Gene-edited babies: Chinese Academy of Medical Sciences' response and action

CRISPR-Cas9, a powerful tool for genome editing, has provided novel strategies and potential for treating human diseases. However, the ethical challenges remain unsolved for many clinical applications. As researchers from the Chinese Academy of Medical Sciences, the national biomedical research institution in China, we and our colleagues are deeply concerned about media reports of the claim of the first gene-edited twin babies "immune to HIV" by Jiankui He and colleagues.[1] At the Second International Summit on Human Genome Editing in Hong Kong, China, Jiankui He disclosed their work on CRISPR-Cas9 mediated genome editing of the *CCR5* gene in human germ cells and embryos.[2] If their claims are verified, we feel compelled to state our position and concerns for the potential scientific ramifications and ethical impacts to our scientific community.[3]

We are opposed to any clinical operation of human embryo genome editing for reproductive purposes in violation of laws, regulations, and ethical norms in the absence of full scientific evaluation. In the rapidly developing area of genome editing technology, our scientific community should uphold the highest standards of bioethics in undertaking responsible biomedical research and applications and uphold our scientific reputation, the basic dignity of human life, and the collective integrity of our scientific community.

The genome editing of germ cells or early embryos is still in the stage of basic research, and its safety and validity need to be fully evaluated. Therefore, scientific research institutions and researchers should not undertake clinical operations of genome editing of human germ cells for reproductive purposes, nor should they fund such research.

Pre-clinical research on genome editing of human reproductive cell lines must follow technical standards and ethical norms. Sufficient evidence for the safety and effectiveness of this technology should be obtained through in-vitro studies of human tissues and embryonic genome editing studies of non-human animals, including primates.

The Chinese Government prohibits the genetic manipulation of human gametes, zygotes, and embryos for reproductive purposes. The relevant government regulations and guidelines are clearly stated in the Guiding Principles of Ethics for Human Embryonic Stem Cell Research (2003),[4] the Ethics Principles for Human Assisted Reproductive Technology and Human Sperm Bank (2003),[5] the Ethical Review Measures for Biomedical Research Involving Human Beings (2016),[6] and the Safety Management Measures for Biotechnology Research and Development (2017).[7] Jiankui He's operations violated these regulations.

Scientists must place social responsibility before their research and evaluate and prevent any potential risks to human health before the implementation of high-risk research. Clearly, more practical guidelines are necessary for emerging technologies. In view of the technological progress of genome editing and new challenges to medical ethics, we will develop and issue further operational technical and ethical guidelines as soon as possible to guide and standardise relevant research and applications to prevent any potential ethical misconduct and to provide authoritative guidance for the development of research according to the highest scientific and ethical standards.

We advocate that all research and medical institutions should strengthen the organisation of ethical committees and supervision of the ethical review and research processes, provide ethical education and training programmes for researchers and medical practitioners, and promote public education programmes of scientific knowledge and ethical awareness. Comprehensive education and training programmes are essential for responsible medical research.

Medical researchers and practitioners are guardians of human health. We call for the protection of the personal privacy of the twin babies and for proper care to ensure their healthy development, psychologically and physiologically. We must abide by the laws and follow the highest scientific and ethical standards to ensure the safe translation of scientific advances to human health benefit. New technologies, such as CRISPR, potentially revolutionise medicine and we are confident—with the collective wisdom of scientific community and government support—that we can reach common ground and policies to guide the rapid development and applications in health sciences.

We declare no competing interests.

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