Journal of Biosafety and Biosecurity 5 (2023) 8–13

Contents lists available at ScienceDirect

Journal of Biosafety and Biosecurity

journal homepage: www.keaipublishing.com/en/journals/journal-of-biosafety-and-biosecurity/

Research Article

Human genome editing after the "CRISPR babies": The double-pacing problem and collaborative governance

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ARTICLE INFO

Article history:
Received 6 October 2022
Received in revised form 4 December 2022
Accepted 15 December 2022

Keywords:
Human genome editing
CRISPR babies
Double-pacing problem
Collaborative governance
China

ABSTRACT

How to ensure the safe, effective, and ethical use of emerging biotechnologies, such as clustered regularly interspaced short palindromic repeats (CRISPR)-based genome editing, is a global challenge. The occurrence of the "CRISPR babies" in 2018 publicly brought this issue into sharp focus, and led to comprehensive regulatory reforms in China and various countries around the world. The current article analyzes this event-driven regulatory reform in China by elaborating the most salient provisions designed to prevent risk and protect individual rights, public health, and social morality relating to human genome editing in four important sectors of law: biosecurity law, civil code, criminal law and patent law. It highlights that, although regulation is being undertaken, the gaps between the law and advancing technology remain discernible, at both a national and transnational level (i.e., the "double-pacing problem"). Further attention and collaboration will be required to address the ongoing challenges associated with the use of human genome editing.

1. Introduction

Human genome editing, the precise alteration of targeted deoxyribonucleic acid (DNA) sequences in living human cells, is associated with major opportunities and serious concerns. Debates about the related ethical, legal, and societal implications and policies go back several decades.[1] Since 2006, the International Society for Stem Cell Research (ISSCR) has issued four versions of the *Guidelines for the Conduct of Human Embryonic Stem Cell Research and Clinical Translation*, promoting professional practice with respect to science and ethics.[2] In its 2016 Guidelines, the ISSCR clearly stated that any attempt to modify the nuclear genome of human embryos for the purpose of human reproduction is "premature and should be prohibited at this time."[3] In its most recent 2021 Guidelines, the ISSCR reaffirmed this position on heritable human genome editing for reproductive purposes and further recommended that another five types of research relating to human embryos should not be allowed because of a lack of "compelling scientific rationale" or because the research is "ethically concerning."[4] Because these Guidelines are inspirational and adherence is voluntary, they might have an impact on national laws and regulations but cannot supersede them.

Additionally, national academies of sciences around the world have published advices regarding national governance on human genome editing (particularly heritable genome editing). For instance, the United States National Academy of Medicine, the United States National Academy of Sciences, and the Royal Society of the United Kingdom provided recommendations regarding appropriate oversight of the practice of heritable human genome editing and have promoted shared responsibility regarding the clinical use of this technology.[5] A sense of urgency for strengthening the oversight mechanisms of human genome editing is observable in the scientific community. However, national regulatory actions often lag behind relevant scientific advances, representing a phenomenon in technology regulation called the "pacing problem." This phenomenon refers to "the gap between the introduction of a new technology and the establishment of laws, regulations, and oversight mechanisms for shaping its safe development."[6] As

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https://doi.org/10.1016/j.jobb.2022.12.003
2588-9338/

illustrated in Section III, this phenomenon operates at the national and transnational levels in the context of human genome editing. In the article, we refer to it as the "double-pacing problem."

The double-pacing problem gathered momentum in mainstream media in November 2018 when Chinese biophysicist, Dr. He Jiankui, alarmed the world by announcing that his team had altered early-stage human embryos using clustered regularly interspaced short palindromic repeats (CRISPR)-Cas9 in an attempt to confer resistance to human immunodeficiency virus (HIV) infection.[7] These embryos were implanted in a woman's body, and two "CRISPR babies" were born.[7] This research was unequivocally condemned by scientists in China and worldwide, who argued that the experiment was unjustified, unnecessary, and even reckless, because a safer and more thoroughly tested method (antiviral drug treatment) can already be used to control HIV infection.[8] The condemnation was contagious, and immediately translated into a public narrative that tapped into widely held beliefs among the public about the importance of naturally-born babies, and accelerating anxieties about human lives being threatened by the unstoppable March of biotechnology advances. As Michael Schiller observed, narratives with contagious elements can "travel the globe and go viral in milliseconds" and have "profound effects on human behavior."[9]

The event of the CRISPR babies prompted Chinese regulators to take a series of actions to systematically address the related multidimensional risks and narrow the regulatory gap regarding the uptake of emerging biotechnologies, including human genome editing. The article provides a comprehensive analysis of this event-driven regulatory reform in China. It focuses on the most salient regulations, describing their features and the challenges of implementation, particularly the much-overlooked double-pacing problem. This analysis is helpful for reassessing responses in China and various countries around the world regarding the use of human genome editing and related emerging biotechnologies.

2. Governing human genome editing after the CRISPR babies

Human genome editing takes two main forms, and each presents a different risk profile. In somatic human genome editing, DNA in a person's body cells is changed, which only affects that individual. In heritable human genome editing, DNA in embryos, sperm or egg cells is changed, which may result in changes in that person and across generations. As recommended by the World Health Organization (WHO), good governance should consider the specific challenges inherent in the different types of human genome editing, whether for research or for reproduction. However, at the national level, regulators generally do not have the capacity to respond to such specific challenges in a timely manner, and thus prefer to implement baseline strategies to prevent risks and harm associated with the use of the technology, or to delay regulatory actions until they are better informed and better positioned to intervene.[10] Before the occurrence of the CRISPR babies, human genome editing was primarily governed by ethical guidelines in China. For instance, the *Ethical Guidelines for Human Embryonic Stem Cell Research* (2003) prohibited genetic manipulation of human gametes, zygotes, and embryos,[11] and required that the period of *in vitro* culture not exceed 14 days from fertilization or nuclear transfer to conduct research on human embryonic stem cells.[12] However, this normative instrument imposed mild sanctions on violation, and enforcement was lax.

This approach to human genome editing in China was disrupted by the advent of the CRISPR babies, which triggered a comprehensive regulatory reform to address concerns about the potential impact of human genome editing on individuals and society as a whole. Essentially, the reform established a whole-process risk prevention system through creating new law or amending extant law across multiple areas, including specific provisions in the new *Biosecurity Law*, *Civil Code*, and updated *Criminal Law* and *Patent Law*. The reform also allocated oversight authority to several agencies. The National Health Commission (NHC) and Ministry of Science and Technology (MOST) are responsible for jointly supervising human stem cell research. The MOST also supervises the utilization and trial of human genetic resources, and the Drug Administration of the NHC is responsible for the ethical review of national drug clinical trials.

This section will elaborate the most salient provisions in the *Biosecurity Law*, *Civil Code*, *Criminal Law* and *Patent Law*, as well as a set of soft laws used to fill regulatory gaps.[13] These laws are promulgated by the National People's Congress and its Standing Committee (NPC), and constitute the top level of the three levels of law within China's legal system (the other two levels are administrative regulations and local statutes). This indicates the significance of biosafety and biosecurity in the view of Chinese legislators. Within the legal system, existing and future lower-level administrative regulations and local statutes should refine the laws promulgated by the NPC, and the laws at the same level should address different dimensions of the concerns associated with human genome editing.

2.1. Risk-based protection under Biosecurity Law

As a reaction to the CRISPR babies, the *Biosecurity Law* was proposed and, later, the COVID-19 pandemic expedited this legislative process in China. Promulgated in October 2020, the law lays out the contour of China's biosecurity governance that makes a clear commitment to a whole-process of risk prevention through collaboration among relevant stakeholders.[14] This law covers eight major areas associated with the life sciences: (a) infectious disease prevention and control; (b) regulating research and applications related to biotechnology; (c) biological laboratory safety and practices; (d) protecting biological resources and human genetic resources; (e) preventing invasive species and preserving biodiversity; (f) tackling drug resistant microbial infections; (g) deterring bioterrorism; and (h) other activities related to biosecurity.[15] Human genome editing squarely fits in category (b). In such situations, a tiered risk management system is required to address issues ranging from risk monitoring and early warning systems, information sharing and publicizing mechanisms, and emergency responses at the national, local, and institutional levels. Accordingly, all biological research and development activities are categorized into three levels: high-risk, medium-risk, and low-risk, according to the degree of potential harm to public health, industries, agriculture, and ecosystems.[16] High-risk and medium-risk activities shall be conducted in an organization with necessary approval in accordance with the law, and relevant risk assessment, prevention and control plans should be in place for such activities.[17] The State Council is designated to take measures to manage the risks that jeopardize public health, biological resources, and ecosystems.[18].

Most provisions in the *Biosecurity Law* are framed broadly with the aim of applying to all relevant activities that go beyond a particular biotechnology. There are three aspects that are particularly relevant to human genome editing. First, the *Biosecurity Law* legalizes bioethics in the four scenarios: (a) all research institutions, enterprises, and universities shall incorporate biosecurity laws, regulations, and knowledge into educational and training programs, to raise bioethical awareness of students and professionals;[19] (b) those engaged in the research, development, and application of biotechnology shall conform to ethical principles;[20] (c) research on new biomedical technology shall pass ethical

review;[21] and (d) the collection, preservation, use, and outbound supply of China's human genetic resources shall conform to ethical principles.[22] These principle-based provisions provide flexibility in response to ongoing scientific advances and evolving societal concerns. Second, legal liabilities for non-compliance are dramatically increased under the *Biosecurity Law* compared with previous ethical guidelines. For instance, individuals engaging in biological research, development and application activities that are prohibited by law shall be ordered to stop the illegal act, and illegal income shall be confiscated, with a fine ranging from 1 to 10 million, or a fine of 10–20 times of the illegal income. Individuals directly responsible for the illegal act shall have their relevant practice certificate revoked and be banned from engaging in related biological research, development and application activities for 10 years or life, in accordance with law.[23] This change increases the level of deterrence for those who might be tempted to cross legal or ethical lines. Third, more laws and regulations are being or will be enacted to implement the requirements set in the *Biosecurity Law* that could further impact individuals and institutions relating to human genome editing activities. For example, the *Law on Scientific and Technological Progress* (2021) prohibits scientific and technological research, development and application activities that endanger national security, harm social and public interests, or violate scientific integrity and ethics. Individuals who seriously violate the rules are recorded in the national database of scientific integrity.[24] The scientific integrity record serves as an important basis for professional promotion, grants, and awards.[25] The National Health Commission released *Regulations on the Management of Clinical Application of New Biomedical Technologies* (2019) to establish an administrative approval system for the clinical application of gene editing technology to replace the filling system used before the occurrence of the CRISPR babies, and the *Measures for Ethical Review of Biomedical Research Involving Human Subjects* (2021) to further strengthen institutional ethical review, particularly regarding the safety and ethical concerns regarding experiments in biomedical research. Research proposals that fail the institutional ethical review are prohibited from being funded or conducted.

In addition to the legally-binding provisions, constantly updated soft laws are adopted to fill the gaps between regulations in various forms, including guidelines, recommendations and codes of conduct. The non-legally binding feature makes them more agile and cooperative with relevant stakeholders. *Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists* initially drafted by experts at Tianjin University Center for Biosafety Research and Strategy, set out 10 principles for scientists to responsibly engage in biological research activities. The Guidelines have been endorsed by the InterAcademy Partnership and disseminated to the 9th Review Conference of the Biological and Toxin Weapons Convention.[26].

2.2. Individual rights-based protection under the Civil Code

The occurrence of CRISPR babies brought about a debate about the protection of individual rights threatened by the emerging biotechnology in China. When the *Civil Code* was passed by the National People's Congress in 2020, it included a section on Personality Rights that tackles the legal challenges on the protection of personal integrity, freedom and dignity posed by scientific advances and potential misuse or abuse. [27]

In direct response to the public concerns regarding risk disclosure and informed consent in the CRISPR babies event, legislators added three provisions to address personality rights in relation to human genetic and embryonic research and medical services in the Code. Article 109 sets the fundamental principle of human dignity on the protection of personality rights.[28] This Article requires that when there is a conflict between the protection of inherent dignity of persons and the protection of property interests, the protection of inherent dignity of persons should be tilted.[29] How this legal principle can be applied to safeguard personality rights in the context of human genome editing, including the rights to life, inviolability, and integrity of the person, and the rights to health under the *Civil Code*, needs to be tested in future court judgments. Article 1008 and Article 1009 jointly reconstruct the existing guidelines on clinical trials and scientific research involving humans in China. Article 1008 requires that "[w]here a clinical trial is needed for developing new drugs and medical devices or developing new prevention and treatment methods, upon approval of the relevant competent authorities and the examination and approval of the ethics committee, the participants or the guardians thereof shall be informed of the details including the purposes, methods, and the possible risks of the trial, and their written consent must be obtained."[30] Future clinical trials for developing new drugs or treatments based on human genome editing, like the experiment carried out by Dr. He Jiankui on the CRISPR babies, fall into the scope of this provision. Article 1009 lays out the requirements for conducting genetically related medical and scientific research. This article holds that "[m]edical and scientific research activities concerning human genes, embryos, among others, shall be carried out according to the laws and relevant regulations issued by the PRC, without endangering human health, violating moral principles, or damaging public interests."[31] This all-complied provision can be used to integrate relevant laws and regulations, enacted before or after the *Civil Code*, when it is applied to a specific case. For instance, the *Basic Healthcare and Health Promotion Law* (2019) elaborates the informed consent and related rights of individuals in medical services, and imposes an obligation to respect these rights on multiple stakeholders who could affect them, including medical and healthcare institutions and professionals. [32] Those who fail to fulfill this obligation or violate medical ethics during the process of conducting medical research or delivering medical and healthcare services shall be subject to various disciplinary actions or sanctions in accordance with law.[33] Compared with previous ethical guidelines on human genome editing before the CRISPR babies, the new regulations build a more solid legal foundation for civil actions against non-compliance regarding respecting the right to informed consent and other related rights in medical services and research. Article 990 of the *Civil Code* further recognizes the inexhaustible nature of personality rights and emerging claims that are not enumerated in the current law but are equally worthy of protection. This provides a pathway for the extension of legal protection to emerging personality rights and claims in accordance with the Code.[34].

2.3. Public health-based protection under the Criminal Law

In 2019, Dr. He Jiankui and two team members were convicted of "illegal medical practice" according to Article 336 of the *Criminal Law of the PRC*, which prohibits illegally engaging in medical practice without obtaining qualification for medical practice when the circumstance is serious.[35] The case signified the inadequacy of offenses tailored to human gene editing in the extant criminal law. Two new offenses on human genetics were adopted to fill this regulatory gap through the XI Amendment of the *Criminal Law* promulgated in December 2020.[36]

One new offense is the "illegal implanting genetically edited or cloned human embryos," which was added to Article 336 of the *Criminal Law*. The wording stipulates that "**[**w]hoever implants any genetically edited or cloned human embryo into the body of a human being or animal or implants any genetically edited or cloned animal embryo into the body of a human being shall, *if the circumstances are serious,* be sentenced to imprisonment of

not more than three years or limited incarceration and a fine or be sentenced to a fine only; or *if the circumstances* are *especially serious*, be sentenced to imprisonment of not less than three years nor more than seven years and a fine."[37] This open-textured provision does not presuppose the violation of laws, administrative regulations or departmental rules, but specifies that merely engaging in the behaviors prohibited herein can lead a person to be held criminally liable *if the circumstances are serious*. What constitutes a "serious circumstance" is open to assessment by judges on a case-by-case basis. Judges may take into account various regulations, interests, and concerns, which might change over time. The offender committing this crime could be anyone who engages in the prohibited behaviors, regardless of whether the person has the qualifications for medical practice. Notably, the regulators chose not to grapple with the difficult decisions regarding the criteria or boundaries between permitted and prohibited uses of human genome editing, but to focus on very specific behaviors related to human genome editing. The regulators appeared to be very cautious about setting the criteria or boundaries at this stage, to avoid over-inclusiveness or causing unnecessary restriction on the trajectory of technological development.

Another new offense is the "illegal collecting or transporting human genetic resources," added to Article 334 of the *Criminal Law*. This offense prohibits anyone from illegally collecting, mailing or carrying human genetic resources in or out of China. Similarly, what constitutes "illegally collect, mail or carry human genetic resources" under this provision is open to comprehensive assessment on a case-by-case basis.[38] Judges in a specific case may take into account all relevant regulations, interests and concerns to draw a conclusion regarding illegality under this provision.

2.4. Social moral-based protection under the Patent Law

The *Patent Law of the PRC* restricts the patentability of inventions for modifying the human germline on the basis of social-moral grounds, which further discourages individuals and institutions from engaging in such activities. Article 5 (1) of the *Patent Law* requires that no patent shall be granted for an invention that "contravenes any law or social morality or that is detrimental to public interests."[39] The term "social morality" in this provision is amenable to new social realities, including new technologies. The *Guidelines for Patent Examination* of the China National Intellectual Property Administration recognize that the connotation of social morality is based on a certain cultural background, which is "constantly changing with the passage of time and social progress, and varies from region to region."[40] Thus, Article 5 remains applicable to preclude the patentability of inventions that modify the human germline in China.[41] This Article also precludes the patentability of inventions that are based on genetic resources if the access or utilization of the resources is in violation of any law or administrative regulation.[42]

3. Discussion

The discussed regulations reflect Chinese regulators' concerns regarding the use of human genome editing after the CRISPR babies in China. In the face of uncertainties of its trajectory of development and implications at this stage, the regulators appear to be highly conscious of the impact of the regulations. The regulators resisted the urge for overregulation and chose to set necessary guardrails to ensure that appropriate legal protection is in place for those most in need of potential benefits of human genome editing or those most likely to experience its potential harms. They deployed necessary legislative techniques, such as using principle-based, all-complied and open-textured provisions, to increase the adaptability of the regulations while avoiding the creation of a chilling effect in the field.[43] Under the legal framework, beneficial use of human genome editing is warranted and certain harmful use is prohibited. The impact of the legal framework on the potential direction of gene editing in China is contingent on how these regulations are interpreted, applied, and further developed.

Because the technology is constantly evolving with an unpredictable trajectory, a major challenge to this regulatory approach is how to implement the regulations that are primarily principle-based, all-complied, or open-textured in a specific circumstance, to achieve the legislative purpose: preventing misuse of this technology without hindering its beneficial outcomes. Scholars have suggested that a unified law for governing activities in this field should be developed in China, as it has been in the United Kingdom, Germany, and Canada.[44] However, such a unified law might not be better at keeping up with the pace of this technology, when its relevant technical, societal and ethical implications continue to unfold and have globe reach. In other words, the pacing problem in regulating human genome editing exists at both the national and transnational levels (i.e., the double-pacing problem), which indicates the inherent difficulties in governing the use of this technology.

3.1. The pacing problem at the national level

The Chinese approach to governing human genome editing after the occurrence of CRISPR babies may be characterized as being both reactive and proactive. This approach entails not only the judgment of regulators regarding the recognizable risks of the technology at this stage, but also adaptive regulations carefully created to integrate future technical and societal changes. However, it should be noted that the pacing problem co-exists with the regulations. One type of pacing problem is the result of technological inventions outpacing relevant regulations, making the latter insignificant over time. For instance, the new offense added to Article 336 of the *Criminal Law* prohibits implanting any genetically edited or cloned human embryo into the body of a human being or animal or implanting any genetically edited or cloned animal embryo into the body of a human being. It is arguable whether the ultimate aim of this provision is to prohibit the implanting behavior *per se,* or also to prohibit the result of the behavior (producing human-animal chimeras). Recently, Chinese scientists generated human-monkey chimeric embryos with human pluripotent stem cells but cultured them *ex vivo* for 19 days, which made this question highly relevant.[45] If the provision is intended to prevent anyone from producing a human-animal chimera by genetically editing embryos, the provision appears to fail to anticipate new technological innovations for culturing the genetically edited embryos *ex vivo,* which could potentially be used to circumvent this provision. From time to time, more technological inventions may pose new possibilities for using human genome editing that could harm significant individual rights and public health, potentially going beyond the situations comprehended by regulators while drafting the law.

The other type of pacing problem is the result of regulators' desire to avoid overregulating an emerging technology. To maintain a delicate balance among the different interests at stake, regulators should resist the urge to overregulate and consciously delay regulatory actions until they are better-informed or positioned, especially when the relevant issue has yet to become a high priority. For instance, Article 1009 in the *Civil Code* uses the general terms of "medical and scientific research activities concerning human genes, embryos, among others," instead of classifying human genome editing as human somatic editing, germline genome editing, and human epigenetic editing, to separately address

more nuanced but different concerns arising from each type of human gene editing, as the WHO did in its report on the framework for governance of human genome editing.[46] In addition, some broader social issues, such as equitable access to the benefits associated with human genome editing, remain unaddressed. Collective efforts from all stakeholders are needed to tackle the inevitable frictions between law and the technology, including the use of informal governance mechanisms, such as ethical guidelines, best practices, peer review and institutional decisions, which must be constantly updated to keep up with the pace of technical and social change. How to utilize these informal mechanisms to shape responsible conduct of practitioners is another issue deserving attention for good governance of human genome editing.

3.2. The pacing problem at the transnational level

Given the global reach of genome editing technology, robust collaboration is necessary, not only at the national level but also at the transnational level. However, the reality is that each country differs in terms of capacity and interest in governing human genome editing. Meanwhile, global technological "innovation arbitrage" is more attractive than ever, by which innovators move to jurisdictions that provide regulatory environments that are more hospitable to entrepreneurial activities.[47] To gain competitive advantages, some countries could deliberately slow down regulations on emerging technologies to attract innovators to their jurisdictions. This complicates the pacing problem in relation to human genome editing.

A recent survey revealed that only 75 of 106 states examined in the study have prohibited the use of genetically modified *in vitro* embryos to initiate a pregnancy (70 countries prohibited it outright, while five allowed for possible exceptions), while other states did not have clear prohibitions or had no relevant information available regarding the issue. [48] Differences in approaches to governing this technology between countries makes it possible for certain human genetic interventions to be illegal or unethical in some countries but legal or entirely unregulated in other countries. To some extent, this gap of regulations across countries is justifiable because countries may have very different social, ethical, or legal circumstances; however, a risk of manipulation obviously exists. The WHO has identified the risks associated with travel to destination countries with limited or no regulation, including the following risks: the technology may be oversold by unscrupulous entrepreneurs in jurisdictions without the capacity to oversee their operation; people may be enticed to engage in unproven and possibly dangerous interventions with no expected benefit; and potentially harmful research might be deliberately moved to countries with little or no oversight. [49] To minimize the cross-border regulatory arbitrage and risks, internationally coordinated efforts for developing robust oversight mechanisms are needed for human genome editing.

The WHO has taken the lead in this regard, launching the *Human Genome Editing Registry* in March 2019, proposing recommendations for developing global standards for governance and oversight of human genome editing in 2021,[50] and providing guidance regarding the responsible use of life sciences in 2022.[51] The Registry collects information about clinical trials using human genome editing worldwide and makes it available to all interested stakeholders. Thus far, there are only 130 records of trials in the database.[52] The recommendations and guidance are inspirational, subject to states' discretion regarding how to integrate them into their national measures. Moreover, some aspects of governance on human genome editing go beyond the mandate of the WHO. This requires political will from the WHO member states to expand the current mandate or take other measures to bridge regulatory differences between countries. For example, the call for an international mechanism to raise concerns about possibly illegal, unethical or unregistered practices of human genome editing in jurisdictions with a lack of regulations has been made for several years following the event of the CRISPR babies, and this has not yet been established.[53] In the absence of such international mechanisms, some countries may be reluctant to take necessary measures to respond to such risks.

4. Conclusion

Human genome editing is not the first technological development to provide transformative opportunities as well as multidimensional risks to individuals and societies. In vitro fertilization, cloning, embryonic stem cells, and other technologies have the same dual-use features. As scientists continue to discover novel gene editing tools, our understanding of human genome editing must keep changing. An updated narrative is necessary to ensure that the promises and risks of technologies are not understated, misrepresented, or overstated.

In the current article, we described the regulatory reforms in China regarding biosecurity in general, and human genome editing in particular, after the occurrence of CRISPR babies, as an example to address concerns about the use of this technology. There is no universally ideal approach for governing human genome editing. Each country faces different challenges to balance benefits and potential risks regarding the use of human genome editing. Additionally, each country needs to improve its own status quo, as well as engaging in international collaboration. If this effort is undertaken, the double-pacing problem in the governance of human genome editing identified in the current article could be effectively addressed, nationally and internationally.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

This research was supported by grants from the National Key Research and Development Program of China (Grant nos. 2019YFA0904600 and 2020YFA0908600).

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