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Ethical Review Based on Health Care Big Data

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Abstract: *China's ethical review regulations related to health care big data can not fully cover all kinds of problems in the application process of health care big data. Through the in-depth study of relevant laws and regulations at home and abroad and the in-depth analysis of relevant research results of researchers at home and abroad, this paper discusses the ethical review issues related to health care big data, in order to provide some reasonable suggestions for the ethical social difference norms for the research and application of health care big data in China.*

Keywords: *Big data; Health; Medical care; Ethical review*

1. Introduction

Today, we are in a new era of "digital, networked and intelligent in-depth development". While enjoying the convenient life brought by the development of science and technology, we are also enjoying the longer life brought by the improvement of medical technology. These scientific and technological means have comprehensively improved the quality and efficiency of our daily life, which depends on the scientific utilization of data resources and the wide application of digital technology. With the organic integration of science and technology and health care industry, the unique health care big data of this era has been produced, which covers the huge resources of national health care data. It not only reflects a country's medical level, but also highlights a country's scientific and technological level. It has become a fundamental basic strategic resource of the country.

While enjoying the benefits brought by the rapid development of medical level and scientific and technological level, we should also be deeply aware of the application of health care big data. As one of the emerging products of the 21st century, health care big data does make a significant contribution to providing the common with convenient medical services and improving medical efficiency. However, while health care big data is widely used, its relevant laws and regulations are not perfect, which leads us to enjoy convenient medical services and face huge risks, such as personal privacy disclosure, informed consent procedure, resource allocation, etc. If these problems cannot be properly solved, it is tantamount to planting a "time bomb" in our lives.

Health care big data is an emerging thing in the new era. It not only brings convenient and intelligent medical life to human society, but also implies a series of risks. At present, China has not yet issued ethical review and management requirements related to health care big data, which means that the current ethical actual review work in China is lack of feasibility. Further, China's current review standards and review procedures related to health care big data need to be improved urgently.

2. Health Care Big Data

The so-called health care big data (as illustrated in Fig. 1), as the name suggests, is a data resource that stores a large amount of health care information [1]. Therefore, health care big data is a huge information asset, which covers the physiological and psychological data of all citizens, involving the national public health field, medical service industry, medical security, drug supply planning, family planning policy, etc.

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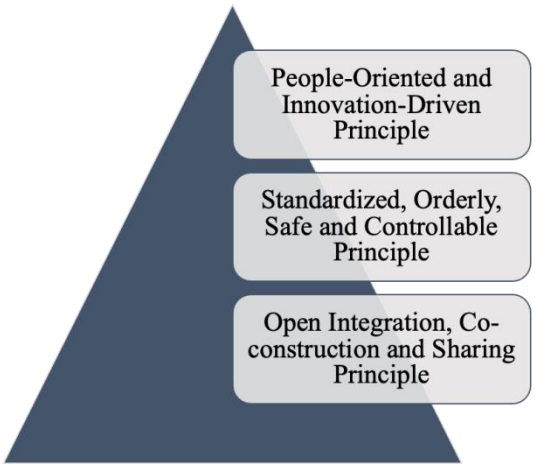

Fig. 1 Three principles of health big data

Big data, as its name implies, is characterized by "huge", which makes it difficult for conventional data processing means to collect, analyze, process and store it. Health care big data belongs to big data [2]. It also has the same attributes and characteristics as big data (as shown in Fig. 2), but it also contains its own characteristics. It has high privacy, which is also determined by the sensitive information such as genes, health and diseases involved in health care.

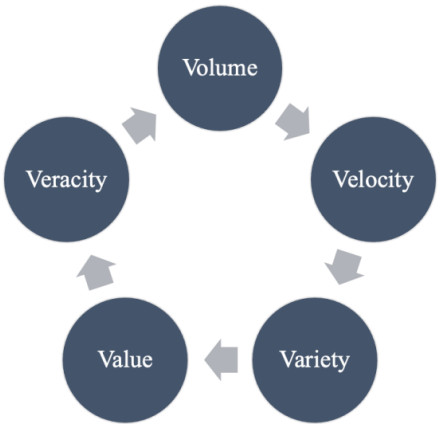

Fig. 2 Characteristics of big data

In the past, the traditional recording method of health and medical data was manual recording, but different medical institutions used case books and information management systems with different word standards, resulting in some deviation and deformity in data recording. With the emergence of big data, the common begin to use big data technology to collect, manage and store huge data information [3]. The common can not only efficiently obtain the required information resources, but also analyze and study the data information in time, modify and adjust it at any time, and realize data sharing between industries. Fig. 3 demonstrates two mainstream storage methods of health care big data.

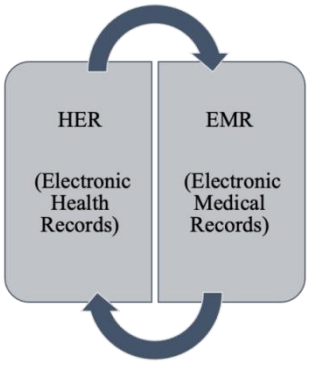

Fig. 3 Two mainstream storage methods of health care big data

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3. Difficulties in Ethical Review Based on Health Care Big Data

Different from ordinary data, health care big data involves national health information and is related to the common's personal privacy. Its ethical review has certain difficulties, mainly reflected in the insufficient perfection of laws and regulations, the unclear ethical governance principles, and the traditional review model no longer meets the current social background and social needs.

3.1 Imperfect Relevant Laws and Regulations

At present, many Internet companies in China have noticed the importance of health care big data and have launched relevant service platforms, as demonstrated in Fig. 4.

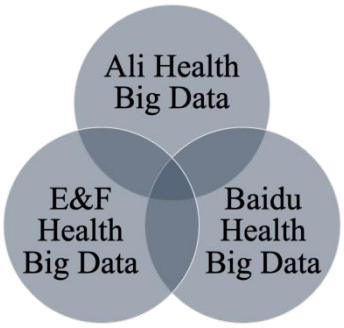

Fig. 4 Health care big data service platform

However, most of the laws and regulations on medical and health big data in China belong to basic and principled terms. These conditions can only play a basic role in the protection of national personal medical and health data, but can not meet the current higher requirements of the public for personal privacy protection. Moreover, the operability of these laws and regulations is low, In addition, some members of the public have weak awareness of personal privacy protection, which also makes it difficult to implement measures related to medical and health big data in many places. This paper believes that China should study and formulate laws and regulations such as ethics code of health care big data as soon as possible to standardize the research and application of big data.

3.2 Unclear Ethical Governance Principles

Health care big data covers a wide range of data information, including cloud computing technology, machine learning technology, artificial intelligence technology and other most popular and advanced science and technology [4]. It also includes the common's physiological data and psychological data. Therefore, many folks regard the collection and utilization of health care big data as a scourge and believe that this practice is suspected of violating personal privacy. In recent years, there are still disputes in academic circles and medical circles about the principles related to the collection and utilization of health care big data.

Compared with ordinary types of big data, the information contained in health care big data involves more personal privacy issues, and the ethical governance problems caused by it also bring us profound reflection [5]. The reason behind the ethical anomie caused by health care big data is that people rely too much on and blindly trust data information, so they gradually lose the ability to control data information and even become slaves of data information. Therefore, this paper believes that the ethical governance principles of medical and health big data should include humanitarianism, unified norms, fairness and so on.

3.3 Obsolete Traditional Review Mode

Different from the collection and processing of ordinary data, the data of health care big data mainly comes from human physiological data and psychological data. The study of health care big data is a research process taking human beings as the research object. Health care big data from human beings is huge data information, which contains all kinds of data in three-dimensional space. This volume of data information is difficult to collect and manage by conventional software means. We should also realize that there is more than one responsible subject involved in the generation, collection and utilization of data. Generally speaking, these responsible subjects are likely to come from different departments,

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medical institutions, even different departments or industries, and even different regions and countries.

In the past, medical research was mostly carried out by medical institutions, and it was easier and clearer to divide the responsibilities of researchers. However, with the development of science and technology and the generation of health care big data, relevant medical staff and researchers rely more on Internet platforms and relevant technical means. Even many medical staff and researchers have to turn to professional data analysis talents who master algorithms and science and technology due to their limited proficiency in information technology means. These phenomena show that the traditional review model has been difficult to continue, and the difficulty of clarifying the responsibility distribution of each personnel has increased sharply.

4. Key Points of Ethical Review Based on Health Care Big Data

4.1 Research Risk Return Ratio

Evaluating the rationality of the risk degree suffered by the collection and utilization of health care big data compared with its income degree, that is, the risk income ratio of health care big data is a necessary prerequisite for accurately evaluating whether the collection and utilization of health care big data can be carried out [6]. Obviously, if the risk level of collecting and using health care big data is higher than the income level, this work can not be carried out; This work can be carried out if the risk level of collecting and using health care big data is lower than the income level.

In the specific practice of health care data collection and utilization, ethics reviewers should also judge the confidentiality and sensitivity of health care big data and confirm the legitimacy of data sources. At the same time, ethics reviewers should also conduct strict evaluation according to the purpose of collecting and utilizing health care big data.

In the process of data collection and use, relevant personnel shall follow the principle of minimum necessity. If not necessary, relevant personnel shall collect and use sensitive data information as little as possible to avoid the leakage of personal privacy and the inconsistency between data collection and data subject authorization. At the same time, the collection and use of health care big data should be in the national and social interests, and should ensure that it will not bring risks exceeding the minimum risk value to the data subject, so that the data collection and use can obtain ethical defense.

4.2 Informed Consent Procedure

For the huge amount of health care data, the traditional informed consent procedure has been disconnected from social development, and it is difficult to deal with the characteristics of data collection and use in the era of big data. According to the characteristics of the big data era, this paper believes that the ethics review committee should judge whether to adopt specific informed consent, extensive informed consent or exemption from informed consent based on the data collection methods, confidentiality, sensitivity, purpose of collecting and using data, social value and difficulty of obtaining informed consent.

4.3 Privacy Protection Measures

On the one hand, the ethics review committee should carefully review the personnel qualification, infrastructure, science and technology involved in the collection and utilization of health care big data, and require relevant personnel to take reasonable and scientific methods to reduce the risk of data disclosure as much as possible [7]. In addition, the ethics review committee shall comprehensively analyze and evaluate the background of the personnel who can access the data, the security of information and data, the signing of confidentiality agreements, and conduct classified and hierarchical approval and management of different types of relevant personnel, so as to clarify the subject responsible for data security. Once the illegal use of health care big data occurs, the ethics review committee can directly hold individuals accountable.

On the other hand, health care big data involves not only various data processing processes, but also various carrier media, such as servers, storage devices, modified devices, etc. Therefore, the privacy protection measures for health care big data must be implemented into all workflow and all carrier media to ensure that the measures to protect the privacy of data subjects are truly implemented.

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5. Conclusion

Through the research and analysis of China's current domestic laws and regulations related to health care big data, this paper believes that China's relevant laws and regulations need to be improved, the ethical governance principles are not clear, and the traditional review mode is divorced from the current social development. These three are the main ethical review difficulties of health care big data.

Based on this, this paper emphasizes that in addition to the need to upgrade and adjust the traditional ethical review model that has been divorced from the current social development, we must also focus on the informed consent procedure and personal privacy protection.

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