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Ethical Issues in Personalized Medicine: Privacy, Consent, and Data Sharing

Wei Wang
Institute of Life Science, Jiyang College of Zhejiang A&F University, Zhuji, 311800, China
Corresponding author email: 874202228@qq.com

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Abstract This study explores the ethical issues involved in personalized medicine, focusing primarily on privacy, consent, and data sharing. First, the background and importance of the development of personalized medicine are introduced, followed by a detailed analysis of the ethical challenges in this field, including privacy, consent, and data sharing. Regarding consent issues, the article discusses the definition and requirements of informed consent, obstacles and challenges in the consent process, and future-oriented consent models. In terms of data sharing, it focuses on the benefits and risks of sharing data, anonymization and de-identification in shared data, data ownership and control, and ethical considerations for international data sharing. Finally, the importance of addressing ethical issues in personalized medicine is emphasized, and future research directions and suggestions are proposed. By comprehensively analyzing ethical issues in personalized medicine, this article aims to provoke deep thinking about medical ethics, promote the standardization and legitimacy of medical practice, and ensure the effective protection of patient rights and public interests.

Keywords Personalized medicine; Ethical issues; Privacy; Consent; Data sharing

Personalized medicine, also known as precision medicine, is a medical model that provides patients with customized treatment plans based on individual genetic information, lifestyle and environmental factors. With the rapid development of science and technology and the deepening of medical research, personalized medicine has been widely concerned and applied in recent years. However, the rapid development of this emerging field also brings with it a host of ethical challenges, including questions about privacy protection, informed consent, and data sharing. The core idea of personalized medicine is to customize the medical process to achieve better treatment outcomes and patient satisfaction. It relies on an individual's genomic information, lifestyle, and environmental factors to develop targeted treatment regimens that improve the accuracy and effectiveness of treatment (Dove, 2017). The emergence of this model has revolutionized the treatment of many diseases, especially for those patients whose traditional treatment methods have not been effective, personalized medicine offers them new hope.

With the rapid development of genomics, biotechnology and information technology, the research and application of personalized medicine have made remarkable progress. Through the analysis of individual genomes and biomarkers, doctors are able to more accurately understand patients' disease characteristics and drug responses, so that they can develop personalized treatment plans for them. This kind of accurate treatment can not only improve the effect of treatment and the quality of life of patients, but also contribute to the reasonable allocation of medical resources and the control of medical costs. The development of personalized medicine also raises a series of ethical challenges. First of all, the issue of privacy protection has become an urgent problem to be solved. In personalized medicine, sensitive information such as a patient's genomic information, lifestyle and environmental factors is widely used in the diagnosis and treatment of diseases. The disclosure of this information may cause a violation of patient privacy and even lead to discrimination and prejudice. Therefore, the protection and management of patient information must be strengthened to ensure that it is not abused and leaked (Budin-Ljøsne and Harris, 2016).

Informed consent is also an important aspect to be paid attention to in the development of personalized medicine. When conducting personalized medicine treatment and research, doctors need to fully explain to patients the purpose of treatment, risks, expected effects and other information, and obtain the explicit consent of patients. This helps to protect patients' right to know and autonomy and avoid unnecessary harm. Data sharing is also one of the important ethical issues to be addressed in the development of personalized medicine (Jain, 2009). In personalized medicine, large amounts of genomic and clinical data need to be shared and integrated for better research and application. However, data sharing also faces risks from privacy breaches and intellectual property rights. Therefore, it is necessary to establish a reasonable data sharing mechanism and management system to ensure the security and legitimacy of data. As a new medical model, personalized medicine brings great hope, but also faces ethical challenges. In order to ensure the sustainable development of personalized medicine and the protection of patients' rights and interests, we need to strengthen the research and discussion of ethical issues, formulate reasonable ethical norms and management systems, and promote the progress of medical technology and the rights and privacy of patients to be fully balanced and protected.

1 Ethical Challenges of Personalized Medicine

1.1 Concept and importance of privacy

Joly et al. (2014) believe that personalized medicine is an emerging medical model, which provides personalized diagnosis and treatment plans for patients by using information such as genes, physiological characteristics and medical history. However, this model also brings a number of ethical challenges, the most critical of which is the protection of privacy. Privacy refers to an individual's autonomous control over his or her personal information and living space. In personalized medicine, the widespread use of personal sensitive information such as patient genetic data and health records directly relates to the importance of privacy.

Cordeiro (2014) pointed out that such information is highly private, and once leaked, it may cause great distress to patients' lives and even have negative psychological effects. Therefore, protecting patients' right to privacy is not only a legal obligation, but also a basic principle for safeguarding individual dignity and rights. In China, the right to privacy is regarded as a basic human right of citizens and is protected by law. China's Constitution clearly stipulates that citizens' personal dignity is inviolable and their human rights, including the right to privacy, are fully protected. With the development of personalized medicine, privacy protection measures must be continuously strengthened to ensure that patients' right to privacy is fully protected while promoting medical progress.

1.2 Principles and practices of consent

As one of the core of medical ethics, the principle of consent emphasizes that patients should be fully informed in the process of medical diagnosis and treatment. This requires medical staff to obtain the explicit consent of the patient before carrying out any medical activity. However, in the era of personalized medicine, the complexity of genetic data and biological information has led to significant differences in patients' understanding of and informed consent to personal information. Therefore, how to ensure the informed consent of patients in personalized medicine has become an important challenge in the field of medical ethics.

Stoekle et al. (2017) mentioned that in facing this challenge, healthcare institutions and healthcare professionals should take a number of measures to ensure that patients are fully aware of their genetic data and biological information. Strengthen patient education to increase patient awareness of genetic testing and personalized therapy so that patients can understand the relevant technologies and their possible benefits and risks. Healthcare professionals need to fully communicate with patients and explain genetic test results and their impact on treatment options in detail to ensure that patients are making informed decisions. In addition, establish and improve the patient consent system, requiring patients to sign consent after clearly understanding the relevant situation, to confirm that patients have fully understood and agreed to receive personalized treatment.

In China, the health authorities should also strengthen the supervision of medical institutions and medical personnel to ensure that the principle of informed consent is implemented in personalized medicine practice. At

the same time, through the formulation of relevant policies and regulations, strengthen the protection of patients' rights and interests, and improve the status of patients in medical decision-making. In addition, increase the investment in medical ethics education, improve the importance of the principle of informed consent of medical staff, so that they can better respect and protect patients' right to know and autonomy in clinical practice.

1.3 Status quo and challenges of data sharing

Dyke et al. (2016) believe that personalized medicine, as an important development direction of modern medicine, relies on the support of large amounts of high-quality data, among which data sharing plays a crucial role in promoting the rapid development of medical scientific research and technological innovation. However, the data involved in personalized medicine often contains personal and private information of patients, which makes data sharing while protecting patient privacy an urgent problem.

Scheibner et al. (2020) proposed. In the field of personalized medicine, the status quo of data sharing faces multiple challenges. On the one hand, due to the concern that the disclosure of patient privacy may cause legal disputes, medical institutions, scientific research institutions and enterprises have concerns in data sharing, which may affect their own reputation and interests. On the other hand, due to the lack of unified technical standards and norms, the existing data sharing mechanism is imperfect, increasing the difficulty of data sharing implementation.

Lawler and Maughan (2017) believe that in order to solve these problems, it is first necessary to establish a sound data sharing mechanism and formulate unified technical standards and specifications to reduce the difficulty of implementing data sharing. Strengthen cross-border cooperation, fully communicate and coordinate legal, ethical and cultural issues in data sharing among countries, and create favorable conditions for data sharing. Finally, strengthen the protection of patient privacy through encryption, desensitization and other technical means to ensure that patient privacy is not infringed.

1.4 Special ethical considerations in personalized medicine

The uncertainty of genetic data is a major ethical challenge in personalized medicine. Genetic testing and analysis largely influence patient diagnosis and treatment options, however, the uncertainty of genetic data can lead to misunderstandings and misdirection in the decision-making process for doctors and patients. Therefore, when using genetic data, medical personnel should be fully aware of its uncertainty and take a cautious attitude to ensure that patients will not suffer unnecessary harm because of the uncertainty of genetic data while enjoying the advantages brought by personalized medicine.

Brothers and Rothstein (2015) propose that the impact of a patient's genetic information on family members is also an ethical issue that needs attention in the field of personalized medicine. In the process of diagnosis and treatment of genetic diseases, family members of patients may be affected to some extent. Medical personnel have the responsibility to ensure that the privacy and right to know of the patient's family members are fully guaranteed, and at the same time, in the process of screening, prevention and diagnosis of family genetic diseases, respect the wishes of family members, and avoid inadvertently causing conflicts and disputes within the family.

Chen and Xiao (2005) suggest that new technologies and approaches involved in personalized medicine may present unexpected ethical challenges. For example, the application of gene editing technology in the treatment of genetic diseases not only involves ethical issues, but also involves legal, social and many other aspects. Therefore, when researching and applying new technologies, medical personnel and researchers should make timely ethical assessments to ensure that the technology is legal, compliant and ethical, and formulate corresponding ethical guidelines and norms to deal with possible ethical problems.

With the development of personalized medicine, the distribution and equity of medical resources have become increasingly prominent. Medical professionals and researchers should focus on social equity to ensure that medical resources benefit patients and avoid inequities caused by unequal distribution of resources. Information security and privacy protection in personalized medicine can not be ignored. In the process of genetic testing and data analysis, the information security and privacy of patients should be fully guaranteed, and medical personnel

and researchers should strictly abide by relevant laws and regulations to ensure that the security and privacy of patient information are not infringed.

2 Case Studies

2.1 Analysis of classic cases

In the field of personalized medicine, a classic case is the gene sequencing analysis conducted by American doctor Adams on a group of families with familial hypercholesterolemia. Familial hypercholesterolemia is a genetic disorder in which cholesterol levels in the body are abnormally elevated, leading to a greatly increased risk of cardiovascular disease. In the past, the treatment of such diseases mainly relied on medication and lifestyle adjustments, but the effect was limited. Through gene sequencing technology, Dr. Adams found the genetic genes of these patients with hypercholesterolemia, thus providing them with a more personalized treatment plan (Yue et al., 2016). This initiative has greatly improved the treatment effect of patients and delayed the progression of the disease.

However, Dr Adams's action also raises a number of ethical questions. Patient privacy issues involved in the gene sequencing process. Genetic data is a patient's personal information and may be used for other purposes, such as commercial development, insurance claims, etc. This can lead to the disclosure of patient privacy and unnecessary distress to patients and their families. The issue of patient consent, whether Dr. Adams obtained the patient's fully informed consent before performing gene sequencing, and whether the patient fully understood the possible consequences of gene sequencing, such as the diagnosis of genetic diseases and psychological pressure on family members, are all ethical issues worthy of discussion (Yuan, 2021). In the field of personalized medicine, the ethical issues of gene sequencing cases require extensive attention. While promoting the development of gene sequencing technology, we should pay attention to the solution of ethical issues to ensure that the rights and interests of patients are fully protected.

2.2 Application of ethical decision-making framework

Take the case of Dr. Adams as an example to elaborate on the application of this framework in personalized medicine. The principle of respect for the individual is of great significance in personalized medicine. This principle emphasizes respect for the rights and autonomy of patients, especially in the face of complex, high-risk treatment protocols. In Dr. Adams's case, the principle of respect for the individual requires that the physician fully understand the patient's family background, values, and lifestyle in order to provide more personalized medical care to the patient. At the same time, doctors also need to ensure that patients enjoy full information and decision-making rights in the decision-making process, so as to ensure that the interests of patients are protected to the greatest extent.

Research by Zeng and Qiu (2018) suggests that the principle of good faith is also a core component of ethical decision-making frameworks. In personalized medicine, doctors need to act in the best interests of patients, and fully exercise professional and ethical responsibility. Dr. Adams should consider the actual needs of the patient when formulating the treatment plan, and strive to achieve the best balance between efficacy, side effects and cost. In addition, doctors also need to maintain good communication with patients in order to adjust the program in time during the treatment process to ensure that patients get the best treatment results. Moreover, the principle of impartiality is equally important in personalized medicine. This principle requires doctors to equitably provide appropriate care to each patient with limited resources.

The principle of non-harm is the basic requirement of ethical decision-making framework. Hou (2003) believed that in personalized medicine, doctors should try to avoid unnecessary harm to patients in the process of diagnosis and treatment. When developing and implementing a treatment plan, Dr. Adams should fully assess the risks of treatment and strive to minimize side effects. At the same time, doctors also need to pay close attention to changes in the patient's condition, timely detection and treatment of possible injuries. By respecting patient privacy, ensuring informed consent, acting in the best interests of patients, allocating medical resources fairly, and minimizing harm, physicians can better address the ethical challenges posed by personalized medicine. In practice,

doctors need to flexibly apply this framework according to individual differences and specific circumstances of patients to provide high-quality, personalized medical services for patients.

2.3 Ethical considerations in policy and practice

El-Alti et al. (2019) proposed that in order to guarantee the healthy development of personalized medicine, a sound legal and regulatory system should be established to clarify the principles of the use and protection of individual genetic data. These regulations should cover all aspects of data acquisition, processing, storage, transmission, etc., and ensure that medical personnel and researchers follow ethical norms in the use of data. In addition, it is also necessary to strengthen the punishment of illegal acts and maintain industry order.

Sleigh et al. (2020) propose that medical institutions and research institutions have a responsibility to ensure ethical compliance when carrying out personalized medicine projects. To this end, each unit should set up an ethics committee or a special ethics review body, responsible for reviewing the ethical compliance of relevant projects. These bodies should have the authority, independence and professionalism to ensure that their audit results are fair and equitable. At the same time, ethical review bodies need to pay attention to patient rights and privacy protection to ensure that patients are fully informed and consent when participating in personalized medicine projects.

Shaw et al. (2016) proposed. Strengthening ethics education and training is essential for medical personnel and researchers to carry out personalized medicine projects to raise their ethical awareness. At the same time, the academic community and the industry are encouraged to carry out ethical exchanges and cooperation, and jointly explore and practice the ethical issues of personalized medicine. Regulatory authorities should strengthen supervision in the field of personalized medicine to ensure that relevant laws and ethics are effectively enforced. At the same time, the public should be encouraged to participate in supervision and jointly maintain the ethical order in the field of personalized medicine.

3 The Concrete Embodiment of Privacy Issues in Personalized Medicine

3.1 Collection and use of patient data

In personalized medicine, the importance of patient data is self-evident. Genomic data can help doctors understand an individual's genetic characteristics, physiological data can reveal a patient’s physiological state, and medical records can provide valuable clues for diagnosis and treatment. The collection and analysis of these data aims to provide patients with more accurate and personalized medical services. However, in the process of data collection and use, the protection of patients’ privacy has become an urgent problem to be solved.

Cordeiro (2014) proposed that in the practice of personalized medicine, patients may lack a full understanding of the purpose and consequences of the use of their personal data, resulting in insufficient informed consent. This may result from a failure by healthcare professionals to adequately inform patients at the time of data collection about the purposes for which the data will be used, the risks, and the possible consequences. Informed consent is the basic premise of protecting patients’ privacy. If patients lack understanding of data use, their privacy rights and interests will be difficult to be protected. Personalized medicine involves the sharing of data between multiple medical institutions and research teams to enable broader research and clinical applications. However, during this process, patient data may be transferred and used multiple times, increasing the risk of privacy breaches. How to ensure that patient privacy is fully protected in the process of data sharing has become an important issue in the field of personalized medicine (Figure 1).

Guan et al. (2017) proposed that relevant laws, regulations and policy systems should be further improved to ensure patient data privacy, and standards and norms for patient data collection, use, storage and sharing should be clarified. Strengthen the supervision of medical institutions and scientific research teams to ensure that they strictly abide by laws and regulations in the data processing process, and effectively protect the rights and interests of patients. At the data collection stage, medical institutions should fully inform patients of the purpose, risks and possible consequences of data use, and ensure that patients voluntarily consent to data collection and use on an informed basis. At the same time, a strict data access permission management system is established to ensure that

data is effectively protected during the sharing process. Medical institutions should strengthen the security of patient data to ensure that data is not illegally obtained and exploited during storage, transmission and processing.

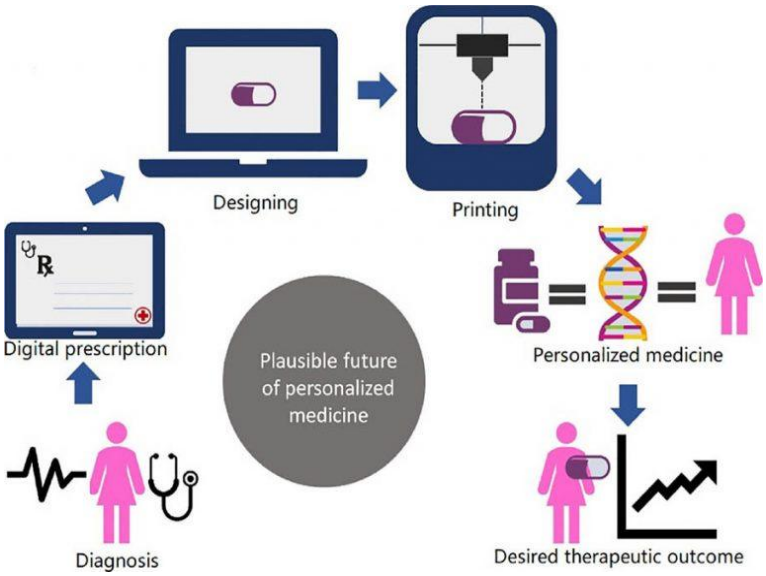

Figure 1 Data-transformation of information in personalized medicine

3.2 Data protection and risk of leakage

Scheibner (2020) proposes that with the rapid development of personalized medicine, the storage, transmission and processing of medical data are becoming more and more complex, and ensuring data security has become an urgent problem to be solved. Not only do we need to focus on the technical aspects, but also the ethical and legal aspects. Key measures at the technical level include data encryption, access control, auditing and monitoring, and security measures to ensure that even if data is stolen, it cannot be interpreted by unauthorized visitors, and only authorized users can access certain data.

Price and Cohen (2019) argue that protecting the security and privacy of medical data is critical from both ethical and legal perspectives. The disclosure of patients' personal data may lead to negative effects such as invasion of personal privacy, breach of trust, and legal liability. The compromised patient data may be used for improper purposes, such as commercial advertising, insurance discrimination, etc., causing distress to patients' lives; The failure of healthcare institutions and researchers to properly safeguard patient data, resulting in a loss of trust in healthcare institutions and researchers; Disclosure of patient data may violate relevant laws and regulations, such as the Cybersecurity Law, the Personal Information Protection Law, etc., and the relevant responsible parties need to bear legal responsibility. In order to ensure the healthy development of personalized medicine, comprehensive measures need to be taken to strengthen technical protection, but also pay attention to ethical and legal norms to protect patient data security and avoid potential risks and negative effects.

3.3 Sensitivity and personal privacy of medical information

The sensitivity of medical information and personal privacy are of great significance in personalized medicine. The personal characteristics of patients, such as medical history, genetic information, physiological parameters, once leaked or abused, may have a profound impact on the personal life and social status of patients. Medical information involves patients' health status, living habits, family history and other aspects, among which genetic information and physiological parameters are particularly important. Such information is highly specialized and individual, so it is particularly important to properly manage and protect medical information. Once this sensitive information is leaked, it may lead to a series of negative consequences.

Martinez-Martin et al. (2018) believe that what citizens need to pay attention to is the protection of personal privacy. In personalized medicine, the disclosure of private data such as patient genetic information and medical history can lead to discrimination and exclusion of patients. For example, certain genetic information may reveal

that the patient has a genetic disease or family genetic history, which may lead to unfair treatment of the patient in employment, insurance, marriage, etc. Therefore, protecting patients' privacy is of Paramount importance.

Zhang et al. (2023) proposed to strengthen professional ethics education for medical personnel, so that they fully realize the importance of protecting patients' medical information and personal privacy. At the same time, establish and improve the code of conduct and supervision system for medical personnel, and seriously deal with violations. Enhance patients' awareness of self-protection: Patients should understand their rights and interests in medical information and actively cooperate with medical institutions to protect personal information. In the process of consultation, examination, treatment, etc., patients have the right to ask medical personnel to keep personal information confidential and refuse to consult irrelevant personnel. Establish an open and transparent regulatory mechanism: strengthen the supervision of medical institutions and medical information to ensure that the use, sharing and disclosure of medical information meet the requirements of laws and regulations. At the same time, the public is encouraged to participate in supervision and jointly maintain the security of medical information.

3.4 Existing laws and regulations for privacy protection

Scheibner et al. (2020) believe that with the increasing attention paid to personalized medicine, this emerging medical model emphasizes the provision of accurate diagnosis and treatment plans based on individual genes, physiological characteristics, medical history and other information. However, an important issue in this process is the protection of patient privacy. In order to ensure that patient privacy is fully protected, many countries and regions have established corresponding laws, regulations and ethical guidelines. For example, the European Union's General Data Protection Regulation (GDPR) imposes strict requirements on the collection and processing of personal data, which includes principles such as data minimization, purpose limitation, transparency, and data security.

Appelbaum (2002) mentioned in his study that the Health Insurance Portability and Accountability Act (HIPAA) in the United States also put forward strict requirements on the protection and privacy security of medical information, stipulating the confidentiality obligation of medical institutions and their staff when handling patients' medical information. To ensure that patient privacy is not violated, these laws, regulations and ethical guidelines provide a strong legal basis and operational guidance for privacy protection in personalized medicine. However, with the development of technology and the increase of medical data, the task of privacy protection is still a long way to go. We need to recognize that in the face of changing realities, the improvement and enforcement of existing laws and rules need to be strengthened.

4 Agree on the Role of Issues in Personalized Medicine

4.1 Definition and requirements of information consent

Scheibner et al. (2020) proposed that personalized medicine has gradually become an important direction in the treatment of diseases in the field of modern medical treatment. This individual-centered treatment pays attention to the patient's genetic information, genetic test results and other factors, so as to provide patients with more accurate and effective treatment plans. However, in this process, the issue of information consent is particularly critical. Citizens need to understand the concept of informational consent. Information consent refers to the process in which patients have a full understanding of relevant treatment or research information before receiving medical services or participating in medical research, and make decisions independently on this basis. In personalized medicine, the importance of information consent is self-evident. This treatment involves sensitive data such as patients' genetic information and genetic test results, which are closely related to patients' life safety and privacy rights. Therefore, information consent plays an important role in personalized medicine.

The requirements for information consent mainly include the following points: medical personnel have the obligation to provide patients with detailed and clear treatment or research information, including the purpose, method, risks and benefits. In this way, patients can have a comprehensive understanding of this information to make informed decisions (Hall et al., 2012).

Respect for the patient's right to know: The core of information consent is to respect the patient's right to know, let the patient know the whole process of the treatment or research they will receive, so that the patient can understand and voluntarily participate. Medical personnel need to personalize communication and interpretation according to individual differences of patients to ensure that patients fully understand relevant information (Stoekle et al., 2017).

Privacy protection: During the information consent process, the medical staff is responsible for ensuring that the personal information provided by the patient is kept strictly confidential to prevent the disclosure of patient privacy. Dynamic consent: In the course of personalized medicine treatment or research, patients have the right to stay informed of new information and adjust their consent wishes based on new information. Healthcare professionals need to respect this right and provide patients with the necessary informed updates.

4.2 Obstacles and challenges in the consent process

del Carmen and Joffe (2005) pointed out in their study that in practice, the consent process is full of various obstacles and challenges. The techniques and methods involved in personalized medicine are highly complex, with many technical terms, and patients may struggle to fully understand the relevant information. This makes it difficult for patients to fully grasp the pros and cons of treatment when making decisions. Secondly, there may be information asymmetry between patients and medical staff. Medical professionals are often more inclined to emphasize the benefits of treatment or research while ignoring the potential risks. This can result in patients not being fully informed about the potential risks of treatment or research during the consent process.

The rapid development of personalized medicine and the constant emergence of new technologies and approaches can leave patients with insufficient time and resources to deliberate before receiving treatment or participating in research. Faced with numerous treatment options, patients may make decisions without full understanding, increasing potential risks (Scheibner et al., 2020).

To address these obstacles and challenges, the following measures are necessary: Strengthen doctor-patient communication: Medical staff should use plain language to explain relevant information about treatment options to patients, including pros and cons, risks, etc., and patiently listen to patients' concerns and needs.

Improve patients' right to know: Ensure that patients can obtain adequate, truthful and timely information during the consent process, improve patients' right to know, and enable patients to evaluate the advantages and disadvantages of treatment options more rationally.

Strengthen ethical review: Strengthen ethical review of medical research to ensure that research projects follow ethical principles, fully consider the interests of patients, and suggest improvements to protect the interests of patients (Moskop, 2006).

Establish a sound patient education system: Through patient education activities, improve patients' awareness of personalized medicine, help patients better understand relevant technologies and methods, and reduce decision-making risks.

Strengthen the formulation and implementation of policies and regulations: Government departments should formulate relevant laws and regulations to regulate the application and development of personalized medicine, and strengthen the supervision of medical institutions and medical personnel to ensure that they strictly abide by laws, regulations and ethical guidelines when carrying out personalized medicine services.

4.3 Future-oriented consent: continuous consent and dynamic consent

In the medical field and scientific research practice, the principle of consent is very important. It ensures that patients and study participants can fully understand and make their own choices when receiving treatment or participating in a study. However, traditional models of consent may struggle to meet demand in the face of complexity, uncertainty, and the passage of time in treatment and research. In order to solve this problem, some scholars put forward future-oriented consent models, including continuous consent and dynamic consent.

Moskop (2006) believes that in the medical process, patients often need to receive continuous treatment and management, which requires medical staff to maintain close communication and information update with patients. Medical professionals need to keep patients informed about the progress of treatment or research, as well as possible changes, so that patients can have a full understanding of treatment options. In this way, the patient's informed consent can continue to be effective, ensuring that they are always in control of the treatment process.

Kegley (2004) proposed that dynamic consent is a more flexible consent model. In the course of treatment or research, patients need to maintain continuous access to information and autonomous choice. This means that medical staff need to constantly communicate and consult with patients in order to understand the patient's wishes and actual situation. Based on this information, medical professionals can adjust treatment or research protocols to better match patients' needs and expectations. This dynamic model of consent helps ensure that patients' rights and interests are fully protected during treatment and research.

Future-oriented consent models, whether continuous consent or dynamic consent, are proposed in response to modern medical and scientific challenges. They emphasize communication and cooperation between medical staff and patients, making the treatment and research process more transparent and humane. Through these two consent models, it is hoped that patients can better exercise their autonomy in medical and scientific practice and obtain higher quality services and care.

4.4 Balance between consent and patient involvement

Scheibner et al. (2020) proposed that in the field of personalized medicine, the importance of balancing patient consent and participation is obvious. Consent is not only related to the patient's choice, but also related to the patient's participation and cooperation in the process of diagnosis and treatment. The active participation of patients is the key to the implementation of personalized medicine. Only when patients and medical personnel establish a good cooperative relationship and jointly develop appropriate treatment or research programs can the ideal curative effect be achieved.

Hall et al. (2012) argued that patients' right to choose freely is a basic human right and should be fully respected. In personalized medicine, patients have the right to understand their condition, treatment options and associated risks, and to make appropriate choices based on their needs and beliefs. Medical personnel have the obligation to provide patients with true, comprehensive and timely information to help patients make informed decisions). In this process, medical staff should fully communicate to ensure that patients understand the information provided and avoid misunderstandings and disputes caused by information asymmetry.

Bell's (2017) study argues that active patient participation is critical to the implementation of personalized medicine. The participation of patients in the diagnosis and treatment process can improve the pertinence and effectiveness of treatment and reduce medical risks. Health care professionals should encourage patients to ask questions, express needs and opinions, and incorporate patient feedback into treatment decisions. In addition, medical personnel also need to pay attention to the psychological needs of patients, provide necessary psychological support and rehabilitation guidance, and help patients actively face the disease. Building trust and cooperation between patients and medical staff is the key to the success of personalized medicine. Trust is the basis of good cooperation between the two sides. Medical staff should sincerely care for patients, respect patients' right to know and privacy, and win patients' trust with integrity and professionalism. On this basis, medical personnel also need to pay attention to the satisfaction of patients, constantly optimize diagnosis and treatment services, and provide patients with personalized and comprehensive medical services.

5 Ethical Issues of Data Sharing

5.1 Benefits and risks of data sharing

Chiruvella and Guddati (2021) believe that data sharing has great potential and value in the field of medical research, which can promote the progress of scientific research, accelerate the development of new drugs, optimize clinical practice, and improve the efficiency and quality of healthcare. With the development of electronic health records and big data, data sharing has become key to driving medical innovation and improving

patient care. By sharing rich genetic data, clinical data and bioinformatics data, researchers can conduct deeper data analysis to provide strong support for disease prevention and control.

Dyke et al. (2016) proposed that data sharing is also associated with risks in terms of data security and privacy protection. Protecting the security and privacy of patients' personal information during data sharing is an important challenge. How to ensure the security of data in the process of transmission, storage and use, to avoid the disclosure and abuse of patients' personal information, is a problem that must be faced and solved. Data sharing may also lead to the misuse of patients' personal information, affecting patients' privacy and rights. Therefore, while promoting data sharing, we must pay attention to and strengthen the protection of patient privacy. While data sharing provides important opportunities for medical research and patient care, it is also necessary to maximize the benefits of data sharing and minimize potential risks through the development of reasonable data sharing principles and practices based on the protection of data security and patient privacy.

5.2 Anonymization and de-identification in shared data

Watson and Payne (2020) argue that the sharing of medical data has become an important means to drive medical research and development. However, this also raises a host of questions about patient privacy and the security of personal information. In order to balance the need for data sharing with the duty of privacy protection, the approach of anonymization and de-identification has become a common solution. Anonymization, as a data processing technique, mainly through the deletion or replacement of personally identifiable information, so that the data can not be directly associated with a specific individual. This way, even if the data is compromised, it cannot be traced back to a specific individual. However, anonymity is not foolproof. In fact, through technological means, it is still possible for attackers to re-identify and correlate data, thereby violating patient privacy.

Chiruvella and Guddati (2021) propose that de-identification is another data processing method, which makes the data lose the characteristics of specific individuals by blurring or transforming the personally identifiable information, thus reducing the identification risk. Compared with anonymization, de-identification can ensure the security of data. However, a high degree of de-identification may affect the availability of data and reduce its application value in medical research. In order to protect the security and privacy of patients' personal information, data sharing needs to take a series of technical and management measures based on comprehensive consideration of the degree of anonymity and security of data. This includes:

Strengthen the technical research of data anonymization, continuously improve the degree of anonymization, and reduce the identification risk. For example, encryption algorithms, differential privacy and other technologies are used to increase the difficulty of the attacker's re-identification.

Improve data security management system and control data quality from the source. Before sharing data, healthcare organizations and data holders should conduct rigorous security reviews to ensure that the data meets the requirements for de-identification.

Formulate and implement relevant data usage regulations and laws and regulations to clarify the responsibilities and obligations of data users. When using patient data, data users are committed to complying with relevant regulations to ensure data security.

Raise public awareness of data sharing and privacy protection, and enhance awareness of personal information protection. Through publicity, education, case warning and other means, let more people understand the risks of data sharing and improve their self-prevention ability.

Establish an emergency mechanism for data security incidents to timely respond to and deal with possible privacy disclosure incidents. Once safety hazards are found, relevant departments should take timely measures to reduce losses.

5.3 Data ownership and control

Ivanova et al. (2020) argue that in today's digital age, data has become a valuable resource. In the medical field in particular, patients, as data generators, have the right to decide how their personal information is used and shared. However, in practice, the ownership and control of data is often held by medical institutions, research institutions or pharmaceutical companies, which results in patients losing control of their personal information to a large extent, increasing the risk of misuse of personal information.

Data ownership refers to the rights and interests generated by data, including the right to use data, the right to profit and the right to dispose of data. Data control refers to the right to manage, use and process data. In the process of data sharing, the protection of patients' data ownership and control is conducive to safeguarding patients' legitimate rights and interests and preventing their personal information from being abused without authorization (Bowen-Ziecheck and Bartlett, 2019; Mirchev and Kerekovska, 2020).

To solve this problem, it is necessary to build a fair and transparent data ownership and control management mechanism. Specific measures are as follows:

Strengthen the construction of laws and regulations: improve the relevant laws and regulations on data protection, clarify the specific content of the ownership and control of patient data, and ensure that the legitimate rights and interests of patients in the process of data sharing are protected.

Improve the transparency of data sharing: medical institutions, research institutions or pharmaceutical companies are required to fully disclose relevant information to patients before data sharing, including the purpose, scope and duration of data use, so that patients clearly understand how their personal information is used and shared.

Establish a patient authorization mechanism: Patients should explicitly authorize the relevant authorities to use and process their personal information after fully understanding the sharing of data. This helps ensure that patients always maintain control during the data sharing process.

Strengthen supervision and enforcement: Relevant authorities should strengthen supervision of the data sharing process to ensure that laws and regulations are effectively enforced. At the same time, the illegal collection, use and disclosure of patients' personal information should be severely cracked down on to effectively protect patients' rights and interests (Mircheva & Mirchev, 2020).

Improve patient data literacy: Improve patient awareness of data ownership and control through the popularization of data protection knowledge, so that they can protect themselves during data sharing.

5.4 Ethical considerations for international data sharing

Personalized medicine has gradually become an important development trend in the future medical field, and international data sharing and cooperation have become an indispensable driving force. However, in practice, international data sharing faces a number of ethical challenges. This article will explore these issues from an ethical perspective and propose corresponding solutions to promote the healthy development of personalized medicine worldwide. Legal, ethical and cultural differences in different countries or regions make data sharing subject to a lack of compliance and transparency. In the process of data sharing, how to ensure that all participants follow consistent ethical standards and legal provisions has become the first problem to be solved in international data sharing. In the process of international data sharing, the risk of data use and abuse cannot be ignored. On the one hand, researchers may use the shared data for misconduct, such as privacy invasion, trade secret disclosure, etc. On the other hand, data sharing can also lead to inequities, such as the disadvantage of developing countries in terms of data resources.

Kalkman et al. (2019) argue that a fair and transparent data sharing mechanism is necessary to address ethical challenges in international data sharing. This mechanism should fully respect the legal and ethical provisions of each country or region to ensure compliance and transparency in data sharing. At the same time, through the development of internationally accepted data sharing norms and guidelines, to promote communication and

collaboration among countries. International data sharing requires the joint efforts of all countries to strengthen international cooperation and communication. Through regular international conferences and seminars, experts from different countries will be encouraged to conduct in-depth discussions and reach consensus on the ethical issues of data sharing. In addition, international coalitions or organizations can be established to promote cooperation and exchange among countries on data sharing.

Dyke et al. (2016) proposed that to address these challenges, it is essential to establish a fair and transparent international data sharing mechanism. The mechanism should fully respect national or regional legal and ethical regulations to ensure compliance and transparency in data sharing. At the same time, promoting communication and collaboration among countries through the development and implementation of internationally accepted data sharing norms and guidelines is the key to achieving the healthy development of global personalized medicine. In addition, to prevent data abuse and protect data privacy, international data sharing should adopt strict security measures, such as data encryption, background checks, and regular audits. In order to eliminate inequities, it is recommended that all countries actively participate in and support data resource sharing, promote the fair distribution and use of data on a global scale through the establishment of an international data resource sharing platform, and provide technical and personnel training support to developing countries to narrow the data resource gap.

6 Conclusion and Prospect

The development of personalized medicine cannot be separated from serious consideration and solution of ethical issues. Ethical issues such as privacy, consent and data sharing are directly related to the rights and interests of patients and the public interest of society, and must be fully valued and dealt with. Protecting patients' privacy rights, respecting patients' informed consent, and ensuring the security and legality of data sharing are fundamental principles and ethical requirements of personalized medicine practice. Only by formulating sound ethical policies and regulations, strengthening doctor-patient communication and cooperation, and promoting technological and institutional innovation can ethical issues in personalized medicine be effectively addressed and the norms and legitimacy of medical practice be promoted (Sharrer, 2017).

Yurkiewicz (2010) proposed that in order to ensure the sensitivity of medical information and the full protection of personal privacy in personalized medicine, the following measures can be taken: improve relevant laws and regulations, establish a strict legal system, and clarify the standards and responsibilities for the use, storage and transmission of medical information. At the same time, the penalties for leaking and abusing medical information will be intensified to ensure that illegal acts pay a price. Strengthen the protection of technical means, and use advanced data encryption, desensitization, firewall and other technologies to provide multi-level and multi-angle security protection for medical information to ensure that information is not leaked in the process of transmission, storage, and use.

Kettner (2014) believes that ethical issues in personalized medicine not only affect current medical practice and scientific research activities, but also may have a long-term impact on future medical development and social progress. If the ethical problem is not solved effectively, it may lead to serious consequences such as infringement of patients' right to privacy, increase of moral hazard in medical research, and damage of doctor-patient trust. Therefore, positive measures and policies must be taken to strengthen the supervision and management of the ethical issues of personalized medicine, ensure the legitimacy and morality of medical research and practice, and safeguard the rights and interests of patients and the public interest of society. At the same time, it is necessary to further study ethical issues in personalized medicine in the future, explore more effective solutions and policy measures, strengthen theoretical research on ethical issues and the formulation of ethical regulations, establish a sound ethical framework and guidelines, and provide norms and guidance for medical research and practice.

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