Journal of Zhejiang University-SCIENCE B (Biomedicine & Biotechnology)
ISSN 1673-1581 (Print); ISSN 1862-1783 (Online)
www.jzus.zju.edu.cn; www.springerlink.com
E-mail: jzus@zju.edu.cn

Viewpoint:

Experiments that led to the first gene-edited babies: the ethical failings and the urgent need for better governance*

Jing-ru LI[1], Simon WALKER[1], Jing-bao NIE[1], Xin-qing ZHANG[†‡2]

[1]*Bioethics Center, Dunedin School of Medicine, University of Otago, Dunedin 9016, New Zealand*

[2]*School of Humanities and Social Sciences, Peking Union Medical College, Beijing 100730, China*

[†]E-mail: xqzhang@pumc.edu.cn

Received Dec. 16, 2018; Revision accepted Dec. 23, 2018; Crosschecked Dec. 29, 2018

Abstract: The rapid developments of science and technology in China over recent decades, particularly in biomedical research, have brought forward serious challenges regarding ethical governance. Recently, Jian-kui HE, a Chinese scientist, claimed to have "created" the first gene-edited babies, designed to be naturally immune to the human immunodeficiency virus (HIV). The news immediately triggered widespread criticism, denouncement, and debate over the scientific and ethical legitimacy of HE's genetic experiments. China's guidelines and regulations have banned germline genome editing on human embryos for clinical use because of scientific and ethical concerns, in accordance with the international consensus. HE's human experimentation has not only violated these Chinese regulations, but also breached other ethical and regulatory norms. These include questionable scientific value, unreasonable risk-benefit ratio, illegitimate ethics review, invalid informed consent, and regulatory misconduct. This series of ethical failings of HE and his team reveal the institutional failure of the current ethics governance system which largely depends on scientist's self-regulation. The incident highlights the need for urgent improvement of ethics governance at all levels, the enforcement of technical and ethical guidelines, and the establishment of laws relating to such bioethical issues.

Key words: Jian-kui HE; Human germline gene editing; Human immunodeficiency virus (HIV); Clustered regularly interspaced short palindromic repeat (CRISPR)-Cas9; Ethical review

https://doi.org/10.1631/jzus.B1800624 **CLC number:** B82-057

1 Introduction

With the support of central and local governments and various institutions, science and technology in China has been advancing rapidly over recent decades, particularly in the area of biomedical research. With this progress, numerous and extensive ethical challenges have arisen and will continue to arise. Bioethics and governance of ethical issues in China have also developed quickly to meet these challenges, but they have not kept pace. A more robust system of ethical governance is now required. This need is made clearly evident in the genetic experimentation recently undertaken by Jian-kui HE and his team.

HE claims to have produced the world's first germline gene-edited babies, and that these babies are naturally immune to the human immunodeficiency virus (HIV). These claims are yet to be confirmed independently. Irrespective of whether they are proved correct, they raise a large number of serious global ethical concerns. These concerns are complex and interrelated but may be broadly mapped into the following four categories: (1) key issues related to biomedical research ethics; (2) broader political,

‡ Corresponding author

* Project supported by the National Natural Science Foundation of China (No. L1824000)

ORCID: Jing-ru LI, https://orcid.org/0000-0003-4484-4320; Xin-qing ZHANG, https://orcid.org/0000-0002-8225-3516

socio-cultural and transcultural issues; (3) fundamental ethical problems on germline gene-editing reproduction itself; and (4) fundamental questions about the moral goals of science and technology. This paper will not cover each of these broad categories but will focus on the first and the third. After we briefly outline the Chinese responses to HE's announcement, we will argue that his experimentation breaches many well-established Chinese and international ethical norms relating to human germline editing and clinical research. We also discuss the institutional ethical failings involved in this case and what they mean for the systems of ethical governance in China and conclude that improvements are urgently needed.

2 Chinese responses to the news of the world's first gene-edited babies

On 25 November 2018, two days before the Second International Summit on Human Genome Editing in Hong Kong, Jian-kui HE, a Chinese researcher of the Southern University of Science and Technology, released a video on YouTube announcing that he and his colleagues have "created" the world's first genetically altered babies, Lulu and Nana.

HE explained the details of his experiment in his address at the Hong Kong conference. HE and his team had recruited eight couples through an HIV volunteer group named Baihualin (BHL) China League (one couple later withdrew from the research). All the male participants are HIV-positive, and all female participants are HIV-negative. The participants' sperm was "washed off" to get rid of HIV and then injected into eggs collected from the female participants. By using clustered regularly interspaced short palindromic repeat (CRISPR)-Cas9, a gene editing technique, they disabled a gene called *CCR5* in the embryos, aiming to close the protein doorway that allows HIV to enter a cell and make the subjects immune to the HIV virus. The process led to at least one successful pregnancy and the birth of the twin baby girls.

The news was rapidly reprinted by Chinese media. At first, HE's research was promoted as a dramatic scientific advancement. For example, People's Daily Online, the most influential newspaper in the Chinese mainland, described HE's research as "a historical breakthrough in the application of gene editing technology for disease prevention" (SinaTech, 2018). However, as more detailed information about HE's research was unveiled by the media, its legitimacy was increasingly challenged by scientists, bioethicists, lawyers, and the general public, both in China and internationally.

On the night of 26 November, 122 Chinese scientists issued a statement strongly condemning HE's action as unethical. They stated that while CRISPR-Cas is not a new technology, it involves serious off-target risks and associated ethical considerations, and so should not be used to produce gene-altered babies. They described HE's experiment as "crazy" and "a huge blow to the global reputation and development of Chinese science". The Scientific Ethics Committee of the Academic Divisions of the Chinese Academy of Sciences posted a statement declaring their opposition to any clinical use of genome editing on human embryos, noting that "the theory is not reliable, the technology is deficient, the risks are uncontrollable, and ethics and regulations prohibit the action". The Chinese Academy of Engineering released a statement on 28 November, calling on scientists to improve self-discipline and self-regulation, and to abide by corresponding ethical principles, laws, and regulations. Finally, the Chinese Academy of Medical Sciences published a correspondence in *The Lancet*, stating that they are "opposed to any clinical operation of human embryo genome editing for reproductive purposes" (Wang et al., 2018).

At the Second International Summit on Human Genome Editing in Hong Kong, Ren-zong QIU, an eminent Chinese bioethicist, described HE's research as "a practice with the least degree of ethical justifiability and acceptability". QIU described that HE's research was conducted on healthy embryos with the aim of making the baby immune to the HIV virus, and this constitutes gene enhancement for medical purposes. This further indicates the cavalier nature of HE's research, as there is currently broad opposition to the idea of gene enhancement, and national or international agreement seems a long way off.

The news also attracted the attention of the general public in China. Though most people do not fully understand the science behind the procedure, they are concerned about the welfare and health of the

twin girls, and the potential adverse consequences to humanity.

The authorities in China promised a stringent investigation of HE's research. Nan-ping XU, vice minister of China's Ministry of Science and Technology, noted that China "explicitly banned" clinical procedures of gene-editing on human embryos for reproductive purposes and ordered a halt to the "scientific activities of relevant personnel". China's National Health Commission has requested the Guangdong Provincial Health Commission to investigate and verify HE's assertions.

3 Breaching Chinese and international ethical conventions on human gene editing

There are three genome modifying techniques: zinc-finger nucleases (ZFNs), transcription activator-like effectors nucleases (TALENs), and CRISPRs. HE used the CRISPR-Cas9 technique to modify the babies' germline gene. Compared with the other two techniques, CRISPR-Cas9 is faster, less expensive, and more precise. Nevertheless, the explicit prohibition of a clinical application of the technique for human germline gene editing is primarily based on concerns about the efficacy and safety of gene editing technology. In other words, though CRISPR-Cas9 is the best gene manipulation technique currently available, its targeting efficiency is still inadequate. For example, the efficiency of CRISPR-Cas9 is 20%–30% on monkey zygotes and less than 5% in mice zygotes (Wu et al., 2013; Baumann, 2016). One study involving human embryo editing shows an efficiency rate of 15% for single gene correction (Liang et al., 2015).

Besides inefficiency, there are other technical problems with CRISPR-Cas9, including off-target mutations, mosaicism, and on-target mutations with unwanted consequences. Researchers have found that off-target mutations could cause defects, disabilities or even cancer in some cases (Kim et al., 2015; de Miguel Beriain and del Cano, 2018). "Mosaicism" induced by genome editing can lead to more than one genotype being present in the single organism, which reduces any therapeutic effects (Baumann, 2016). Furthermore, these side effects are hard to identify and assess, which makes it difficult to predict, prevent, or manage related consequences. In Jian-kui HE's address at the Hong Kong conference, he reported that one off-target site was detected by whole gene sequencing in one embryo. The off-target site was not identified by Sanger sequencing and deep sequencing in the baby's cord blood, but it is as yet unknown what effects this once-detected off-target site will bring to the girl. Additionally, a particular concern about germline gene editing is that unintended and undesirable changes on germline cells may be passed on to offspring, which might result in unforeseen effects on future generations. Though there are different views on this, it warrants serious consideration, considering how many aspects of genome modification remain uncertain, and how much remains unknown about the nature of gene functioning.

Due to these technical limitations, China has issued several regulations prohibiting genome modification on human embryo for reproductive purpose. "The Technical Norms on Human Assisted Reproduction" and "The Ethics Principles for Human Assisted Reproductive Technology and Human Sperm Bank" issued by the former Ministry of Health (MOH) in 2003 stipulate that "genetic manipulation of human gametes, zygotes and embryos for reproductive purposes is prohibited". "The Guiding Principles of Ethics for Human Embryonic Stem Cell Research", issued jointly by the Ministry of Science and Technology and the former MOH in 2003, stipulates that "(1) blastocysts obtained by in vitro fertilization, somatic cell nuclear transplantation, single-sex replication technology or genetic modification shall not be cultured for more than 14 d after fertilization or transplantation; (2) the human blastocyst for research shall not be implanted into the reproductive system of a human or any other animal."

The First International Summit on Human Gene Editing was held in 2015. At this summit the Chinese Academy of Sciences, the UK Royal Society, and the US National Academy of Sciences came together and agreed several policies on human gene modification. One of these is to call for a moratorium on human germline genome modification for clinical use unless and until: "(1) the relevant safety and efficacy issues have been resolved, based on appropriate understanding and balancing of risks, potential benefits, and alternatives, and (2) there is broad societal consensus about the appropriateness of the proposed application."

This constrained approach towards human gene editing and human germline gene editing was restated at the second international summit, though in more positive terms. For instance, while the second summit's statement reasserted the consensus that "the scientific understanding and technical requirements for clinical practice remain too uncertain and the risks too great to permit clinical trials of germline editing at this time", strongly prohibitive terms such as "ban" and "moratorium", included in the initial statement, were omitted, and the following was added: "progress over the last three years and the discussions at the current summit, however, suggest that it is time to define a rigorous, responsible translational pathway toward such trials." This is probably why George DALEY, the Dean of Harvard Medical School and a member of the summit's leadership, described HE's research as "a wrong turn on the right path" and proposed that "it's time to start outlining what an actual pathway for clinical translation would be."

It is unknown how long it will take germline gene editing to get used in clinical research, but the nuanced shift in attitude might suggest that the realization is around the corner. Nevertheless, despite these more moderate views on the clinical use of genome modification on human germline, the consensus at the Hong Kong conference was that it is "irresponsible" to proceed with human germline genome editing for clinical use at this stage. HE's research clearly goes against this. Moreover, HE's research is aimed at making the babies immune to the HIV virus, which as noted by QIU, seems to be an "enhancement" of questionable value. As mentioned, there is no consensus over the ethics of genetic enhancement, whether for medical or non-medical purposes, and most scientists and bioethicists are conservative about the idea.

4 Specific ethical issues with HE's research

Apart from these general scientific and ethical challenges that are faced with human germline gene editing, HE's research presents other ethical and regulatory issues.

4.1 Questionable scientific and therapeutic benefit

Scientific research on the functions of the *CCR5* gene is in the early stage, and its role is far from fully understood. *CCR5* has been found to play a "bad role" in HIV infection and the *CCR5* Δ32 mutation could block the entry of HIV into cells (Bauer and Anderson, 2014). Allers et al. (2011) have reported an apparent cure of an HIV-positive patient with leukemia after receiving the transplant of bone marrow with *CCR5* Δ32 mutation. The success of this study generated increased scientific interest in the possibility of treating acquired immune deficiency syndrome (AIDS) with *CCR5* Δ32 deletion (Liu et al., 2012; Tebas et al., 2014). However, HIV is a highly mutable virus and *CCR5* is not the only chemokine co-receptor for HIV virus entry. Li et al. (2014) have found that CRF01_AE, a major HIV-1 subtype in Chinese HIV-1 sexually infected patients, might be attributed to a high proportion of *CXCR4*, a different type of HIV co-receptor. This result suggests that *CCR5* knockout does not necessarily prevent Lulu and Nana from getting HIV infection. It is not known whether *CCR5* knockout will bring other risks, and it is premature to think that modification of this kind on human embryos will be of benefit to the persons born.

Another factor to consider is that the enrolled male participants were currently receiving standard HIV treatment, and so the infection was "deeply suppressed", which meant that there was only a small chance of it being transmitted to offspring. In contrast with the high-risk and expensive gene modification treatment, there are more effective, more accessible, and cheaper methods to prevent transmission of HIV, such as antiretroviral drugs and sperm washing, the technique which has been used in this experiment. In other words, to prevent HIV transmission by gene-editing is nothing but "shooting birds with cannon", as commented by Prof. QIU. Furthermore, scientists questioned that HE's experiment has done anything but merely random deletions within *CCR5* locus, and that one child ended up as a heterozygous. Whether and how much these consequences will impact on the children's health is immeasurable and unpredictable. So, the germline gene modification on *CCR5* brings little substantial benefit to the babies, while exposing them and their future generations to unknown and uncontrollable risks.

The off-target effects are inevitable due to limitation of emerging biotechnology; therefore the germline gene-edited babies will no doubt take the risks of such side effects. This demonstrates that Jian-kui HE was well aware of the high incidence of off-target and the

potential adverse consequences induced by off-target effects but did not fully inform the participants of the potential harm. To subject research participants and others to such substantial risks, while providing no coping strategy or support, is a major breach of established international research standards.

4.2 Illegitimate ethics review procedure

Jian-kui HE claimed that he received ethical approval for his research from a private hospital: Shenzhen HarMoniCare Women and Children's Hospital. However, the Ethics Committee (EC) of this Hospital was not a registered committee, and so its apparent approval is all but meaningless, from a regulatory perspective. "The Ethics Review Measures for Biomedical Research Involving Human Subjects" issued by the China's former National Health and Family Planning Commission (NHFPC) in 2016 explicitly stipulates that "health care institutions shall register with their professional registration authorities within 3 months after the establishment of the ethics committee and register with the Medical Research Registry and Management System".

4.3 Problems with the information and consent processes

Though HE gained consent from his participants for inclusion in his study, the process he used is highly questionable. The consent form provided to the participants was reportedly a 23-page document, written entirely in English and full of technical words. It is likely that at least some of the participants would have had difficulty in understanding what they were consenting to. In addition, the consent sheet stated that: "all the costs generated from clinical trials will be paid by the project team. That is 280000 RMB, including lodging fee, charge for loss of working time, payments, and insurance expenses… However, any costs exceeding the budget will be paid by participants… If participants withdraw at the late stage of research, they must refund the payment spending on them. If the payment is overdue, the participants need to pay an additional fee of 100000 RMB as a fine." This requirement to repay expenses and the threat of a fine seriously compromise the participants' freedom to withdraw from the trial, and so violate the principle of voluntariness for research involving human subjects.

4.4 Other procedural failings

There were several procedural ethical problems with HE's study. Firstly, HE did not provide scientific evidence, such as a detailed report about his preclinical research on mice and monkeys, as a basis for the research on human embryos to EC. Such information is mandatory in an ethics application according to China's regulation. Secondly, HE began the medical trial long before he received approval (such as it was), which violates No. 24 Article of "The Ethics Review Measures for Biomedical Research Involving Human Subjects" that research should only proceed when ethical approval has been granted by an EC. Thirdly, HE's research was not registered at the Medical Research Registry and Management System. This violates the regulatory requirement that research project leaders should upload the main content of research and ethics review decisions for registration, before proceeding to trials.

5 Need to enhance the ethical governance of scientific practices in China

The series of ethical and procedural failings surrounding HE's study reveal the inadequacy of some ECs in China to review and govern research practices. The EC of Shenzhen HarMoniCare Women and Children's Hospital illegitimately approved a procedure that is clearly forbidden by relevant regulations. As stated before, certain regulations or ethical norms have made it very clear that genome editing in human embryo should not be used for pregnancy. In addition, "The Notice of The State Health and Family Planning Commission on Canceling the Approval of Admission of Clinical Application of Category III Medical Technology" released by former NHFPC in 2015 stipulates that medical technologies that involve problems with safety and efficacy, and significant ethical issues, should not be used for clinical purposes. Genome modification on human germline gene obviously falls into this type of technology. HE's research contains high risks with trivial benefits to subjects, and little innovative and scientific value; the rationale as well as the risk-benefit ratio of the research is far beyond the reasonable standard. According to "The Ethics Review Measures for Biomedical Research Involving Human Subjects",

research involving human beings should abide by the controlling risk principle: "personal safety and health rights and interests of subjects should be given priority, followed by scientific and social interests. The risk and benefit ratio of research should be reasonable, so that the subjects can avoid harm as far as possible."

It seems that some scientists, like Jian-kui HE, are ill-equipped to regulate themselves, perhaps due to a lack of ethical training. HE thought the fact that his participants "volunteered" for the procedure justified his research. This suggests that he was oblivious to the obligations that scientists have to protect research subjects from unnecessary and unreasonable risks. As mentioned, the rapid development of innovative medical technology in recent years continues to generate complex ethical challenges. Public and academic discussion of these challenges, and how they should be met, is desperately needed. We cannot rely on scientists to meet these challenges alone.

China has established a three-level ethics governance system to review and supervise biomedical research involving human beings. "The Ethics Review Measures for Biomedical Research Involving Human Subjects" stipulates that the National Medical Ethics Expert Committee, governed by the National Health Commission, undertakes research on significant ethical issues in biomedical research involving human beings, provides policy advice, and guides the ethics review work of provincial medical ethics expert committees. The provincial medical ethics expert committees assist in promoting the institutionalization and standardization of the ethics review of biomedical research involving human beings within the administrative regions. They are also required to guide, inspect, and assess the work of the EC engaged in biomedical research involving human beings in the administrative region, and to carry out training and consultation work. Local health administrative departments, at or above the county level, shall be responsible for the supervision and administration of the ethics review of biomedical research involving human beings in their administrative regions.

However, the actual capability of ethics governance varies from one EC to another. Some ECs do not have sufficient ethics capability to review and supervise research, as was the case with the EC of Shenzhen HarMoniCare Women and Children's Hospital. Especially since 2015, under the reform of administrative examination and approval system led by China's State Council, the main management responsibility for the clinical application of medical technologies containing technical difficulties and risks, or significant ethical risks, which were assumed by the former MOH, has been devolved to the EC. The reform sets a higher standard for ethics review and governance capacity of ECs. The EC's ethics review and governance capacity, and the oversight over ECs and provincial medical ethics expert committees need urgent improvements.

6 Conclusions

In conclusion, gene editing techniques are not sufficiently safe or effective to be used on human reproductive cell lines. Evidence for the safety and effectiveness of this technology can only be obtained through basic and preclinical research, on the basis of strictly following technical standards and ethical norms. The construction of regulations and laws should be accelerated to meet the rapid development of emerging biotechnologies. Existing technical and ethical guidelines should be refined and more rigorously enforced to guide and standardize relevant research and applications. The lessons of illegal stem cell therapy in the Chinese mainland in recent years should not be forgotten, and stakeholders must take actions on regulating CRISPR-Cas germline editing as early as possible (Zhang, 2016).

The academic community should respect the dignity of human life and remain sensitive to the risks that research can present to participants and the wider community. Biomedical researchers and practitioners must abide by the relevant regulations and laws and firmly hold to the well-established ethical guidelines for the safe translation of scientific results to human health. Building the ethical review capacity at all levels should be strengthened. Ethics education and training should be provided to researchers, medical practitioners, and EC members, and education programs on science and ethics should be provided to the general public.

We have entered the era of human gene therapy. Somatic gene editing has been used on patients for a long time, and it has helped improve the lives of cancer patients and patients with inherited genetic

diseases (Qiu, 2016; Dunbar et al., 2018). The clinical application of human germline gene editing is in the near future. We appeal to policy-makers to pay serious attention to the relevant issues, actively confront the challenges, and come up with a responsible and feasible pathway for clinical translation of human germline gene editing. Contemporary bioethics governance of human germline gene editing and other areas must by definition be transnational and global. More transcultural dialogues between China, the West and the rest of the world are much needed (Nie and Fitzgerald, 2016).

Contributors

Jing-ru LI and Xin-qing ZHANG both contributed to the original ideas of the paper. Jing-ru LI is the main contributor to the content of the work. Simon WALKER and Jing-bao NIE made contributions to the revision of the paper.

Compliance with ethics guidelines

Jing-ru LI, Simon WALKER, Jing-bao NIE, and Xin-qing ZHANG declare that they have no conflict of interests.

This article does not contain any studies with human or animal subjects performed by any of the authors.

References

Allers K, Hütter G, Hofmann J, et al., 2011. Evidence for the cure of HIV infection by CCR5Δ32/Δ32 stem cell transplantation. *Blood*, 117(10):2791-2799. https://doi.org/10.1182/blood-2010-09-309591

Bauer G, Anderson JS, 2014. Gene Therapy for HIV. Springer, New York, NY. https://doi.org/10.1007/978-1-4939-0434-1

Baumann M, 2016. CRISPR/Cas9 genome editing—new and old ethical issues arising from a revolutionary technology. *Nanoethics*, 10(2):139-159. https://doi.org/10.1007/s11569-016-0259-0

de Miguel Beriain I, del Cano AMM, 2018. Chapter 12 Gene editing in human embryos. A comment on the ethical issues involved. *In*: Soniewicka M (Ed.), The Ethics of Reproductive Genetics: Between Utility, Principles, and Virtues. Springer, Cham, p.173-183. https://doi.org/10.1007/978-3-319-60684-2_12

Dunbar CE, High KA, Joung JK, et al., 2018. Gene therapy comes of age. *Science*, 359(6372):eaan4672. https://doi.org/10.1126/science.aan4672

Kim D, Bae S, Park J, et al., 2015. Digenome-seq: genome-wide profiling of CRISPR-Cas9 off-target effects in human cells. *Nat Methods*, 12(3):237-243. https://doi.org/10.1038/nmeth.3284

Li YJ, Han Y, Xie J, et al., 2014. CRF01_AE subtype is associated with X4 tropism and fast HIV progression in Chinese patients infected through sexual transmission. *AIDS*, 28(4):521-530. https://doi.org/10.1097/QAD.0000000000000125

Liang PP, Xu YW, Zhang XY, et al., 2015. CRISPR/Cas9-mediated gene editing in human tripronuclear zygotes. *Protein Cell*, 6(5):363-372. https://doi.org/10.1007/s13238-015-0153-5

Liu SJ, Kong CJ, Wu J, et al., 2012. Effect of *CCR5*-Δ*32* heterozygosity on HIV-1 susceptibility: a meta-analysis. *PLoS ONE*, 7(4):e35020. https://doi.org/10.1371/journal.pone.0035020

Nie JB, Fitzgerald RP, 2016. Connecting the east and the west, the local and the universal: the methodological elements of a transcultural approach to bioethics. *Kennedy Inst Ethics J*, 26(3):219-247. https://doi.org/10.1353/ken.2016.0023

Qiu RZ, 2016. Debating ethical issues in genome editing technology. *Asian Bioeth Rev*, 8(4):307-326. https://doi.org/10.1353/asb.2016.0026

SinaTech, 2018. The first human immunodeficiency virus (HIV) immune gene-edited babies were born in China. https://tech.sina.cn/d/bk/2018-11-26/detail-ihmutuec3688779.d.html [Accessed on Nov. 26, 2018] (in Chinese).

Tebas P, Stein D, Tang WW, et al., 2014. Gene editing of *CCR5* in autologous CD4 T cells of persons infected with HIV. *N Engl J Med*, 370(10):901-910. https://doi.org/10.1056/NEJMoa1300662

Wang C, Zhai XM, Zhang XQ, et al., 2018. Gene-edited babies: Chinese academy of medical sciences' response and action. *Lancet*, in press. https://doi.org/10.1016/S0140-6736(18)33080-0

Wu YX, Liang D, Wang YH, et al., 2013. Correction of a genetic disease in mouse via use of CRISPR-Cas9. *Cell Stem Cell*, 13(6):659-662. https://doi.org/10.1016/j.stem.2013.10.016

Zhang XQ, 2016. Risk-benefit analysis of CRISPR-Cas germline editing clinical research on human embryos and its ethical governance. *Sci Soc*, 6(3):12-21 (in Chinese). https://doi.org/10.3969/j.issn.2095-1949.2016.03.002

中文概要

题　目：人类首例基因编辑婴儿试验：伦理失范和善治的迫切性

概　要：近年来，中国生物医学研究快速发展的同时，也在伦理治理方面带来了挑战。贺建奎公开声称其胚胎基因编辑婴儿诞生后，立即招致广泛的批评、谴责和激烈的伦理和法律大辩论。以生育为目的的胚胎基因编辑操作违反了公认的伦理规范，具体包括：较低的科学价值、不合理的风险–受益比、伦理审查不合规、并非真正的知情同意等。这说明主要依靠科研人员自律的机构伦理治理体系是成问题的，为此需要在不同层面上改进伦理治理水平，强化技术和伦理指南和法规。

关键词：贺建奎；人类生殖细胞系基因编辑；人类免疫缺陷病毒（HIV）；CRISPR-Cas9；伦理审查