AI technology in clinical medical diagnosis, such as "the development of artificial intelligence in conventional medicine and its medical image expert system", "digital technology transformation of medical information application system ", "the design and development of new products of intelligent hospital bed", "the design and implementation of medical diagnosis auxiliary system of electronic medical record" "research and development and implementation of automatic integrated intelligent anesthesia robot" and other aspects. And China's research on artificial intelligence in medicine mainly focuses on "the application and development of artificial intelligence in the field of medical health", "the deep neural network evaluation of a disease", "the application and challenge of artificial intelligence and big data in clinical engineering", "the application of artificial intelligence in the field of medical testing", "the application of intelligent guidance robot", etc.

## 4.2 The Evolution of Research Hot Spots of AI in Medicine + Risk and Regulation from the Analysis of Subject Words

Subject words are standardized terms that can express the main content of literature, which have the characteristics of conceptualization and standardization. Since there is no literature on "AI in medicine + risk, legal regulation" from 2000 to 2016, the author makes a statistics on the subject words (frequency ≥ 1) of "AI in medicine + risk, legal regulation" related documents from 2017 to 2019 (see Table 1). In 2017, disease risk management and medical imaging are the two most popular application scenarios, and their core technologies are gene sequencing and image recognition. Image recognition is one of the most classical applications of machine learning, which is full of controversy in the transformation of medical field. Chinese scholars began to pay attention to the ethical aspects of AI in medicine. In 2018, moral hazard and risk prevention and other related issues were mentioned. Then in 2019, more scholars paid attention to the legal regulation, medical damage liability, personal information protection, legal personality, legal risk, product liability and other issues of AI in medicine (see Table 1).

Table 1 Statistics of information related to the subject words of "AI in medicine + risk, legal regulation" in domestic research (frequency ≥ 1)

| Year | Year 2017 (frequency) | Year 2018 (frequency) | | Year 2019 (frequency) | | | | |
|---|---|---|---|---|---|---|---|---|
| keyword | Ethical issues (1) | Artificial intelligence (3) | personal information (1) | Artificial intelligence (9) | Artificial intelligence on medicine (1) | Civil Subject Status (1) | privacy protection (1) | Internet hospital (1) |
| | Medical data (1) | Ethical issues (1) | medical institution (1) | Legal Regulation (4) | patent protection (1) | Mobile medical services (1) | Big data medicine (1) | medical service system (1) |
| | Medical informatization (1) | Online pharmacy (1) | medical staff (1) | Medical damage liability (3) | APP (1) | legal countermeasure(1) | creation (1) | technique basis (1) |
| | Prescription drug (1) | Innovative characteristics (1) | Industry Association (1) | individual information protection(2) | medical staff (1) | legal issue (1) | new technology (1) | Right of information self-determination (1) |
| | Ethical Regulation (1) | Moral subject(1) | risks and precautions (1) | challenges and countermeasure (2) | subject of right(1) | Intelligent Medical Robot (1) | Legal Object (1) | Surgical robot (1) |
| | Medical ethics (1) | Moral risk (1) | Mobile Internet (1) | legal personality (2) | Smart medicine (1) | Copyright (1) | Smart pension (1) | Medical risk (1) |
| | | Converse option issue (1) | Information Asymmetry issue (1) | Legal risks (2) | Medical risk sharing (1) | Health (1) | multiple regulation (1) | Soft Regulation (1) |
| | | | Ethical decision-making (1) | product liability (2) | | | | |

## 4.3 The Evolution of Research Hot Spots from the Analysis of Highly Cited Authors

Since 2017, only one document related to "AI in medicine+ risk, legal regulation" has appeared. Although the number has increased in 2018 and 2019, the total number of documents is relatively small, which shows that China's research on "AI in medicine + risk, legal regulation" is relatively backward. Among the 26 documents of "AI in medicine + risk, legal regulation" retrieved, the top 10 cited documents are selected (see Table 2). According to the analysis, seven authors, including Professor Cao Yanlin, director of the medical and Health Legal Research Office of Medical Information Research Institute of Chinese Academy of Medical Sciences & Peking Union Medical College, published the paper "opportunities and challenges of artificial intelligence for medical services" in June 2018, which was cited 13 times and downloaded 1075 times in 26 documents analyzed in CNKI database. In this paper, Professor Cao Yanlin and others introduced the development process of artificial intelligence and AI in medicine, mainly analyzing the five opportunities of AI for medical services, such as helping patients to carry out preliminary analysis and assessment of self-health status before treatment, helping doctors to manage patient information and improve service, helping hospitals to guide and manage patients for medical treatment, easing the tension of medical human resources and reconstructing medical service mode; and also put

forward the challenges faced by AI in medicine in terms of the protection of citizens' health information and patients' privacy, the acceptance of medical staff, fund raising, risk liability regulation and the legal status of AI in medicine.[1] They believe that the protection of citizens' health information and patients' privacy is a major challenge faced by AI in medicine. Some medical staff are worried that AI in medicine will replace them, so they may resist or treat the development of AI in medicine negatively. Through the AI medical system or platform to see a doctor, the doctor-patient relationship has become a relationship among three or four parties such as patients, AI medical system or platform, medical institutions and medical staff, and the main body of legal relationship has increased one party. Seeing a doctor through virtual information system or artificial intelligence system enhances the uncontrollability of medical risk, so it is a very complex and profound historical proposition whether the AI medical robot can obtain the legal status. Secondly, the paper "ethical issues of artificial intelligence: challenges and solutions" published by Wang Jun, Doctor of law at the center for philosophy post-doctoral studies of Hunan Normal University in July 2018 was cited five times and downloaded 2506 times in the 26 documents analyzed in the CNKI database. In this paper, Wang Jun discusses the moral subject of artificial intelligence from two aspects: whether artificial intelligence can become moral subject and whether artificial intelligence should be given moral status;

Table 2 Top 10 cited documents

| Author | Source | Headline | Cited frequency | Downloads | Journal composite influencing factors (2019) | Journal comprehensive influencing factors (2019) |
|---|---|---|---|---|---|---|
| Cao Yanlin, Wang Jiangjun, Chen Pu, Jia Fei, Xu Hailin, Su Man, Zhao Ruiqin | Chinese Hospitals | Opportunities and challenges of artificial intelligence to medical services | 13 | 1075 | 1.511 | 1.125 |
| Wang Jun; | Studies in Ethics (Chinese core journals) | The Ethical Issues of Artificial Intelligence: Challenges and Solutions | 5 | 2506 | 0.607 | 0.324 |
| Li Xingchen; | Medicine and Law | Legal Responsibility of Artificial Intelligence Medical Service | 5 | 892 | 0.742 | 0.407 |
| Liu Honghua; | Northern Legal Science (Chinese core journals) | Negation of Artificial Intelligence Legal Subject Qualification and Conception of Legal Regulation | 1 | 892 | 0.416 | 0.226 |
| Cao Yanlin; Chen Pu | Chinese Health | Artificial Intelligence: A Bright Future Facing Legal Vacancy | 1 | 434 | 1.715 | 0.782 |
| Deng Mingpan, Liu Chunlin | China Health Law | Research on Medical Damage Liability of Surgical Robot | 1 | 283 | 0.607 | 0.260 |
| Gao Lumei | Journal of Henan University of Technology (Social Science Edition) | On the Legal Regulation of Mobile Medical App | 1 | 169 | 0.345 | 0.264 |
| Hu Yuancong, Zhang Xinyu | Credit Investigation (Chinese core journals) | Personal Information Protection in the Era of Artificial Intelligence from the Perspective of Government Intervention | 0 | 506 | 0.366 | 0.237 |
| Ma Liping | Human Rights | On the Development and Innovation of Smart Pension in China | 0 | 43 | 0.869 | 0.443 |
| Li Runsheng, Shi Biao | Journal of Shenzhen University (Humanities & Social Sciences) | The application and Evolution of Medical Damage Liability Rules from the Perspective of Artificial Intelligence | 0 | 34 | 1.107 | 0.639 |

Expounds the ethical challenges brought by the development of artificial intelligence from three aspects: the moral decision-making risks caused by artificial intelligence, the possible social ethical problems caused by artificial intelligence, and the ethical problems of the existence and development of the subject person; gives some suggestions to deal with the ethical problems of artificial intelligence from the following four aspects: guiding the development of artificial intelligence with Marxism, strengthening the construction of ethical system, correctly handling the development of human and artificial intelligence, and strengthening the supervision in the field of artificial intelligence.[2]

## 5. Conclusion

Synthesizing Figure 6, Figure 7, table 1, and table 2, and interpreting the subject words got in the second retrieval, it can be found that in recent years there are three themes in the research of "AI in medicine + risk, legal regulation" in China. They are "ethical issues of AI in medicine", "personal information security of AI in medicine" and "damage liability of AI in medicine".

### 5.1 Ethical Issues of AI in Medicine

Nowadays, with the rapid development of AI in medicine, some problems begin to emerge. As mentioned above, Dr. Wang Jun talked about the possible ethical problems of AI to medical treatment in the article "ethical issues of artificial intelligence: challenges and solutions". The first problem is the impact on medical equity. Because of the high cost of AI medical treatment, most ordinary patients are not willing to accept the treatment of AI medical equipment, so its main audience is only limited to minority groups. The second is the challenge to medical security. Even though the AI medical technology is more and more accurate and intelligent, its ability to respond to emergencies still brings many problems to be solved, such as the definition of responsibility for medical processes and accidents.[3]

### 5.2 Personal Information Security of AI in Medicine

With the rapid development of artificial intelligence in medicine, it is still a challenge for the AI medical system that needs to be updated frequently to better realize dynamic supervision. On the one hand, it is difficult for medical institutions to share medical data. On the other hand, the legal system can not explain and define the ownership of data well. The ownership and privacy protection of personal medical data, the use, circulation, charging and other security norms of cross institutional data need to be explored clearly. Hu Yuancong, researcher of the AI Law Research Institute of Southwest University of political Science and Law, wrote the paper "personal information protection in the era of artificial intelligence in the perspective of government intervention" which was downloaded 506 times in 26 documents analyzed in CNKI database. He talked about that with the establishment of big data platform, the new AI products represented by biometric identification, intelligent medical treatment and automatic driving not only brought convenience to people, but also great challenges to the traditional mode of personal information protection. He believed that China should strive for the coordinated development of AI technology innovation and personal information security protection. [4] As mentioned above, Dr. Wang Jun talked about the potential threat of AI to patients' privacy in the article "ethical issues of AI: challenges and solutions", such as the AI machine will automatically store and analyze the patient's information after understanding the patient's information. Even if the personal privacy information can be deleted manually, it is still possible to recover it under today's technical conditions, so there is a greater risk of privacy disclosure. [5]

### 5.3 Damage Liability of AI in Medicine

AI in medicine plays a great role in solving medical problems. In the future, AI medical robots are becoming more and more human while the idea of experts in the medical field will be more and more close to the that of robots, therefore the right of AI medical robots need to be limited. For example, the intelligent development of surgical robot has changed the traditional medical behavior mode, resulting in many legal problems, especially the liability. The occurrence of adverse events, such as surgical accidents caused by surgical robots, not only causes the public to question the technology of surgical robots, but also causes heated discussions on the legal status of surgical robots and the liability of adverse events in the theoretical and practical circles. For example, Deng mingpan, a lawyer from Sichuan Runze law firm, published the paper "Research on medical damage liability of surgical robot" in March 2019, which was cited once and downloaded 283 times in 26 documents analyzed in CNKI database. In the paper, Deng talks about the social value of surgical robot, such as improving the accuracy and safety of operation, innovating diagnosis and treatment mode, reducing the workload of doctors, etc., but the biggest problem is the problem of

liability caused by the medical damage caused by the safety loopholes of surgical robot. He classified the medical liability of medical robots into the following four categories: the first category is that the hospital is responsible as the user or operator, such as the "medical damage liability theory" and the "employer alternative liability theory"; the second category is the producer and the seller is responsible, such as the "product liability theory"; the third category is that the surgical robot itself is responsible; the fourth category is that other infringers is responsible, such as hackers and virus carriers.[6]

## 6. Prediction of Future Research Hot Spots

At present, there is no general law to regulate the development of AI medical technology in the world, including China. It is urgent for relevant international organizations and China to attach importance to it and timely issue corresponding policies, rules, legal interpretation, adjudication standards to restrict and regulate the development of AI technology.

With the growing popularity of artificial intelligence in China, artificial intelligence may be first applied in the field of medical treatment, mainly focusing on "medical robot, intelligent drug research and development, intelligent diagnosis and treatment, intelligent medical image recognition, intelligent health management", etc. The author predicts that how to make legal guidance on the specific application scenarios of AI in medicine will be the theoretical and practical problems that the legal community and experts and scholars in these fields need to face and solve together in the future. It may involve the following aspects:

### 6.1 Research on Market Access Rules of AI Medical Products

From the perspective of medical product access, the market access system of AI medical products involves laws, regulations and rules. China has basically established a legal system for market access supervision. CFDA certification is not required for products related to voice input and data structure in AI medical system, but a considerable number of AI medical products must pass CFDA certification to enter the market. With the rapid development of AI-aided diagnosis software and equipment, medical interventions is enhanced. In the high-tech industry where machine learning and deep learning are more and more popular, it is increasingly popular to use artificial intelligence for image 3D segmentation, pathological image analysis and processing, personalized precision medicine and other work to assist doctors in diagnosis and treatment scheme formulation. "Catalogue of Medical Device Classification" issued by the State Drug Administration (CFDA) and officially implemented from August 1, 2018 added the relevant classification of AI-aided diagnosis. The catalogue pointed out that medical software can be divided into auxiliary diagnosis and treatment according to its intended use. The risk degree of the diagnostic function software is not only determined by the processing object (such as the image of cancer, malignant tumor and other diseases), but also determined by the risk degree, maturity degree and openness degree of the algorithm. If medical AI products provide diagnosis suggestions through algorithms and only assist diagnosis without directly giving diagnosis conclusions, it should be classified as the second type of medical devices. If the medical AI product automatically identifies the pathological part through its algorithm, and provides clear diagnosis tips, then its risk level is relatively high and should be classified as the third category of medical devices. The industry calls AI medical products of the corresponding categories "AI II" and "AI III". "AI II" can be directly applied to the provincial drug administration, and "AI III" must be approved by the State Drug Administration, and be studied in clinical trials. Most of the AI medical products on the market fall into the "AI III". It is worth noting that the third type of medical devices need to undergo clinical trials, the second type of devices have the catalog of clinical trial exemption, and whether the application of diagnostic software can enjoy the exemption has not been specifically regulated by the State Drug Administration. In China, according to the registration process of medical devices, products need to go through six steps from application to final review, including product finalization, testing, clinical trial, registration and application, technical review and administrative approval. The clinical trial of the three types of medical devices needs about 2 to 3 years. The cost of early validation and clinical

trials varies from 3 million to 5 million, and the more prospective patients in clinical trials, the higher the cost. According to the case number generally specified of AI medical products, if prospective studies are conducted on all patients, the cost of clinical trials alone is about 10 million, which is very difficult for AI medical enterprises. However, the performance, algorithm model and application interface of AI medical products are updated rapidly. For example, the iteration cycle of intelligent medical imaging products is 3-5 days, and the traditional approval process is obviously unsuitable, which needs relevant departments and experts in this field to study the market access rules for AI medical products. In February 2017, National Institute for Food and Drug Control set up an artificial intelligence team and officially launched the research on the inspection and testing methods of artificial intelligence medical devices. According to Yang Zhaopeng, director of the Institute of medical device inspection of National Institute for Food and Drug Control, the AI team has carried out research on performance evaluation methods based on standard test data sets in combination with the situation of the products to be inspected, and has made certain achievements, which can solve the evaluation needs of the vast majority of products to be inspected. On this basis, they are promoting the research on the methods of testing database authentication, confrontation testing, modeling testing and so on established by enterprises to lay the foundation for drafting industry standards. Therefore, the research on market access rules of artificial intelligence medical products will be the research hot spot in the future.

## 6.2 Research on the Definition of the Nature of AI Medical Activities

At present, the development of AI in medicine is at the stage the doctor in charge puts forward the request, and the artificial intelligence robot will answer the request, such as Watson robot. [1] Some AI medical robots begin to have some primary abilities to obtain information and analyze it spontaneously. They can choose their own processing methods according to their own thinking, such as Da Vinci robot surgery system.[2] At present, many sensors have come out in the form of monomer and enter the clinical experiment stage, which is expected to be integrated into medical AI in the future. When every step of medical advice given by medical AI is most in line with the medical knowledge system or even beyond the cognitive level of human doctors, the medical scheme can be decided by artificial intelligence. However, once AI medical treatment reaches the stage of "active thinking and action" thinking chain, human may lose control of it, and the potential risks are self-evident. From the current implementation path of AI medical treatment we know, according to the "expert-algorithm-data" mode, the "intelligence" of AI robot is the result of learning from human doctors, which mainly seems to be the medical experience of human doctors. But as an artificial intelligence robot, it is a kind of product. Then who is the main body of medical activities among "designer", "engineer", "production enterprise", "medical expert" and "artificial intelligence robot"? AI medical products are the form of AI to play a role. How to define the identity of intelligent robots, how to build the relationship between human and machine, and how to solve the conflict are all issues to be considered.

## 6.3 Research on Regulatory Risk in AI Medical Treatment

The application of AI technology is realized by code and algorithm. With the development of AI, code and algorithm will become a new way of regulation. At this stage, AI medical treatment only shows the results to doctors, but does not explain the logic behind the results. The designers of AI medical products "sometimes don't disclose the source code, so users can't see the rules clearly, can't make different opinions, can't participate in the decision-making process, but can only accept the final results", which will bring about problems of order and justice. For example, "Watson doctor" comes up with a diagnosis and treatment plan after design experts input a lot of medical literature into it. It is impossible for the outside world to know which literature has been used and how the algorithm gives relevant evaluation to different diagnosis and treatment schemes. In the absence of logical interpretation of AI medical algorithm, it is difficult to determine the regulatory boundary of AI medical technology. In the academic field of medical science, it will be a hot issue to explain the decision-making process in the algorithm black box, so the research on regulatory risk in the field of AI medical treatment will also be a hot topic in the future.

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