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Legal Framework for Security of Organ Transplant Information in the Digital Age with Biotechnology

Qinghui Wan [1*], Xiaowei Hu [2*]

[1*] Ph.D. Candidate, Department of Law and Administration, International College, Krirk University, Bangkok, Thailand. E-mail: w59066198@163.com

[2*] Professor, Law and Administration, International College, Krirk University, Bangkok, Thailand. E-mail: zscqfxyj@163.com

Abstract

In the context of the digital age, organ transplantation, as a life-saving technology, has become increasingly prominent in its information security. This paper aims to explore and construct a legal framework for organ transplant information security that meets the requirements of the digital age. First, the article outlines the legal background of organ transplantation and its new challenges in the digital age, emphasizing the centrality of information security in the organ transplantation process. The article then elaborates on the legal definitions and classifications of organs and discusses how digital technologies are changing these definitions and classifications. In the same way, the study of how people think about organ donation and transplantation used non-parametric tests, analysis of variance, and logistic regression to determine how people think about these things differently in different groups. Dichotomous logistic regression models were also created. This paper examines the current legal frameworks that protect organ transplant information in the digital age. The focus is on how biotechnology is linked to data privacy, security measures, and ethical concerns. This shows the importance of a complete regulatory framework to protect individuals' health information about organ transplants. This paper's research goal is to make a stronger legal guarantee for organ transplant information security. This will help organ transplantation technology grow healthily, protect the rights and interests of donors and recipients, and keep people's sense of dignity.

Keywords:

The digital age, organ transplantation, information security, legal framework, biotechnology.

Corresponding Author: Qinghui Wan, E-mail: w59066198@163.com

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Introduction

Organ transplantation (Han, 2023), as an essential medical technique and method, has brought hope of rebirth to countless patients (Zambudio, 2023). However, in the digital age, with the rapid development and widespread application of information technology (Nancy, 2023), organ transplantation faces new challenges and risks, including information security. Ensuring the security and reliability of organ transplant information (Xiaoling et al., 2022) involves protecting patients' personal privacy rights and interests and directly affects the normal operation and sustainable development of the entire medical industry. At the legal level, countries have enacted laws and regulations to ensure organ transplantation's legality, ethics, and fairness (Wright & De la Rosa, 2022). For example, many countries have implemented laws and regulations such as the Poverty Alleviation and Prosperity Law to prohibit the sale of organs in the market and crack down on illegal activities such as illegal organ trade and human organ trafficking. In addition, many countries have established organ donation and transplantation management agencies to ensure transparency and fairness in organ donation and transplantation.

With the advent of the digital age (Ietto-Gillies & Trentini, 2023), the field of organ transplantation is also facing a new set of challenges. The widespread application of digital medical technology has made storing, transmitting, and sharing organ transplant information easier. Still, it has also increased the risk of information leakage and hacker attacks. In addition, big data analytics and artificial intelligence (AI), part of the digital age, have brought more organ matching and transplantation possibilities. Still, they have also brought challenges regarding privacy protection and ethical prudence.

Therefore, it has become an urgent issue to establish a legal framework to ensure the security of organ transplant information in the digital age (Abid et al., 2022). From the perspective of law and organ transplantation, this paper analyzes the challenges the existing legal framework faces in the digital age. It proposes corresponding legal solutions to provide useful references and guidance for ensuring the security of organ transplant information (Bossen & Bertelsen, 2023).

Digital Medicalization

In recent years, with the development of science and technology, medicine has gradually entered the digital era. The proposal of digital medicine has also aroused more and more people's interest, and its importance has been increasingly widely discussed by society (Junbok et al., 2023). Professor Fu Zheng elaborated on the connotation of digital medicine: "The connotation is the application and combination of digital technology in various disciplines and specialties in the entire medical field (Ruokolainen et al., 2023). The scope includes digital medical engineering, digital medical technology, digital essential medicine, digital hospital construction,

digital health management, and many others. The fields involved in big data in the digital era are shown in Figure 1.

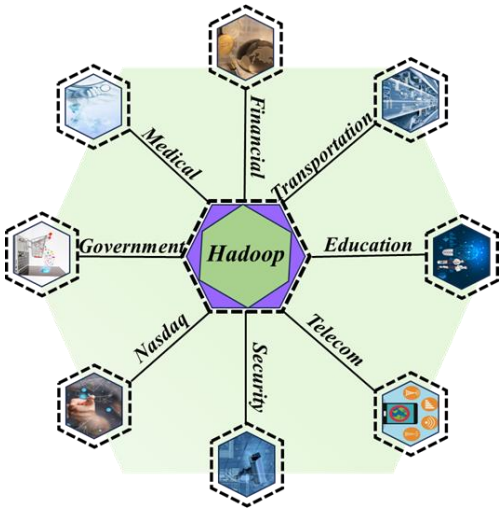

Figure 1. Areas covered by big data in the digital age

The connotation of digital medicine is based on digital technology (Cingolani et al., 2023), information technology, and communication technology and penetrates all disciplines in the field of primary medicine, clinical medicine, preventive medicine, rehabilitation medicine, and other medical fields in an all-round way (Khandelwal et al., 2022; Sunder-Plassmann et al., 2023) and radiates from multiple angles to various specialties of medical and health institutions, medical research institutions, medical administrative departments, primary medical and health units, and deeply covers all corners such as scientific research and teaching, clinical treatment, disease prevention and control, and rehabilitation and health care (Akimoto et al., 2023; Tanni & Qian 2023), as shown in Figure 2.

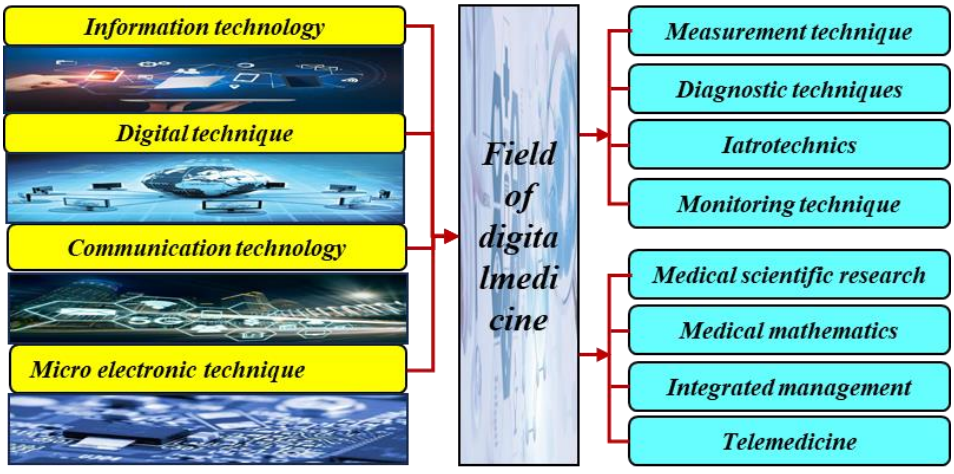

Figure 2. Application of information technology in the medical field

Role of Biotechnology

Whether the human body is considered property has gained significance due to organ transplantation and biotechnology advancements. Biotechnology advancements have established novel applications for bodily tissues previously deemed useless or valueless post-removal (Hong, 2022). Currently, biological tissues are utilized in transplantation, research, education, and business applications. Although human tissues and organs are typically donated and cannot be commercially traded like other consumer products, they retain significant commercial value owing to their heightened utilization in the biotechnology sector to treat various ailments and injuries.

The recent escalation in the biotechnology sector has generated a prospective billion-dollar business for cells and their by-products. These cells and by-products have gained significant value primarily because of their patentability as human-made organisms. The heightened need for transplant organs is attributable to the severe organ deficit. The proliferation of potential applications for human body parts and tissues requires reevaluating the legal status of the human body.

This paper aims to illustrate the necessity for standardized legislation to establish possessory rights over human remains and permit a certain level of commercialization and remuneration based on the specific organ or body part utilized for medical or scientific purposes. This remark highlights the absence of consistency and practicality in the current approach to addressing property rights concerning the body. The main objectives of this work are:

- Examine the existing legal structures that safeguard organ transplant information.
- Examine the function of biotechnology in enhancing security protocols.
- Examine the ethical and privacy issues stemming from the digitalization of organ transplant files.

Legal Regimes for Human Organ Transplantation

Definition and Classification of Organ Transplantation

Organ transplantation refers to surgical treatment for failure or loss of organs with ectopic or ectopic organ replacement. From a medical point of view, organ transplantation is divided into three types: autologous, allogeneic, and allogeneic. Autologous transplantation is the transplantation of organs from one part of an organism to another part; transplantation refers to the transplantation of organs of the same species but different individuals, and allogeneic transplantation is the transplantation of organs of one organism into other organisms. Legally, it refers to the lawful act of transplanting healthy organs to patients when necessary(Bridi Cavassin et al., 2023), following the provisions of the law and the wishes of the parties, to restore the function of human organs and save human life. Article 2 of the Regulations on Human Organ Transplantation points out the definition of organs: "Human organ transplantation," as used in these Regulations, refers to the process of harvesting all or part of the heart, lung, kidney, pancreas and other organs of a human organ donor with specific

functions, and implanting them into the recipient's body to replace the damaged organs (Laura et al., 2022; Tomohiro et al., 2022). Accordingly, organ transplantation is to restore the patient's health using medical allogeneic transplantation, in which the donor's physiologically functional heart, lung, kidney, or pancreas organs are transplanted into the recipient's body to replace the failed organ (Adeniyi et al., 2023).

Organ transplantation is the process of donors, recipients, doctors, or medical institutions helping to donate and receive organs, and it is also the process of information communication between donors, recipients, doctors, or medical institutions (Huang & Han, 2023). From the definition of organ transplantation in Article 2, paragraph 1 of the Regulations on Human Organ Transplantation, it can be analyzed that organ transplantation has the following characteristics: first, there is a donor and a recipient, the two are one-to-one relationships, and the term "donor" excludes organ transactions; Second, the limitations of transplantable organs, only "all or part of organs such as the heart, lungs, kidneys or pancreas" can be transplanted (Zermi et al., 2021); Third, the necessary condition for becoming a recipient is to have "diseased organs," and the author believes that the term "diseased organs" is not appropriate and should be changed to "failed organs"; Fourth, it must be implanted in the recipient body and replace the failed organ." The general view is that once the transplanted organ is detached from the human body, it has the properties of a thing, and the right person is the donor before it is implanted in the recipient's body. The right person after implantation is the recipient. Usually, the transplanted organ must be cross-matched with the recipient to decide whether organ transplantation can be performed. The donated organ needs to be transplanted into the recipient as a whole during surgery, so in principle, there can only be a one-to-one correspondence between the donor and the recipient, excluding the separation of the organ and transplantation into the two recipients. As the recipient's "diseased organ" is not a complete loss of function, and even if there is a "disease" the human body can compensate, a person's right to health should not be deprived, and restoring the health of a person who has no urgent need for survival becomes a sufficient condition for transplantation, it should be understood that dysfunction cannot meet the needs of life, and "diseased organs" are inappropriate (Lee & Seomun, 2021).

Research on the Cognition of Organ Transplantation and Donation Based on the Logistic Model

Through the results of the questionnaire survey, we judged which are the awareness questions about organ transplantation and donation (Anand & Singh, 2020), and after analysis, three questions: "Have you heard of organ transplantation?", "Do you know the procedure of organ or body donation?" and "Do you know which organ is the most donated organ now?" were selected as the awareness questions of organ transplantation and donation. Secondly, the options of the selected questions are assigned to obtain the organ transplant and donation awareness scores of a single sample. Finally, the relationship between gender, age, religious belief, education level, occupation, organ transplantation, and donation awareness was analyzed according to the basic information of the sample.

1. The relationship between different gender and age and awareness of organ transplantation and donation. Is there a significant difference in awareness of organ transplantation and donation between gender, age, and religion? Using software, the non-parametric test method of multiple independent samples was used for testing, and the results were obtained in Table 1.

Table 1. Non-parametric tests for multiple independent samples

	Gender	Age	Religious beliefs
$\chi 2$	0.000	28.352	11.241
df	1	4	3
Progressive salience	0.990	0.000	0.010

As can be seen from Table 1, The P-value of the sex test was 0.990, which was greater than 0.05, so there was no significant difference in the awareness of organ transplantation and donation among people of different sexes. In comparison, the P-value of age and religious belief was less than 0.05, which indicated that people of different ages and religious beliefs had significant differences in their awareness of organ transplantation and donation. The difference in age of awareness of organ transplantation and donation, young age, less understanding of external things, less understanding of organ transplantation and donation, differences in religious beliefs in the cognition of organ transplantation and donation, belief in different religions, such as Buddhism and Christianity. These religious beliefs affect people's perception of organ transplantation and donation.

2. The relationship between different education levels and awareness of organ transplantation and donation. For the difference in awareness and different education levels of organ transplantation and donation, the variance homogeneity test was first carried out, and the one-way ANOVA analysis was performed after passing the test to obtain the relationship between the two. H0: People with different levels of education have the same awareness of organ transplantation and donation. H1: People with different levels of education have different levels of awareness of organ transplantation and donation. The Levene homogeneity test for variance was performed using software, and the results are shown in Table 2.

Table 2. Levene homogeneity test of variance

Levene statistics	df1	df2	Salience
0.637	3	1346	0.591

It can be seen from Table 2 that under the significance level of 95%, the P value (0.591) is more significant than 0.05, so accept the null hypothesis, people with different education levels have the same awareness of organ transplantation and donation, and the variance homogeneity test passes and univariate ANOVA analysis can be performed on the education level and awareness. The results are shown in Table 3.

Table 3. ANOVA analysis results

	Sum of squares	df	Mean square	*F*	Salience
Between groups	91.245	3	30.415	44.624	0.000
Within the group	923.615	1346	0.686		
Total	1014.860	1349			

The questionnaire data are quantitatively processed to study the factors influencing organ transplantation and donation awareness (Mapp et al., 2022), and the options on the questionnaire that belong to the awareness of organ transplantation and donation are assigned. The awareness score of organ transplantation and donation of a single sample is obtained. Secondly, the effects of gender, age, religious belief, arital status, education level, and occupation on the cognition of organ transplantation and donation were analyzed, and the binary logistic regression analysis was carried out according to the results of logical assignment to obtain the regression equation. Finally, the equation is tested to verify the rationality of the model. According to each person's awareness score on organ transplantation and donation, 60% of the total score (5 points) is used as the passing score; that is, those who exceed the passing score of 3 points are considered to be qualified for organ transplantation and donation, and less than 3 points are considered unqualified. The factors influencing the awareness of organ transplantation and donation are assigned as shown in Table 4.

Table 4. Logical assignments of awareness factors for organ transplantation and donation

Variable	Name	Value
Y	Awareness	Awareness pass = 1, awareness failure = 0
X1	Gender	Male = 1, female = 2
X2	Age	Under 18 = 1, 18-30 = 2, 31-45 = 3, 46-60 = 4, 61 and over = 5
X3	Religious beliefs	None = 1, Buddhism = 2, Christianity = 3, Others = 4
X4	Marital status	Married = 1, unmarried = 2, divorced = 3, widowed and others = 4
X5	Education	Primary = 1, Secondary = 2, University = 3, Master's degree and above = 4
X6	Occupation	Non-medical staff = 1, medical staff = 2

Whether the awareness of organ transplantation and donation is qualified is a dichotomous variable, select Logistic regression to analyze the relationship between model variables and establish a logistic regression model between the dependent variable (awareness of organ transplantation and donation) and independent variables (gender, age, religious belief, marital status, education level, occupation):

$$p = p(y = 1 | x_1, x_2, \cdots, x_6) = \frac{\exp(\alpha + \beta_1 x_1 + \beta_2 x_2 + \cdots + \beta_6 x_6)}{1 + \exp(\alpha + \beta_1 x_1 + \beta_2 x_2 + \cdots + \beta_6 x_6)}$$

Convert to a linear model as: $\ln(\frac{p}{1-p}) = \alpha + \beta_1 x_1 + \beta_2 x_2 + \beta_3 x_3 + \beta_4 x_4 + \beta_5 x_5 + \beta_6 x_6$

Thereinto，$\beta_i(i=1,2,\cdots,6)$ Estimated coefficients indicating gender, age, religion, marital status, education, and occupation.

Table 5. Logistic regression analysis of cognitive influencing factors

	B	S.E,	Wald	df	Sig.	Exp(B)
X1	-0.069	0.147	0.219	1	0.640	0.934
X2	-0.049	0.089	3.302	1	0.035	0.952
X3	-0.032	0.094	0.112	1	0.738	0.969
X4	-0.280	0.133	4.435	1	0.035	0.756
X5	0.839	0.123	46.634	1	0.000	2.314
X6	0.383	0.155	6.071	1	0.014	1.466
常量	-0.300	0.548	0.299	1	0.584	0.741

Therefore, the logistic regression equation for the factors influencing organ transplantation and donation awareness is as follows:

$$Y=-0.3-0.069x_1-0.049x_2-0.032x_3-0.28x_4+0.839x_5+0.383x_6$$

HosmerLemeshow test was used to test the goodness of fit of the Logistic regression equation, and the data were shown in Table 5. Null hypothesis: no significant difference in model fit; alternative hypothesis: significant difference in model fit. According to the result of software operation P=0.728 > 0.05, the original hypothesis is accepted; that is, there is no significant difference in the fitting of the model, so the fitting effect of the model is better.

Legal Nature and Governing Principles of Organ Donation

(1) The Legal Nature of Organ Donation

Organ donation is an important part of ensuring the security of organ transplant information (Ngai et al., 2022). Regarding legal attributes, organ donation involves many issues, such as protecting personal rights and interests, determining legality, informed consent, and prohibiting commercial trading. Many countries have established relevant laws, regulations, and institutions to ensure organ donation's transparency, fairness, and legitimacy. For example, China has implemented regulations on organ donation and transplantation, which clarify the rights and obligations of organ donors and recipients and the responsibilities and professional standards of relevant institutions. In addition, China has established an organ donation and transplantation information management system to ensure information sharing and confidentiality and to combat illegal organ trade and human organ trafficking. Therefore, in the digital age, it is necessary to improve the legal framework further and establish a digital regulatory mechanism and data security measures to ensure organ donation information security and transparency.

(2) Ethical Principles

The right of donors and recipients to informed consent is an essential prerequisite for the voluntary principle of organ transplantation, and consent is considered to be an integral part of the overall medical contract and the most concrete expression of patient autonomy. In clinical practice, when the doctor believes that the patient has the necessary surgery, he will recommend the operation to the patient and give surgical consent. The patient signs the surgical consent form so the doctor has a legal procedural basis for the operation. This model is valid informed consent and is also in line with the principle of patient autonomy so that the medical contract is established. The patient's commitment becomes the core reason for the justification of medical behavior. Organ transplantation is a surgical procedure, so the principle of informed consent is also necessary for organ transplantation, including the right to know and consent. The right to know means that the organ donor has the right to know all the truth about the donated organ, while the right to consent means that the donor's medical decisions are arbitrary and free from any external pressure. In other words, human organ transplantation must follow the principles of informed consent and voluntariness. Physicians who maintain good clinical knowledge and skills exercise caution to achieve "appropriate standards of care" and avoid placing any undue risk of harm on patients, i.e., fulfilling the principle of non-harm. Regardless of whether the doctor harms the patient during the medical process due to insufficient technology, personality problems, or fraudulent and illegal acts, it is a breach of the obligation not to harm. Physicians should inform patients of the purpose of the donation, the risks and evaluation of organ removal surgery, and the consequences of organ removal that may cause health damage due to loss. They should correctly evaluate the risks and benefits of organ transplantation. For non-renewable organ transplants, as well as organ transplants whose loss is sufficient to cause danger to life or severe health damage, doctors have the right to make particular risk and benefit assessments to safeguard patients' best health interests.

Although a broader standard of brain death may save many people, under the principle of "no harm," a hasty death judgment should never end a person's life early because the doctor's wrong death judgment exists. Rawls believes in "The Theory of Justice" that procedural justice must be enforceable in medical and health care. A fair procedure must be established to achieve fair and just results, and the realization of its principle of fairness and justice mainly lies in the equal treatment of patients and balanced resource allocation. The core principle of Article 25 of the Universal Declaration of Human Rights is based on protecting fundamental human rights. China's Constitution also emphasizes the equality of the right to human health. However, this equality should adopt the principle of proportional equality rather than mechanical form equality, that is, consider the criteria of medicine, social value, family role, and life expectancy to judge the priority of human organ transplantation and the reasonable difference in distribution, which is also substantive equality. Therefore, patients should promptly receive necessary and adequate medical treatment under fair and equal conditions. Different groups or stakeholders, including governments, medical institutions, and healthcare professionals, should share responsibility for ensuring the accessibility and equitable use of organ transplantation; in other words, the organ distribution principle should be equitable and efficient.

(3) The Legal Properties of Organs Implanted in the Human Body and the Exchange of Information

Organs implanted into the human body have important legal attributes, including personal body rights, privacy protection, and informed consent. In the digital age, information exchange has also become an important link in organ transplantation. With the widespread application of digital medical technology, organ transplant information faces security and privacy protection challenges during storage, transmission, and sharing. Therefore, it is necessary to establish a legal framework adapted to the digital age to ensure the legality, transparency, and reliability of organs implanted in the human body and to guarantee the security and privacy protection of information exchange. This includes the development of relevant laws and regulations, establishing institutions responsible for managing and regulating the exchange of information, strengthening data security measures, and clarifying legal principles such as individual privacy and informed consent. By establishing an effective legal framework, it is possible to promote the legal operation of organs implanted in the human body and protect the rights and privacy of patients while promoting the sustainable development of digital technologies in organ transplantation. The right to life is guaranteed by human beings (Albezreh et al., 2022). Chapter 1, paragraph 1 of the German Basic Law stipulates that human dignity is inviolable and that all State powers are obliged to respect and protect human dignity. Most countries enshrine this philosophy as the supreme guiding principle of the Constitution. From the perspective of human dignity, every organ transplant patient, especially the donor, has autonomy and subjectivity and is not coerced by any external force. To conform to the constitutional requirements for human dignity and practice the self-development of the personality, individuals or social groups should have the authority to autonomy and self-discipline following their status, and such rights are the right to self-determination. It is undeniable that the development of organ transplantation has enhanced the gospel of present and future generations, but its misuse may also lead to the endangerment of human dignity. Efforts should be made to find a possible framework that would value the importance of human life as an individual and as part of the human person while recognizing the need to guarantee human dignity.

(4) Legal Deficiencies in Biotechnology for Organ Transplantation

Biotechnology firms developing sophisticated matching algorithms or post-transplant monitoring systems frequently possess access to susceptible genetic and health information. No comprehensive legal framework exists regulating the sharing, storage, or utilization of this data in biotechnology. Furthermore, the regulations governing the application of AI and machine learning (ML) in biotechnology are still developing, resulting in numerous ambiguities regarding data security.

(5) Regulation of AI in Biotechnology for Organ Transplantation

AI has become an important tool in biotechnology, helping to find new ways to do organ transplants. Adding AI to biotechnology has changed the organ transplant process by making it easier to match donors with recipients and improving care after the transplant. As our reliance on AI grows, it brings new problems for

regulators, especially regarding data privacy, moral issues, and security threats. The most important thing that needs to be done is to make sure that AI works in a way that protects patient rights and keeps data safe.

(i) Using AI to Make Matching Algorithms Better

Artificial intelligence has made it easier and more accurate to match organ donors with recipients using large datasets and machine learning algorithms to look at compatibility factors. AI runs these systems and can look at genetic information, blood types, and organ conditions to find the best matches. This cuts down on wait times and improves the success of transplants. Privacy concerns exist because the algorithms depend on personal personal health data, like genetic information. A thorough set of rules must be implemented to ensure that AI systems protect patient privacy. This means that data must be encrypted and anonymized very carefully.

(ii) Privacy of Data and Ownership

Much personal and medical data must be analyzed for AI to be used in organ transplants. This data may include very private things like genetic markers. An example of a law that protects patient information in a big way is the General Data Protection Regulation (GDPR) in the European Union and the Health Insurance Portability and Accountability Act (HIPAA) in the United States. Still, these rules don't always consider how artificial intelligence and biotechnology have complicated healthcare. Regulators need to make clear rules about how AI algorithms can access, process, and store data, and they need to make sure that patients give clear permission, especially when genetic data is used in matching algorithms. In addition, a dispute over who owns the data has not been resolved. Patients own their health records, but AI systems often use data shared between research institutions, biotechnology companies, and hospitals. Clear rules must be established to protect patients' ownership rights and give them control over their data as it moves between different parts of the organ transplantation network.

(iii) Concerns about Ethics and Bias

Even though AI systems are very useful, they may reinforce bias if they are not properly controlled. Biased data could make it harder for people from marginalized groups to get organ transplants, which could change the results of organ matching for some groups. Regulatory bodies must implement strict rules on AI training data to ensure fairness and diversity. AI decisions must be clear, and all decisions made by AI during the organ transplant process must be able to be explained and justified to avoid unfair or discriminatory practices.

(iv) Threats to AI Security and Cyber Safety

Using AI systems in healthcare is linked to a higher risk of cyberattacks. Cybercriminals could use the AI algorithms used in organ transplants to interfere with the procedures or get private data. Tough cybersecurity rules must be put in place for AI systems by regulatory bodies. These rules should include encryption, multi-factor authentication, and regular security checks. AI systems that handle data about organ transplants need to follow cybersecurity standards specific to healthcare to lower the risk of data breaches and other bad things.

(v) Proposals for Rules

To deal with these issues, governments, and healthcare regulatory bodies need to create a legal framework that is just right for AI in biotechnology regarding organ transplants. This framework needs to pay attention to:

Data Privacy: Make sure that any personal information AI handles is encrypted, anonymous, and only used with the patient's permission.

Bias Mitigation: Making AI systems go through tests for bias and making sure that training data includes people from a wide range of demographics.

Transparency: Making AI algorithms produce results that can be explained helps medical professionals understand and trust AI's decisions.

Cybersecurity means putting complex security measures in place to protect AI systems from cyber threats, which protect patient data. Society can maximize AI's potential while upholding ethical standards and patient privacy by proactively regulating its use in organ transplantation. These rules will be very important to ensure that AI works as a trustworthy, fair, and safe tool in the progress of biotechnology and healthcare.

Multiple legal and regulatory approaches for organ transplantation

Role of the Legal System in Organ Transplant Information Security

The qualitative issue of organ transplantation is quite complex because the legitimate rights and interests of the parties involved in the entire process of organ transplantation (including organ donation, harvesting, and implantation) need to be reasonably protected and will involve social ethics, justice, legislation, administrative management, and many other aspects. It is precisely because of the complexity of organ transplantation that it is voluntary and irreversible, so how we should formulate laws to regulate the behavior of organ transplantation is more critical. The development of organ transplantation technology is inseparable from the regulation of law, and improving organ transplant legislation is the need to develop organ transplantation technology. The large number of organ transplants in practice and related legislative gaps will leave organ donation and transplant activities confused (Weiss et al., 2022).

In the digital medical scenario, the patient's digital medical file not only contains the personal health and medical information provided by the patient but also records the medical diagnosis results and treatment plans of all the receiving physicians of the patient, forming a complete personal digital medical information system for the patient. The simulated Internet healthcare financing situation is shown in Figure 3.

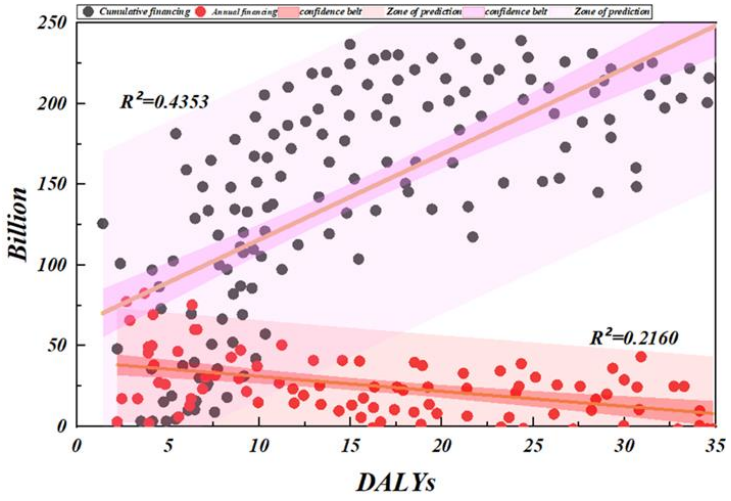

Figure 3. Simulation results of financing in the Internet healthcare industry

In the era of digital health, all medical processes and links will be digitized, resulting in substantial medical data, which can help patients enhance their ability to manage their health and help medical institutions and medical staff improve the level of medical technology and medical management capabilities. They can also promote the development and production of medical products such as drugs, medical devices, and medical insurance products, which will provide a steady stream of energy and power for the development of digital medical care. The number of digital health and those who have not joined in 20 years is shown in Figure 4.

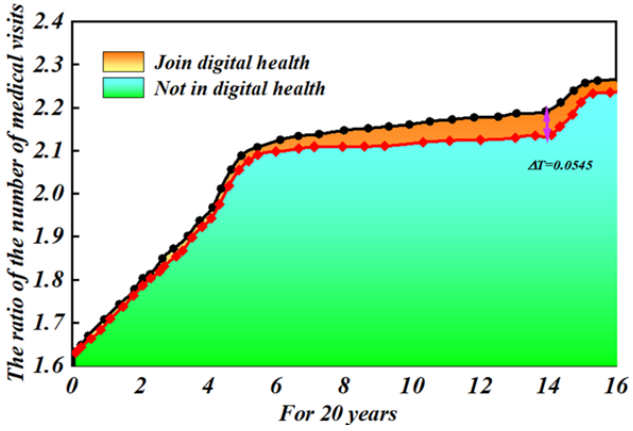

Figure 4. Ratio of visits over 20 years

At present, the two laws that need to be devoted the most attention in China are the "Organ Donation Law" and the "Organ Transplantation Law" (Behera et al., 2021). Among them, the Organ Donation Law can stipulate the subject of donation, the process of donation, and measures to encourage donation. The contents of the Organ Transplant Law include the subjects of organ harvesting, the qualifications required for organ transplantation, the procedures and procedures for organ harvesting, the distribution rules for obtaining organs, and the handling of organs of unknown origin. In short, each link of the organ transplantation process

should be stipulated in detail from beginning to end, as well as how exceptions should be handled and violations punished. The 2023 Legislative Work Plan of The State Council mentions that the Regulations on Human Organ Transplantation will be amended. The revised regulations will emphasize the importance of organ donation, promote the principle of voluntary and unpaid donation, and improve donation conditions per the Civil Code. The new regulation will also strengthen the management of medical institutions and impose stricter penalties on medical institutions and staff that violate the rules. Promulgated on May 28, 2020, and implemented on January 1, 2021, the codification of personality rights in the Civil Code has brought innovation to China's legal system. It not only meets the demand for personality rights in the information age but also ensures the basic rights of citizens while promoting the development of medical science and technology. The chapter on the Rights of personality provides a systematic regulation of personal rights, which provides a solid legal basis for organ donation and human experimentation. The separate listing of these rights in the "Series of Personality rights" not only guarantees the basic rights of citizens but also clarifies the limits of these rights. At the same time, other ministerial laws also restrict and regulate some details of organ transplantation and organ donation. For example, in civil law, criminal law, administrative law, and other laws, relevant provisions can be formulated to supplement the unified law on organ transplantation and organ donation to improve the legal system of organ transplantation and organ donation and the timeline of China's organ donation and transplantation laws and regulations is shown in Figure 5.

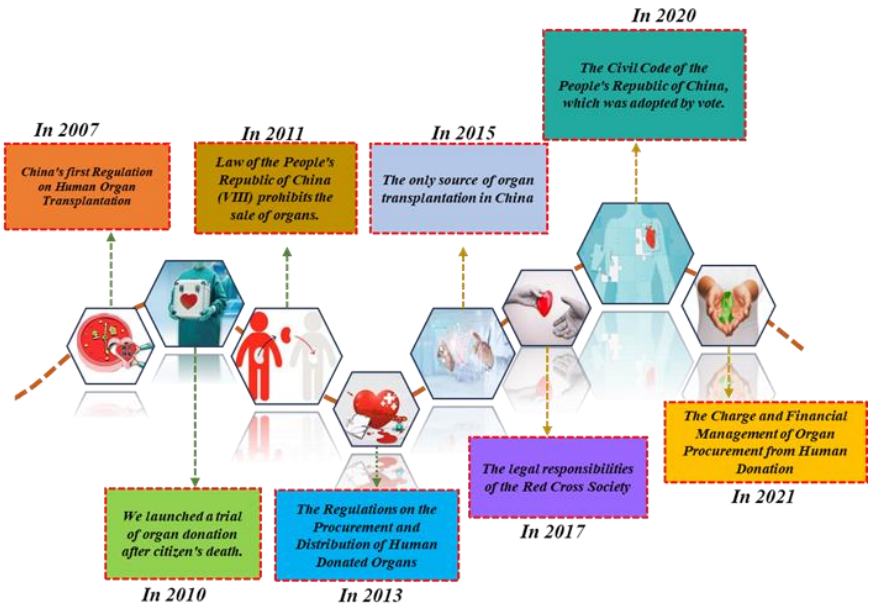

Figure 5. China's Organ Donation and Transplantation Laws

Organ Donation and Information Security

Internet medical care is a digital age, which profoundly integrates and applies network technology in the medical field. Medical institutions and doctors provide relevant medical and health services through Internet information technology. There are various Internet medical service models in China, including consultation,

pharmaceutical e-commerce, appointment registration, telemedicine, and other models, all of which will generate information once applied. Under normal circumstances, personal data is thin, and legally, it is not considered economic or property, and data becomes property only when the data has economic exchange value and dominance. Information security requires that the data and information in the system are duly protected and will not be leaked by information for any reason or tampered with, interrupted, or destroyed. In the past, traditional diagnosis and treatment records and handwritten medical records were quickly replaced by electronic technology, and there was a large amount of essential data in the whole process of patients, from appointment to treatment to drug purchase to rehabilitation. Through the wide application of Internet medical treatment, these primary data can enable patients and doctors to break the limitations of time and space; patients transmit personal health data to medical institutions, medical institutions, and doctors conduct professional analysis and then provide patients with diagnostic results, which significantly facilitates patients and makes patients more convenient for medical treatment.

Nevertheless, at the same time, what must be addressed is the security protection of patient medical information. At present, Internet medical care has entered a period of rapid development, changing the previous state that patient information, doctor's information, and medical resource information are only known to each other, which integrates resources to a certain extent and breaks the phenomenon of information islands, but also makes patients' personal health information wholly exposed to the open network public domain. After obtaining this private information data, some unscrupulous medical institutions and some pseudo-experts in the market harass patients, peddling counterfeit and inferior drugs to patients, and problems such as fraud and sales have emerged one after another (Al-Busaidi et al., 2021). Figure 6 shows the analysis framework of the SU-CO supervision model, and internal and external supervision bodies play a synergistic role in supervising the decision-making, implementation, coordination, control, and supervision of production management activities.

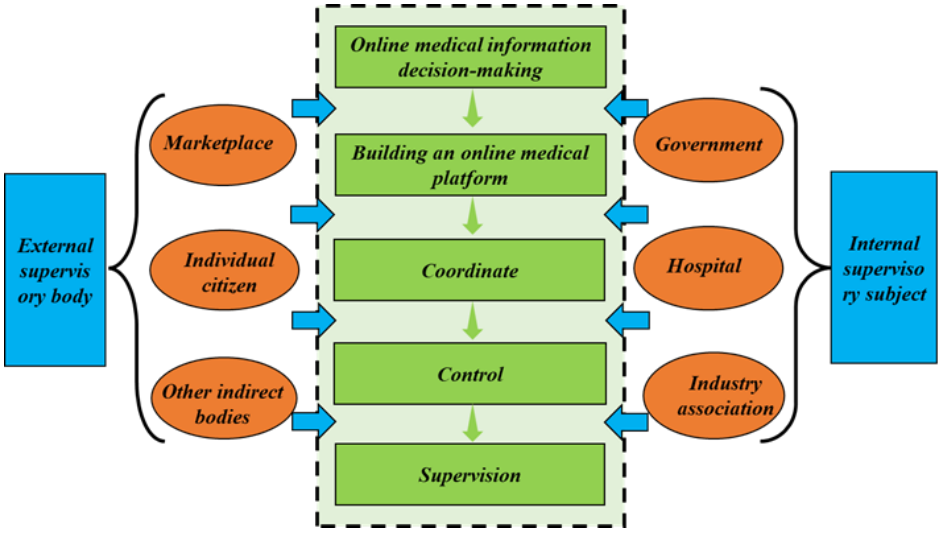

Figure 6. Digital Health Information Oversight Framework

Improve the Legal System for Organ Transplant Information Security

(1) Protection of Donor and Recipient Information and Legal Requirements

To combat "transplant marriage" and clarify the scope of "family relationship formation due to assistance, " the former Ministry of Health issued Several Regulations on Regulating Living Organ Transplantation in 2009. According to paragraph 2 thereof, the relationship between a living organ donor and a recipient is limited to a spouse who has been married for more than three years or who has children after marriage, except for direct blood relatives or collateral blood relatives within three generations, and the relationship between adoptive parents and adopted children, and between stepparents and stepchildren, is limited to the relationship between adoptive parents and adopted children, and between stepparents and stepchildren. This regulation strictly limits the scope of donors for living organs, which is conducive to combating disguised organ trafficking. However, this provision needs to be more balanced and raises two new problems: First, the qualifications for spouses are too strict. Although some couples have been married for less than three years, one of the parties is diagnosed with the need for organ transplantation after marriage; the above provisions exclude the legality of living organ transplantation in this case, which is unreasonable and should be recognized by amendment. Second, there is no room for the legalization of "cross-transplantation." The legality of cross-transplantation varies around the world. Its emergence undoubtedly provides a new way to supply organs, which is expected to balance supply and demand. Still, at the same time, it may also trigger potential dangers of organ trading, such as family members feeling psychological pressure or guilt for donating organs to each other, especially if one of the operations fails or complications occur. To avoid such risks, countries like the United States have established a comprehensive management system, such as organ management commissioners, to ensure the process is fair and transparent. In China, the law on cross-transplantation is still strict. We can draw on international practice and formulate clearer and more practical cross-transplant regulations. At the same time, to ensure the fairness of cross-transplantation, it is recommended that an independent review body be set up to monitor the whole process carefully. Cross-transplantation has opened up a new path in the field of organ transplantation in China, and we need to formulate appropriate legal provisions to ensure fairness and transparency to cope with the growing demand for organs. If the above provisions are strictly applied, this "cross-transplantation" is illegal. However, if it is blindly prohibited, it will harm the fundamental interests of patients and society; after all, safeguarding the legal interests of patients is the most important.

Moreover, the "Transplantation Regulations" do not explicitly prohibit "cross-transplantation." However, the provisions mentioned above as departmental regulations exclude the legality of "cross-transplantation," which is suspected of violating the superior law. Austria and Switzerland allowed "cross-transplantation" under strict scrutiny, which not only did not increase the risk of organ commercialization but solved some organ demand and inhibited the growth of organ trade. Therefore, China should not prohibit

"cross-transplantation" and should revise the above "regulations" to further optimize the scope of living organ donors.

(2) Strengthen Interpretation, Improve Legislation, and Effectively Regulate New Organ Crimes

New illegal and criminal acts, such as infringement of ex vivo organs and smuggling of human organs Living organs undergo a process of transfer from inside the body to outside the body between donors and recipients, so we need to analyze their legal properties from two different perspectives, namely in vivo and in vitro brought about by the development of organ transplantation technology, can be dealt with by strengthening criminal law interpretation and improving criminal legislation (Halpin, 2021). Because the ex vivo organ has separated from the human body, it is no longer the body and has the properties of things. However, compared with ordinary "things," it has a certain degree of life, personality, independence, availability, non-renewability, and vulnerability and should enjoy higher "protection." Nor are dead bodies and their attached organs ordinary objects. They contain the remnants of the personality rights of the deceased, are the continuation of the rights and interests of personality, and carry the meaning of social ethics, public order, and good customs. Therefore, the possession, inheritance, proceeds, use, and disposal of carcasses and their organs are restricted by law and cannot be freely bought and sold. The disposal and use of corpses and their organs must strictly follow legal and ethical norms to respect the dignity of the deceased and protect the public interest of society. Ideally, this should be protected explicitly through criminal legislation, such as the addition of the crime of "encroachment on ex vivo organs" through amendments to the Criminal Law, which provides a higher purpose of criminal law protection than "theft" and "intentional destruction of property" but lower than "intentional homicide" and "intentional injury." However, under the existing criminal law system, before the legislation is perfected to achieve the purpose of criminal law protection, for the time being, the ex vivo organ can only be recognized as a "special thing." In this way, theft and intentional destruction of ex vivo organs can be temporarily punished by the crime of theft or intentional destruction of property. However, the protection is inadequate; it is at least more substantial than the absence of criminal law protection (i.e., it does not constitute a crime). Pursuing substantive justice through interpreting criminal law can realize the substantive human rights protection function of a country ruled by law. In addition, the smuggling of human organs not only infringes on the right to life or health of donors and recipients and the order of medical and health care but also infringes on the intractability of organs, that is, the legal interests of human dignity, and the legal interests infringed have reached the level of requiring criminal law to be regulated, but the existing laws of the criminal law do not regulate the smuggling of human organs. Moreover, the smuggling of human organs is inherently more harmful than the sale of organs, so it is necessary to add the smuggling of human organs to the crime of smuggling through amendments to the Criminal Law.

Conclusion

Through the study of the legal framework for ensuring the security of organ transplant information in the digital age, we can draw the following conclusions:

1. The digital age has brought new challenges to the information security of organ transplantation, and the traditional legal framework needs to be updated and improved, including the formulation of laws and regulations, the regulation of ethics and social responsibility, the construction of regulatory mechanisms, etc. At the same time, attention should be paid to the education and training of personnel related to organ transplantation information security, strengthening the support of technical means, and improving the data management and exchange system. Relevant institutions should strengthen cooperation and consensus, form integrated mechanisms and standards, and jointly safeguard the security of organ transplantation information.

2. Human organ transplantation technology is a double-edged sword. On the one hand, it can rekindle the hope of patients who were originally in a desperate situation, which is excellent progress in the history of medicine. On the other hand, misuse can violate the health and life interests of donors and recipients and even human dignity. Law is the last barrier to promoting the development of organ transplantation technology and protecting the rights and interests of donors and recipients; reasonable and effective legal regulation can avoid risks and give full play to the beneficial aspects of organ transplantation. Otherwise, it may violate human rights and bring great harm to society. Based on drawing on the world's advanced experience and combining it with China's actual situation, China should scientifically and reasonably solve the relevant problems in the legal regulation of human organ transplantation and promote the healthy development of human organ transplantation.

In the digital era, safeguarding organ transplant data is increasingly vital, particularly as biotechnology assumes a prominent role in the procedure. Although strong in some aspects, current legal frameworks lack specificity regarding the distinct challenges associated with organ transplants. To protect sensitive information, governments and institutions must cooperate to formulate comprehensive regulations that respond to technological advancements in this domain.

Author Contributions

All Authors contributed equally.

Conflict of Interest

The authors declared that no conflict of interest.

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