Genome Editing for Human Benefit: Ethics, Engagement and Governance

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Case study: Public participation and regulation of human germline gene editing in China

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Background

As soon as the advantages of low cost and high efficiency were recognized, CRISPR-Cas9 technology began to be widely used in scientific research. In November 2018, He Jiankui - an associate professor at Southern University of Science and Technology announced the birth of twin girls whose genes were edited by CRISPR. Although modern assisted reproductive technology enables the birth of unaffected children to an HIV-infected father, He Jiankui still determined to use the method of editing the genes of embryos in an attempt to immunize against HIV. Experts from scientific and medical communities at home and abroad immediately questioned the motivation and necessity of the experiment, its compliance with research standards, and the impact of unpredictable biological consequences of the experiment. He's work increased the public's awareness of genome editing and sparked online debates in China.

Ethical issues

1. Lack of prior public awareness: On November 9, 2018, Key laboratory of big data analysis and simulation of public opinion in Guangdong province of Sun Yat-sen University released the first domestic research report on the understanding and attitude of the Chinese public towards gene editing technology. The report looked at attitudes towards gene editing technology among the general public and people living with HIV. From June to August 2018, the study sent questionnaires to the general public, and collected 4196 valid questionnaires. In September 2018, electronic questionnaires were sent to HIV-infected people nationwide, and 575 valid questionnaires were collected. There were two important findings: (1) they knew little about gene editing technology but (2) their response to the idea, when it was introduced to them, was generally positive.

Commentary: Relevant government departments should cooperate with mainstream media to release accurate information related to gene editing technology. They should improve information dissemination and help the public to understand gene editing technologies. A national advisory department should be established and include people with technical expertise, ethicists, lawyers, etc. It should undertake consultations and provide guidance services for patients and the public interested in learning about the science, ethics and governance of gene editing. The guidance should be published online and be publicized through various media channels (newspapers, news, microblogs, WeChat, etc.).

2. Social participation: On May 11, 2019, a preparatory conference on the topic of "ethics and governance of human genome editing" was hosted and co-sponsored by the Institute of Philosophy of the Chinese Academy of Social Sciences. Almost 50 participants attended, including the party secretary of institute of philosophy, Chinese Academy of Social Sciences, bioethics scholars, researchers, doctors, law professors, philosophy scholars and students. The meeting discussed the current situation of gene editing technology and the ethical and governance issues of both somatic and heritable gene editing. The purpose of the meeting was to formulate a set of ethical and governance guidelines on gene editing to assist researchers and inform government decision-making. Draft guidelines were developed subsequent to the meeting, written by speakers at the

conference (eight speakers from the fields of ethics, law and philosophy). The guidelines will be published when a draft has been agreed.

Commentary: The preparatory conference was a promising start but could be both broadened to include a wider range of contributors and carried beyond the development of guidance - to the research, development, application and promotion of new technologies. Such a meeting should not be a one off. Stakeholder (including public) engagement should be a core part of governance at all stages of the technology's development and application. Regular seminars and open meetings would help the public to learn more about the risks and benefits of genome editing research. Further, input from the public could help develop more acceptable ethical norms. Responsibility for engaging the public should be shared between the government, researchers, and the national advisory department. In particular, the involvement of government would encourage public participation and send a strong signal that people's voices would be taken seriously.

3. Approval and oversight of research: In China, ethical oversight of medical research has three articulated levels involving the National Medical Ethics Committee, Provincial Medical Ethics Committees and Institutional Ethics Committees that are established by local institutions. Institutional Ethics Committees review the scientific and ethical justification of biomedical research projects involving humans. The review mode is mainly a combination of pre-examination, passive examination (written examination of materials submitted by scientific research institutions) and post-approval supervision. The reliance on written submissions provided by the researchers arguably does not offer sufficient basis for discussion and review by the ethics committee and led to a failure of the review process in the He case. China has a number of normative documents that related to human gene editing, all of which point out that: "Genetic manipulation of human gametes, zygotes and embryos for reproductive purposes is prohibited in China". However, there are no stated disciplinary measures for contravening this rule. An investigation into He Jiankui's research showed it involved violation of scientific integrity, falsification of consent forms for ethical review, blatant conduct of embryo gene editing banned by China, all resulting in the birth of the gene edited twins. However, no punishment has been imposed except for the termination of his employment at the University. This reveals inherent problems in the field of heritable gene editing in China such as ineffective legislation, improper incentives (e.g. recognition for 'world first' research), lax supervision and inadequate penalties.

Commentary: A reliable supervision mechanism should be established, such as global, unified registration system for gene editing related research (as recommended by the World Health Organization) with regular and timely upload of research progress and results. As a major research area, China should be an active participant in this. The Institutional Review Board (IRB) in each region (e.g. the provincial Ethics Committee) should check the progress of the responsible project at any time, and randomly check whether the research project conforms to the established ethical rules. Those identified as high risk should be flagged for enhanced scrutiny. Also, it is desirable to strengthen the supervision and coordination among all levels by forming a regional group model (e.g., village-town-county-city-province) to achieve more effective supervision. Institutional supervision alone is not enough on its own but could be supported by mass supervision (e.g., colleagues and subjects), self-supervision (enhanced ethical training and reflection) and whistle blowing (and protection of whistle blowers). In addition, clear and consistently enforced law is also an important measure. In China, new regulations with increased penalties have been drafted, which require administrative approval. Perfecting those steps might prevent problematic studies, such as He's work, or help them to be detected earlier.

Discussion points

1. How can the public be better informed about developments?
2. How can the public participate in shaping guidance?
3. How can the public contribute to supervision/ governance?

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