A Study on the Legitimacy of Human Gene Editing Technology

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Abstract. Human gene editing technology has great potential in the fields of disease treatment and life science research, but there are also complex risks and legitimacy challenges. In the face of these problems, in terms of international cooperation, unified regulations should be formulated and synergistically governed, the role of international organizations should be strengthened, and technical and regulatory information should be shared. In terms of legislation, the legal system should be improved, the scope of application, the approval procedures and the liability subject should be clarified, the penalties for violations should be increased, and severe punishment should be meted out for serious violations of the law on gene editing of germ cells. In terms of supervision, a multi-sectoral, coordinated and whole-process supervision mechanism should be established, modern information technology should be utilized to achieve information sharing, patients and their offspring undergoing gene editing therapy should be tracked throughout their lives, and adverse reactions should be reported promptly, so as to provide a basis for technological improvement and policy adjustment.

Keywords: Gene editing; Intergenerational justice; Uncontrolled risk; Chain management

1 Introduction

Human gene editing technology represented by CRISPR-Cas9 has shown great value in treating genetic diseases and advancing life science research. However, its rapid development is accompanied by technical defects, ethical disputes and legal risks. The 2018 gene-edited baby incident exposed the hazards of unregulated application of this technology, and the corresponding judicial ruling also drew public attention to the legitimacy of human gene editing.

Current gene editing techniques still have hidden dangers such as off-target effects, which may threaten human health. Improper use may trigger genetic discrimination, intergenerational right conflicts and long-term risks to the human gene pool. At the global level, relevant international declarations lack binding force, and national regulatory rules are inconsistent. In China, the existing regulatory system also faces deficiencies in specialized legislation, liability determination and whole-process supervision.

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On this basis, this paper analyzes the potential risks and institutional loopholes of human gene editing. It proposes governance strategies from international coordination, legal improvement and full-cycle supervision, in order to define the legitimate scope of the technology and realize the balanced development of technological innovation, ethical norms and legal regulation.

2 Origin of the Problem

In 2018, He Jiankui used CRISPR-Cas9 gene editing technology to edit the CCR5 gene of embryos in an attempt to make babies immune to AIDS. In 2019, the People's Court of Nanshan District, Shenzhen City, Guangdong Province, issued the first-instance judgment on the case of He Jiankui and others for "illegal medical practice". He Jiankui was sentenced to three years' imprisonment and a fine of RMB 3 million yuan for the crime of illegal medical practice. This judgment highlights the seriousness of the law in punishing illegal gene editing, and has also triggered profound reflection on the legitimacy of human gene editing technology by all sectors of society. Gene editing technology has shown great potential in the fields of disease treatment and life science research, but there are still a series of risks in the process of research and application of gene editing technology. This article will propose effective ways to control the use of gene editing technology from multiple dimensions such as technology, application and system, which aims to build a set of scientific, reasonable and targeted system.

3 Research Review

3.1 Arguments in Favor of the Research and Application of Gene Editing Technology

At present, gene editing technology shows remarkable potential in the field of genetic diseases and other therapeutic areas. According to the research of Prof. Yao Kai's team, the current CRISPR gene editing technology can correct gene mutations at one time, carry out any form of genetic modification at any site in the genome of any cell, and can also be used to study gene function through genome-level CRISPR libraries, which has shown a wide range of prospects for application in the treatment of various diseases in animal models, such as sickle-cell anemia and severe combined immunodeficiency disorder.[1] For example, a representative of the new generation of gene editing technology, CRISPR-cas9 can accurately correct defective genes to prevent and treat diseases, such as sickle-cell anemia and cystic fibrosis, from the source, which is conducive to lowering the incidence of diseases and improving the overall health of human beings.

3.2 Criticism Against the Misuse of Gene Editing Technology

Hidden Dangers Related to Social Justice and Meritocracy. The act of utilizing gene technology may lead to injustice and genetic discrimination. From the perspective of

social justice, the inappropriate use of gene editing technology may increase social injustice by giving more advantages to groups with better gene editing conditions, while disadvantaged groups are put in a worse position. From the perspective of meritocracy, "merit" criteria based on genetic characteristics may emerge, which may lead to "genetic meritocracy" replacing traditional values of justice and triggering discrimination and exclusion of individuals with so-called "inferior" genes.

Lack of Global Uniformity in Legal Regulation. The legal position on gene editing varies significantly from country to country. Article 13 of the European Union's *Convention on Human Rights and Biomedicine* prohibits interventions aimed at any modification of the genome of any offspring. China has explicitly criminalized the illegal implantation of gene-edited embryos through its *Amendment (XI) to the Criminal Law*. Article 5 of the Germany's *Embryo Protection Act* clearly states that any artificial alteration of the genetic information of human germ cells, or any attempt to use edited germ cells for reproductive purposes, is punishable by up to five years' imprisonment or a fine. The binding nature of gene editing and the variability of regulatory standards across countries lead to the risks of transnational research. Therefore, it is particularly important to establish internationally unified standards to address cross-border technological risks.

Academic Consensus on the Limits of Legitimacy. Despite the continuing controversy, a consensus is emerging in the academic community on the following aspects: First, the distinction between therapeutic and enhancement purposes. In particular, the Human Gene Editing Research Committee has proposed standards for gene editing of heritable reproductive systems that is "limited to the prevention of a serious disease". Second, the need for public participation is emphasized. Existing explorations of global governance of human gene editing have emphasized the importance of public participation. The fundamental principles of science, ethics and regulation, as set out in the study published by the Human Gene Editing Research Committee, state that any genome editing for heritable reproduction should be carried out under adequate assessment and public participation.[2]

4 Potential Risks in the Research Process of Human Gene Editing Technology

4.1 Health Risks from Technological Research

At present, gene editing technology carries the risk of causing "off-target effect" and retrotransposition, which may be harmful to the health of subjects. p53 gene, as a key tumor suppressor gene, plays a central role in the DNA damage response. Normal p53 genes inhibit CRISPR-Cas9 gene editing, which means that the p53 genes of successfully-edited cells are likely to be defective. Cells with CRISPR/Cas9 gene editing will pose a potential carcinogenicity risk if used in therapy.[3] Meanwhile, DNA undergoes

rearrangement when its breaks are not repaired during the gene editing process, i.e., the process of retrotransposition brought about by the CRISPR technology. [4] This event is uncommon, but theoretically triggers the risk of developing cancer.

4.2 Alienation of the Researchers' Starting Point for Research

The dual nature of gene editing technology requires researchers to uphold rigorous scientific and ethical values, but in reality, the motivation of research may be misdirected due to multiple pressures. Under the coercion of capital, gene editing research may deviate from the original medical intention and turn to more profitable commercial applications. Besides, the over-promotion of the "right of first publication" in the scientific research evaluation system may induce researchers to take risks, which was exposed by the "He Jiankui incident" in 2018.

5 Potential Risks in the Application of Human Gene Editing Technology

5.1 Risk of Leakage of Personal Information

Genetic information not only contains biological attributes such as individual physiological characteristics, but also implicitly contains information on family genetic lineages, racial characteristics and other correlative information. Once leaked or used inappropriately, it may cause serious discrimination and damage to individuals in many aspects such as employment, insurance and marriage. The introduction of the U.S. *Genetic Information Nondiscrimination Act (GINA)* highlights the protection of genetic information and the constraints on potential discrimination caused by gene editing.[5]

In the application scenarios of technology, the risk of genetic information leakage is mainly manifested at three levels: First, defects in the data collection. When some medical institutions or scientific research institutions carry out clinical research on the gene editing, there are problems such as ambiguous content of informed consent and ill-defined use of data. Second, loopholes in the data storage. Gene databases face risks such as server failures and confusion in operator management. Third, risks of data sharing. When gene editing technology is combined with medical treatment and drug research and development, it is easy for genetic information to be used for commercial purposes without full authorization.

5.2 Risk of Intergenerational Decision-Making Power

The intergenerational application of gene editing technology, particularly the editing of fetal genes, has given rise to ethical and legal controversies concerning the distribution of intergenerational rights. When parents or researchers edit the fetal genes for the purpose of "enhancing the offspring", they exercise the right to determine the genetic composition of the unborn individual, while the fetus, as a subject of rights, is unable to express the will. Under the traditional model of reproduction, the genetic characteristics

of offspring are determined by natural selection, whereas gene editing technology gives parents the possibility of "designing their offspring", thus exacerbating intergenerational conflicts over rights.

From the perspective of legal rights structure, the genetic autonomy of the fetus should include the right to be free from illegal interference with genetic integrity, the right to be informed of genetic information and the right to make decisions. Although China's *Civil Code* has established a system to protect the interests of the fetus, there is still a gap in the configuration of intergenerational rights in the field of gene editing. In the process of intergenerational rights thinking to harmonize the rights relationship between the present and future generations, balancing the distribution of obligations between the present and future generations can provide a perspective and a possibility for effective control of the unknown risks brought by new technologies such as gene editing.[6]

5.3 Harm to Others from Spillover Risks

The gene editing technology has significant spillover, and its impact is not limited to the target individual, but may cause harm to others and the social community through gene transmission and social demonstration. The off-target effect of gene editing technology may bring about mutations in non-target genes, and its low technological efficiency brings about the unpredictable impact of "chimerism", which may cause technological and ethical problems, such as "being sick" without being informed.[7] Gene editing technology can cause permanent changes to genes, and such changes can be passed on from generation to generation. Society cannot take away the reproductive rights of individuals who have undergone gene editing, and the edited information that can be passed on to the next generation will challenge society's existing ethical perceptions.[8] The public nature of this risk determines that gene editing technology needs to be included in the scope of social public interest protection, and a strict technology access system and risk warning mechanism should be established.

6 Legal and Institutional Loopholes in the Control of Human Gene Editing

6.1 Lack of Principles and Enforcement Mechanisms for International Treaties

First, the limitations of the *Universal Declaration on the Human Genome and Human Rights.* Although the *Universal Declaration on the Human Genome and Human Rights*, adopted by UNESCO in 1997, establishes the principles of "uniformity of the human genome" and "prohibition of genetic discrimination", it lacks a legally binding enforcement mechanism. Article 15 of the *Declaration* only requires countries to "take appropriate measures" to regulate gene editing research[9], and does not explicitly prohibit reproductive system editing or gene enhancement technology, which leads to significant differences in interpretation among countries in practice.

6.2 Lack of Specialized Legislation and Difficulties in Determining Liability

From the perspective of existing laws, China's *Biosecurity Law and Regulations on the Administration of Human Genetic Resources* only mention how to regulate gene editing in principle, and have not yet formed a systematic norm. Meanwhile, the *Measures for the Administration of Clinical Application of Medical Technology* issued by the National Health Commission of the People's Republic of China categorizes gene editing as a "third type of medical technology", but does not detail the approval procedures. Taking the protection of the rights and interests of edited babies as an example, when attempting to sue for damages on the basis of torts such as "wrongful birth" or "wrongful life" under the existing legal framework, it is difficult to clearly define and prove the long-term effects of gene editing due to the high degree of uncertainty.[10] This makes it difficult to clarify the certainty of the consequences of damage and the causality between the act and the consequences of damage in the traditional elements of tort liability. The existence of such a risk makes it necessary for the determination of legal liability not to be limited to the acts and consequences of present generations, but also to consider prospectively the possible effects on future generations.

7 Effective Ways to Regulate the Research and Application of Gene Editing Technology

7.1 Building Globally Unified Regulations and Synergistic Governance

The cross-border nature of gene editing technology determines the key position of international cooperation in the regulation. In 2015, scientists from China, the United States and the United Kingdom co-sponsored the International Summit on Human Gene Editing, which held in-depth discussions on basic research on human gene editing, somatic cell gene editing and germ cell gene editing, and formed an important consensus. The Summit emphasized that governance regarding gene editing should place greater emphasis on international cooperation and public participation.[11] In the future, the role of international organizations in the regulation of gene editing technology should also be further strengthened. For example, the World Health Organization (WHO) can take the lead in formulating global safety standards for gene editing technology, and promoting countries to follow unified norms in technology research and development, clinical trials and other aspects.

7.2 Improving Legislation and Strengthening Penalties

At present, many countries have introduced relevant laws on gene editing technology. In China, for example, Article 109 of the *Civil Code of the People's Republic of China* stipulates that medical scientific research activities related to human genes and human embryos should comply with laws, administrative regulations and relevant national provisions, and should not harm human health, violate ethics and morals, or damage the public interest. The *Ethical Guidelines for Human Genome Editing Research* are used to clarify the scope of application, the approval procedures, the liability subject, and

other key elements of human gene editing technology. However, the existing laws and regulations are mostly based on uniform principles, and the classification standards and mandatory measures of "enhancement" and "therapeutic" gene editing technology need to be improved.

The level of punishment is an important means to ensure the effective implementation of the law. For behaviors that violate the relevant legal provisions on gene editing technology, penalties should be increased and the cost of violating the law should be raised. For illegal gene editing of germ cells that causes serious social harm, it should be included in the scope of "crimes against public security". Consideration should be given to creating the "crime of misuse of gene editing technology" under the crime of endangering public security, and severe penalties should be imposed.[12] In addition to administrative penalties, organizations and individuals involved in gene-editing clinical trials should be subject to an industry banning system, prohibiting them from engaging in relevant scientific research and medical activities for a certain period. Through severe punitive measures, a strong legal deterrent will be formed to ensure that gene editing technology operates on a legal track.

7.3 Whole-Process Supervision and Lifelong Tracking

In terms of whole-process supervision, a multisectoral coordinated supervision mechanism should be established. In the basic research stage of gene editing technology, scientific research management departments should conduct strict review of research projects. In the clinical trial stage, health departments should strengthen the supervision of the trial process. Meanwhile, modern information technology should be used to establish an information platform for the regulation of gene editing technology, so as to realize the sharing of information among various regulatory departments to facilitate synergy. A lifelong tracking mechanism is an important measure to safeguard the safety of gene editing technology. For patients undergoing gene editing treatment, medical institutions should set up lifelong health records to regularly track patients' physical conditions and monitor whether gene editing has produced any long-term adverse effects. The lifelong tracking mechanism not only helps to identify and resolve technical risks in a timely manner, but also provides a scientific basis for subsequent technical improvements and policy adjustments.

8 Conclusion

As a cutting-edge technology in the field of life sciences, the development of human gene editing technology is full of possibilities and challenges. It not only has brought hope for overcoming difficult and complicated diseases and promoting the progress of life sciences, but also has triggered many risks and controversies. In the face of these loopholes to be solved, we not only need the efforts of the scientific and legal communities, but also the extensive participation and common concern of the whole society. Through the cooperation of all parties, the construction of a fully transparent monitor-

ing process, and the improvement of laws and regulations, the human gene editing technology can truly become a useful tool for the benefit of human society and bring more possibilities for human health and future development.

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