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Supervision and Application Analysis of AI Medical Devices

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Abstract: The objective of this paper is to sort out and analyze the application and supervision status of AI medical devices, so as to find out the problems existing in their application and supervision, and then put forward targeted suggestions. The methods of this paper is to summarize the relevant theories and status quo of the supervision and application of AI medical devices by means of literature research and theoretical induction. Through the comparative analysis method, the current situation of the supervision and application of AI medical devices at home and abroad is compared and analyzed, so as to find the current shortcomings in the supervision and application of AI medical devices in my country. The results of this paper is in the application and supervision of AI medical devices, the legal status is not yet clear, personal data and privacy protection issues, and social equity issues that may arise. The conclusion of this paper is that AI medical devices are in a period of vigorous development, and the corresponding technologies and formats are constantly being formed. It is necessary to differentiate the status of AI medical devices, pay attention to patient privacy and data information security, and ensure that the public can equally enjoy the development results of AI medical devices.

1. Introduction

In recent years, with the rapid development of the "Internet + medical" model, AI has taken a place in paramedicine, medical image processing, health management and other fields. With the "notice on the issuance of a new generation of AI technology development strategic plan" and the "14th Five-Year Plan" and other policies released, the integration of AI-related industries in China has very popular in recent years.

In the context of China's accelerating population aging, the spread of chronic diseases, and the shortage of medical professionals, the development and application of AI medical devices is of urgency and importance. However, as the use of AI in healthcare becomes more common, the attendant regulatory issues are in urgent need of improvement. The lack of regulation will not only directly slow down the pace of clinical application of AI medical devices, but also induce various conflicts and problems that directly affect the development of AI medical devices. Therefore, this

paper aims to study the current situation of the application and regulation of AI medical devices, analyze the problems in their application and regulation from ethical and legal aspects, and thus make recommendations in a targeted manner.

2. Overview of Artificial Intelligence Medical Devices

Artificial Intelligence ("AI") is an emerging technical science of theories, methods, technologies, and application systems that simulate and extend human intelligence. Research in this area includes intelligent robotics, language recognition, image recognition, expert systems and so on[1].

The development of AI in healthcare can be roughly divided into two phases from the timeline: knowledge-driven and data-driven. The first phase was from 1956 to 1987, during which scientists focused on knowledge-driven systems that empowered computers with logic and causal reasoning, resulting in the creation of a series of research results based on expert knowledge bases, such as diagnostic systems to assist in internal medicine diseases[2]. However, as healthcare data becomes increasingly informative and complex, knowledge-driven research paradigms are unable to satisfy further intelligence.

The second phase is from 1993 to the present, in order to support further intelligence, data-driven research and applications began to gradually become the mainstream of the market. Deep neural networks have been developed and enhanced in electronic medical records, medical imaging, etc., because of their superior data fitting capabilities. By using natural language processing technology, graph neural network, medical knowledge mapping and other technologies, text information of medical cases is analyzed and constructed to realize intelligent consultation, auxiliary diagnosis, treatment recommendation, prognosis prediction and other functions. Medical image analysis and learning based on imagomics, convolutional neural networks and generative adversarial network technologies are used for lesion location, detection, segmentation, classification and image reconstruction [2].

3. Overview of Artificial Intelligence Medical Devices

3.1 Application in supplementary treatment

The definition of "AI + assisted diagnosis and treatment" model is to use AI technology for assisted diagnosis and treatment, allowing the computer to "learn" medical knowledge, simulate the doctor's thinking and diagnostic argumentation, and develop a reliable treatment plan. This model can reduce patient access time, improve the quality and efficiency of physician visits, and thus improve the accuracy of diagnostic results. It plays an indispensable role in today's medical field and has a broad and bright future.

In the actual diagnosis process, the main responsibilities of AI are: First, to understand the main data information of the patient. Second, the medical knowledge is perfected and targeted for common diseases: such as influenza. Then, after having some medical experience, medical knowledge and the basis of the condition, we make a more accurate judgment of the main cause of the patient's illness and the presence or absence of allergens. At the end, the effects, side effects and toxicity of the treatment modalities can be analyzed, providing doctors with an important reference, thus improving the efficiency and accuracy of treatment.

Currently, IBM's artificial intelligence Watson is the most mature example of this model, having been certified as an occupational physician in the United States 10 years ago and providing complementary care to several hospitals. Since Waston can quickly read a lot of medical papers, etc., it can learn a lot of medical knowledge to improve its system. After several years of development, Watson has developed three cancer treatment solutions, such as: Waston Oncology Solution, Waston

Genetic Solution and Waston Clinical Trial Matching Solution.

3.2 Application in Health Management

The model of "AI + health management" is that it can prevent diseases in the early stage, control the development of diseases in time after the disease, and reduce the cost of treatment. Raising the public's perception of health can help improve the overall health of the nation and prevent serious or widespread diseases, which means that health management can be used for the purpose of "treating diseases before they occur"[3].

Through the algorithm of AI, people can not only monitor their health condition in real time and eradicate possible diseases at the source in the early stage, but even analyze the development of infectious and seasonal diseases through big data, which helps people to make appropriate preventive measures based on the data obtained from the algorithm and big data analysis. To a certain extent, this model can be called the closest to people's lives in the clinical application of AI medical devices. The development of such models is driving human health care to a higher quality and deeper level. Based on the current general development, relying on big data and algorithm technology, this model has a wide range of applications in the areas of big data and flu prediction, artificial intelligence blood sugar monitoring, data technology and personalized nutrition plan, facial recognition and emotion monitoring, and scientific prediction of life expectancy.

3.3 The current status of foreign regulation

Currently, AI medical devices are developing rapidly, and various countries and regions are at the same starting line at this stage. However, due to realities such as the serious aging of the world's population, it has prompted a desire to dominate the field of AI medical devices, thus accelerating the pace of standardization and revision of AI medical devices. Developed countries such as the USA, the UK and international organizations such as the EU have developed standards programs, and groups such as the Global Association of Diagnostic Imaging, Medical Information Technology and Radiotherapy Industries are actively laying out[4].

Currently, AI is widely used in the medical field as a popular and innovative technology, and the regulatory awareness and regulation construction of AI in various countries continues to deepen. The regulatory classification of AI medical devices is currently one of the very important regulatory initiatives, and both the U.S. Food and Drug Administration (FDA) and the International Medical Device Regulators Forum (IMDRF) have risk-graded the regulation of AI medical software. Two points in particular deserve attention. First, low-risk AI medical software does not have to be reviewed. Second, because the system must use a large amount of data for accurate training, existing human biases may be transferred to the AI system in the meantime. Both organizations have strict and rigorous review systems for reviewers and manufacturers of medical software, as this can lead to faulty algorithm results that can cause serious harm.

The FDA has made different requirements for the regulation of AI medical software and ordinary medical software. First of all, the assessment of the applicant organization and its products is diversified. In addition to the most basic and conventional pre-certification rating of software product features and performance, it is more important to rate whether the manufacturer's corporate culture is humane and excellent, and whether the internal structure of the enterprise is advanced. Second, it is divided into serious situations, critical situations, non-critical situations, etc. according to the different scenarios in which the AI medical devices are applied. The three main categories are critical situations, severe situations, and non-critical situations based on the impact on the importance of medical decisions. The most important thing is that a variety of AI medical devices are emerging, with the corresponding product review process must also keep pace with the simplification, to provide a strong

guarantee for the listing of AI medical products.

IMDRF's Artificial Intelligence Medical Devices Working Group has organized several online meetings. During the conference, delegates sent from all over the world had a detailed and intense discussion on how to standardize the terminology and manuscripts of AI medical devices. It is worth noting that keywords such as "continuous learning" and "algorithm change" have attracted widespread attention in Europe and the US, emphasizing the role of good machine learning practices in quality management.

3.4 The current status of domestic regulation

On July 7, 2021, the National Medical Products Administration ("NMPA") released the medical device industry standard revision plan project, involving 2 AI medical device industry standards. July 8, the NMPA issued "artificial intelligence medical software product classification definition guidelines" to strengthen the supervision and management of AI medical software products, to help the industry's high-quality development[5].

In recent years, the regulation of AI medical devices abroad has become stricter and stricter, and the regulation of AI medical devices in China has become more and more perfect. In 2020, the first batch of China's AI medical device industry standards, "AI Medical Device Quality Requirements and Evaluation Part 1: Terminology" and "AI Medical Device Quality Requirements and Evaluation Part 2: General Requirements for Data Sets", are already in the submission stage for approval[6]. Part 1 is to provide the basic generic terminology for quality assessment of smart medical devices and to provide a reference for the preparation of future standards. Part 2 is about incorporating data into an intelligent medical device quality assessment system and specifying its assessment objectives and technical approaches. At the same time, the "Expert Consensus on Construction and Quality Control of Chest CT Lung Nodule Dataset" was released to provide a reference for the implementation of the standard. According to the standard making and revision plan announced by the NMPA, in 2021, the National Institutes for Food and Drug Control, as the authorities, will carry out standard drafting work around two topics: "Artificial intelligence medical device quality requirements and evaluation part 3: general requirements for data annotation" and "artificial intelligence medical device lung image analysis software algorithm performance test method"[4].

While improving the relevant laws, China is also continuing the process of standardization of AI medical devices. Among them, the IEEE standard for artificially intelligent medical devices, led by the China Academy of Food and Drug Control, and in cooperation with organizations in more than a dozen countries, including the Netherlands, has gained worldwide recognition. The China Academy of Food and Drug Control is working with enterprises, research institutions, etc., in a joint effort so that the standard can be implemented on the ground and improve product testing services.

Currently, China is conducting research on standardization of intelligent medical devices at both theoretical and practical levels. With the development of AI industry and standardization research, China's standardization of intelligent medical devices is gradually moving towards innovation, providing technical support for the development of the industry and the development of regulation.

4. Problems in regulation and application

4.1 Personal data and privacy protection issues

The application of AI medical devices in health management is to provide more accurate and personalized services to users, which usually requires the collection of a large amount of physiological and life data from users. However, most of the collected data involves user privacy, and only a simple analysis of it is enough to obtain sensitive information about the user. If this

information is intentionally or unintentionally leaked, it can result in a major privacy breach that could be very costly to the user. Assuming that the patient's medical information is known to the company he or she works for or is interviewing with, it is likely that the patient will lose a job or employment opportunity because of a previous illness.

In the case of traditional medicine, there are already relevant laws such as the Law on Medical Practitioners and the Law on Tort Liability that prohibit doctors from selling patient information and protect patient privacy. Unlike traditional medicine, AI medical systems store the collected patient information in memory, and even if it is deleted, it can be recovered through appropriate technology. In terms of handling information, AI medical devices are much less confidential, and whoever wants information about a patient can easily access it on the system. Let all hospitals use AI medical devices, even if there are strict confidentiality measures, there is a chance that they will be hacked. So should we be extremely protective of privacy and thus strongly resist the clinical use of AI medical devices? Or should we put aside the issue of privacy protection and just care about the benefits that AI medical devices offer? The answer is that neither is desirable.

The EU now has the strictest data management regulation ever: the General Data Protection Regulation. The regulation regulates the legality of data, the specific forms of personal data processing, the right to be forgotten, and large fines. Even though there is still a lack of relevant legal protection in the field of medical big data privacy protection in China, the draft of "Health Care Big Data Security Management Measures" has been formulated and will be released soon. As AI healthcare becomes more popular in application areas, there is an urgent need to find a balance between open sharing and patient privacy protection and data security.

4.2 Social Equity Issues Raised

The clinical application of artificially intelligent medical devices will inevitably create social inequities. Due to the current economic development there is still an imbalance between regions, which leads to disparities in medical conditions and uneven distribution of resources such as technical equipment. AI medical devices are more expensive, making it difficult for such medical devices to be used in primary care applications such as community hospitals and Grade II Level A hospitals, and their applications are mainly concentrated in large Grade III Level A hospitals [7]. The large Grade III Level A hospitals are basically located in the heart of the city, which means that patients in remote areas still have the problem of difficult access to medical care, and it is difficult to enjoy the services brought by high-tech medical technology. This will cause the already unbalanced medical resources to be tilted even more towards the cities, leading to an increasing social injustice in medical care. And one of the purposes of the clinical application of AI medical devices is to reduce the pressure of Grade III Level A hospital visits, and this will not accomplish that purpose.

We leave aside the possibility of inequitable resource allocation and assume that resources are distributed equally to each region and hospital, allowing AI medical devices to achieve full penetration. However, the application of AI medical devices in the short term is bound to require higher prices to be available, and mass acceptance is not high. There is also a gap in the financial ability of patients, and only a small percentage of people may be willing to accept the diagnosis and treatment of AI medical devices and be able to afford the high cost. As a result, the majority of ordinary patients do not have access to the benefits of high-tech products such as AI medical devices, thus creating resistance and dissatisfaction.

However, AI medical devices for diagnosis, such as AI fundus imaging systems, can assist doctors in condition analysis, thereby rapidly improving the diagnosis level of primary care institutions, narrowing the gap with large tertiary hospitals and alleviating the problem of uneven medical resources. Therefore, the issue of social equity raised by AI medical devices requires our attention

and consideration of "how to balance social issues".

4.3 The legal status of the issue

For the regulation of AI medical devices, we currently have to consider the following issue: the legal status of AI medical devices are in. AI medical devices have been developed in depth in the fields of paramedicine, medical image processing, health management, and clinical research. Because artificially intelligent medical devices have great potential and vast future, contributing to the improvement of patient treatment conditions and alleviating the huge gap of doctors in the medical industry, among other advantages, the law is supportive and encouraging for the development of artificially intelligent medical devices. However, there is currently discussion as to whether AI medical devices represent themselves or physicians in clinical applications. Suppose an AI medical device has an accident during treatment, will the consequences of this be borne by the AI medical device itself, or by the hospital, or by the manufacturer of the device?

In reality, the application of AI medical devices must involve the issue of legal obligations and legal responsibilities of AI medical-related subjects. So how should we determine? The EU proposes that automated robots should be taxed, pensioned and registered. Saudi Arabia has announced that it has granted full citizenship to a U.S.-made female robot named Sophia. This has also caused great controversy as to whether AI medical devices can be independent civil subjects in civil matters.

5. Suggestions

5.1 Focus on patient privacy protection and data security

In developing laws on big data and privacy protection for smart medical science, it is important to take into account both data security, patient privacy, and the need for AI development to prevent excessive medical data and privacy restrictions[8]. We should uphold the principle of "encouraging innovation and being tolerant and prudent", learn from European and American countries about the problems of personal data leakage and imperfect privacy protection in the regulation and application.

First, traditional medicine and AI medicine need to differentiate privacy issues, and the boundaries between data applications, information security and patient privacy must be clear[3]. In order to safeguard patient privacy, a set of norms must be established during its development, production and use. When conducting data training and result analysis, authorization management of data is needed to desensitize and strongly encrypt important private information of patients, such as ID numbers and cell phone numbers, in order to better guarantee the availability and privacy of data. Currently, some European and American countries have issued regulations for medical safety and security, and any access to data must go through strict access control procedures, as well as strong encryption of data, which is to prevent cracking in case of data leakage. At the same time, in order to ensure the security of the data, it must be processed mosaic, all-round to win the "data security war".

Second, innovative management methods should be established to protect patient privacy and data information. In the present time of pursuing electronic and information technology, the owners of electronic health records and medical records are the patients themselves, and if the information collection and storage units want to keep and use the patients' medical records, their prior consent must be obtained. In special cases, for example, when it is impossible to locate the patient, or when the patient is too far away, or when the patient's information is needed in an emergency and the patient cannot be consulted in advance, etc. In this case, smart medical devices must be managed in a hierarchical manner according to the user's needs when collecting and storing data from patients. The relevant staff should take initiatives such as identification and coding, data separation, comprehensive security review, and deletion of personal information to prevent conflicts occurring.

5.2 Ensure public equitable access to the fruits of AI medical device development

In recent years, with the continuous integration of AI technology and medical development, AI medical devices usher in new prospects. While enjoying the benefits of AI healthcare, we also need to think about a question: how to distribute the results brought by AI healthcare technology.

In order to avoid the harm caused by unfair social distribution, we need to distribute the convenience and services brought by AI healthcare in a more equitable way. This also requires the government to perform its function to allocate and utilize valuable healthcare resources in a rational manner. This is a dual dilemma concerning economics and ethics. The allocation of AI healthcare resources should be done in such a way that it is both fully utilized and justified. In setting allocation priorities, the government must evaluate them thoroughly and take a proactive and cautious approach.

Let's imagine if AI medical devices are unfairly distributed to the society, the medical resources are originally abundant in the region with more perfect medical resources, while the medical resources in the region with relatively backward medical resources are still at the backward level, that will further aggravate the current situation of unfair distribution of resources.

Therefore, the government must play a governmental function to reasonably assess the needs of individual localities for AI healthcare, so that people in each region can share the fruits of AI healthcare development, and people in each region can benefit from the benefits created by AI[7].

5.3 Differentiation to determine the legal status of AI medical devices

The key issue in the current legal regulation of AI healthcare is: how to clarify and obtain the legal status of its subject. The solution to this problem can effectively fuel the advancement of AI medical devices. The legal issues in AI medicine are not only about how to develop treatment norms and how to determine medical torts of AI, but also related to the issue of the qualification of practicing medicine with AI as the subject.

In terms of appearance, the current domestic intelligent medical treatment is not so different from traditional medical devices. In terms of its own function, current AI medicine is simply a machine, designed and controlled by humans, to assist doctors in making diagnoses, allowing them to obtain more accurate medical judgments in less time, without being able to assume the role of "doctor" themselves.

From the viewpoint of popularity, in recent years, the rapid development of AI in the medical field, but still need a long time to fully popularize. More importantly, AI medical devices are just machines that are unable to empathize with the patient's fears and anxieties as well as the concerns of the patient's family during the patient's treatment. Moreover, although AI medicine has a "brain" that can extrapolate information after acquiring it, AI medical devices can only judge the symptoms of conditions that already exist in its "brain", and it does not have the pioneering and creative thinking that doctors have when they encounter new diseases.

From the current state of affairs, AI medical devices do not have the legal status of the subject, as natural persons through the study, examination to obtain the qualification of the practice as well as the state awarded the qualification to practice medicine, it has never been able to become a "real doctor". For now, we don't need to worry about whether AI will replace doctors; AI will stay in the passenger seat, improving our workflow and making our operations more rational, helping to make more optimal decisions and reducing the fearful uncertainty we face in decision making[11].

If in the future, AI medical devices develop to a level with the human brain or even beyond the human brain, we cannot simply distinguish between human and AI medical devices, if AI does not have the same legal status as the current, it is easy to cause social barriers and legal irrationality. Therefore, in the future, when it can be compared with the human brain, it should have the status of a clear legal subject, have legal practice qualifications, and build a legal relationship based on

interpersonal society with AI as the main body[3].

6. Conclusions

At present, the global AI technology is basically in the same starting stage, but China is lagging behind in the regulation and application of legal and ethical research. China's medical industry has not yet formed a consensus on the concept, ethical norms, and ethical risks of AI medical care, and the construction of ethical design standards and evaluation criteria is still in its infancy, greatly limiting the future development of AI medical care[9]. The AI medical devices are special and complex, so both the AI medical products themselves should be regulated and their manufacturers should be strictly controlled.

Due to the current rapid economic and technological development, the State Council of the People's Republic of China has proposed the principle of prudential regulation, which means that while having a cautious attitude towards the emerging field of AI medical devices, the policy regulation is appropriately relaxed to allow room for its free development. But as AI medical devices continue to develop, it has to shoulder more responsibility, which has to help us to carry out better regulation and legislation for them. In order to promote the standardization of the development of intelligent medical devices, a set of AI medical liability system with clear legal boundaries should be established to clearly define the responsibilities and rights of its developers, producers and users[10].

Although the current AI medical devices in the application and regulation of the problem of personal data and privacy protection, may raise the issue of social equity, etc. But compared with these shortcomings, its advantages are also particularly obvious, and it holds great promise in the medical field. If we could realize machine medical care, it would meet the current huge medical gap and relieve the huge medical pressure caused by the aging of society and the shortage of medical personnel. In addition, AI healthcare allows for real-time monitoring and can detect problems at an early stage of disease so that patients can receive timely treatment, thereby enhancing public health and improving public health. Finally, with the advantage of its big data processing power, AI medical devices can improve the accuracy and efficiency of diagnosis, thus helping doctors to better diagnose and treat.

Although the future of AI medical devices is bright, but its vague threat is always present. We must now ensure that the development of AI healthcare benefits and serves humanity, which requires good regulation by all of humanity in terms of rule of law, regulation, technology, and standards. With the improvement of application, regulation and policy, AI medical treatment will go deeper into clinical treatment, continuously improve the efficiency and quality of doctors' diagnosis, and let doctors have more energy to truly shift from "disease-centered" to "patient-centered".

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