**Comments on Gene-editing Case**

1. Diverse and continuous responding to the case

On 26 November 2018 – one day before the Second International Summit on Human Genome Editing - the news on ‘CRISPR babies’ broke out: Twin girls named Lulu and Nana were born in China after their parents received *in vitro* fertilisation (IVF) treatment in combination with the use of CRISPR-Cas9 genome editing technology to alter *CCR5* genes (Marchione, 2018). He Jiankui, a biophysicist from Southern University of Science and Technology, led the experiment that shocked the world.

In Mainland, it was started from the biggest network, People’s Net, and later reporting by other famous network, such as Guangming Net, Xinhua News Agency and other popular web portals such as Sina, and Sohu, they brought the case to more wide audience.

Soon after the case exposed, Southern University of Science and Technology (SUST, where He Jiankui works) announced that He Jiankui has been off from university on Feb.1, 2018. SUST wants to say He’s behavior has nothing related to SUST. Similarly, Shenzhen Hemei Women and Children Hospital, and other relevant departments also declared that they have nothing to do with it.

Quickly, diverse resources of media contacted different scholars to express their opinions. Chinese scientists and regulators soon responded to the news and condemned He’s experiment (CSCB and GSC, 2018; Zhishifengzi, 2018; Yicai, 2018; Xinhua, 2018). A great number of academic associations, including China Reproduction Association (one branch of China Medical Association), Stem Cell Sub-association of Biology Association, ethics committee of China Genetic Association, China Medical Ethics Association, etc. and some institutions, including Chinese Academy of Medical Sciences have released their opinions on website or in journals. The main points are similar, mainly focused on the uncertainty of the technology, the risk for gene pool, unnecessity of the use of this technology, and his experiment/clinical practice result should be published in peer-review journal first before released to public, and his research and practice both had broken existing national regulations and had done so in a discrete manner during his annual leave from SUST (Shepherd and Ruwitch, 2018). Moreover, more than 120 scientists in co-issued one declaration to condemn the behavior. But whether he could be affirmed as illegal, remains unclear due to the defects of the regulation.

It is the first time in China that so big number of scientist and institutions gave a voice towards a specific case. On the one hand, they couldn’t agree at all with his behavior; on the other hand, this event let many Chinese scientists in this area lose face, they couldn’t face the criticize that why it is always Chinese scientists who broke the international guidelines?

National Health Commission (NHC) of People’s Republic of China, Ministry of Science and Technology (MOST), both have held 2-3 times meeting early since Nov. 27, 2018. They invited relevant scholars to help to clarify the situation, analyze the impact of the event and set up an investigation group, and assigned them to go to Shenzhen to do investigation.

Ministry of Education (MOE) quickly responded in December 2018, required the universities and institutions to initiate the self-check, and sent feedback to MOE about whether universities have approved such kind of research, and what is the plan for those who have supported such research and how to supervise its process.

Definitely, the government agencies hope to improve the management of biotechnology through this specific case and its lessons, to revise the related regulations, and required the institutions to strengthen their management.

The National Science Foundation Commission also released an open letter on its website, indicating the concern on the case, and insisted that the scientific research related to genetic editing must be implemented in the legal and ethical way, and must be subject to the supervision and restraint of research ethics (NSF, 2019). The background might be that the National Natural Science Foundation (NSF) of China have funded a total of 31 CRISPR technology-related projects in 2014, with a total approved amount of about 13 million RMB. In 2015, the NSF funded 57 CRISPR technology-related projects, which was significantly higher than that in 2014, and the amount exceeded 31 million RMB (Fan Yuelei,2018).

In sum, we can see two kinds of responses: those institutions which have potential connection to the case, declare there is nothing relationship between the event and the institution; more scientists, associations and institutions expressed their condemns on He’s behavior.

So far, there is almost no comment to provide support to He and his behavior.

1. Primary investigation result

On January 21, 2019, the provincial investigation committee revealed its preliminary findings of He’s case (Xinhua, 2019). According to the investigation, He Jiankui assembled a research team consisting of foreign and domestic researchers and started this project no late than June 2016. To pursue this project, He took an annual leave from the University of xx and withheld this project from his employee. The investigation stressed again that He’s experiment on using human genome editing to edit to-be-implemented embryos violated national regulations. It also revealed that He fabricated the ethics review approval and further broke research regulations in using assistant reproductive technologies (ART) for HIV-positive patients. The inclusion criteria for He’s research specified that to-be-enrolled husbands be tested as HIV-positive, while the wives HIV-negative. From March 2017 to November 2018, eight such couples were recruited. Genome editing was conducted in combination with these couples’ IVF treatment. During the course of research, one couple withdrew their participation. Among the remaining seven couples, two female participants were successfully pregnant. One of them gave birth to Lulu and Nana, and the other is expecting her baby (babies). The investigation committee concluded that He’s research violated scientific integrity and research ethics, broke relevant regulations, and exerted far-reaching adverse effects on science and society in, and outside of, China.

Relevant personnel and institutions are now under police investigation. The provincial government also announced its plan to conduct observational studies and follow-up examination of Lulu, Nana and the other pregnant female participant. These studies will be guided by relevant national regulatory agencies and coordinated among relevant parties.

The primary investigation result is very simple. Actually, the further investigation is still going on. It is guessed that this May might be the time to release the whole investigation report.

1. Update of the case

Scientists are living in a global community, many scientists abroad also expressed deep worry as well. He is called rogue scientist by one journalist: “Some U.S. researchers knew of a Chinese scientist’s intentions to implant edited embryos but were unable to stop him. Now scientific institutions are trying to devise global safeguards” (Pam Belluck, 2019).

He’s home universities, both Stanford and Rice University responded that they are doing investigation. In an e-mail, Stanford confirmed the inquiry. “We have a review under way of the circumstances around Dr. He’s interactions with researchers at the university,” said spokesperson Ernest Miranda” ([Antonio Regalado](https://www.technologyreview.com/profile/antonio-regalado/), 2019). No further investigation results are available till now.

Behind the gene-editing case, there is one hidden issue not discussed widely, which is about whether the parents of Lulu and Nana have right to make the decision to remove CCR5 to avoid HIV infection? Parents should and need make decision for children, is no doubt. The point is that if the parents didn’t follow the best interest of child, then society usually reluctant to involve, especially in the medical context. Though this phenomenon is not limited in China, some cases have revealed its problems and its disadvantage, and this debate has not aroused the sense among society in China.

Accordingly, if such intervention can enhance the IQ, whether the parents still have right to do this? To have high IQ child, is a common desire for many parents, Chinese parents might be more desired. Coincidentally, Antonio reported that China’s CRISPR twins might have had their brains inadvertently enhanced, this raised another question. New research suggests that a controversial gene-editing experiment to make children resistant to HIV may also have enhanced their ability to learn and form memories. Similarly, because it is impossible to predict, that is why it should not be done **(Antonio Regalado, 2019**). Who can make decision for the child’s future, Society or parents? And whose opinion represent society, are issues faced us.

On national level, the most update is the call for suggestion/recommendations on “Regulation on clinical us of new biomedical technology”, which was issued by National Health Commission on Feb.26, 2019. The update of the regulation is composed of 63 articles, two layer-management mechanism is designed. For the high risk biomedical technology, gene-editing is included, it is required to be reviewed firstly on provincial level and then need be submitted to national health agency for review. If the new biomedical technology is proved to be safe and effective, the local institution that implemented the research can apply to the provincial government for transforming, to translate the research outcome to clinical use. Besides these, another improvement is that clear legal responsibilities have been stated, for both individual and institution if they break it.

From my personal perspective, some gaps which once represented a big hidden trouble for this case, are still there. The background is that the regulation issued by NHC can only cover the institutions and hospitals, and NHC has not legal authority to those non-health institutions. But, in reality, there are many departments of biology in non-medical universities, and many biotechnology companies in society, etc, neither of them is responsible to NHC. The gene-editing case was just happened in SUST, and He is a faculty of department of biology, and SUST is responsible to Ministry of Education, rather than NHC. Another gap in this update regulation is that it involves more administration procedures, and might decrease the efficacy. Central Office of the Communist Party of China, Office of the Central Government co-issued one document: On deepening the reform of examination and approval system, and on encouraging innovation on drug and medical devices, issued on Oct.8, 2017. This document addressed strongly about the efficiency of ethical review. How to make balance of quality and efficiency, is an important issue by extension.

1. Some reflection and beyond

The issue of conflict of interest is ignored and not yet well addressed by different stake holders of this case.

Actually, He Jiankui was encouraged by the SUST’s policy on translating knowledge to industry/ patent/production. On February 26, 2016, the Central Government once issued a notice on Promoting the Transformation of Scientific and Technological Achievements (Guo Fa [2016] No. 16). The Ministry of Education and the Ministry of Science and Technology also issued similar documents (Teaching Technology [2016] No. 3). It encourages colleges and universities to take measures for transfer and transformation of scientific and technological…”, if the transformation is successful, obtaining patent, or getting licensing, then not less than 50 percent of the net income from the technology transfer or licensing can be rewarded to individuals who complete this translation...".

The national level policy and university level policy about encouraging transforming is good for the social development, but the policy of conflict of interest should also be developed in parallel, to help the researcher not involve any conflict of interest. In 2016, SUST reported that Professor He was on the call of “encouraging faculty to start up business”, and set up a company (focus on gene sequencing to support clinical diagnosis, named “Hao Hai Gene”), his role in the company is CEO. Though there is not investigation result about conflict of interest, it is a seriously potential issue related to the case and related to motivation behind the decision making.

Another reflection is about the values of moral judgment. He Jiankui once answered questions on the conference: I know my research has caused big debate, but I believe this can help those families in need. I’d like to face the problems and take responsibility.

Many bioethicists think: it is impossible to predict benefit, that is why it should not be done **(Antonio Regalado, 2019**). Just suppose: if some years late, the follow up data of the twin girls provides evidence to show He’s research and application is successful, how we response to today’s condemn? Good outcome but breaking the rule, or following the rule but bad result for the babies, which is more acceptable? Is the way of consequence-based judging mechanism tenable?

What should be the fundamental values behind?

Acknowledge Yeyang Su for her help to collect some materials.

**References**

CSCB & GSC (2018) Official Statement from CSCB & GSC: Condeming the reproductive application of gene editing on human germline. [online]. Available from: http://www.cscb.org.cn/news/20181127/2988.html (Accessed March 1, 2019).

Marchione, M. (2018) Chinese researcher claims first gene-edited babies. AP NEWS. 26 November. [online]. Available from: https://apnews.com/4997bb7aa36c45449b488e19ac83e86d (Accessed March 1, 2019).

Shepherd, C. & Ruwitch, J. (2018) Scientists, officials in China abhor gene editing that geneticist... Reuters. 27 November. [online]. Available from: https://www.reuters.com/article/us-health-china-babies-genes-letter-idUSKCN1NW0A7 (Accessed 1 March 2019).

Xinhua (2019) Guangdong releases preliminary investigation result of gene-edited babies - Xinhua | English.news.cn. 21 January. [online]. Available from: http://www.xinhuanet.com/english/2019-01/21/c\_137762633.htm (Accessed March 1, 2019).

Xinhua (2018) Research activities of persons halted over gene-edited babies incident. 29 November. [online]. Available from: http://www.xinhuanet.com/english/2018-11/29/c\_137640246.htm (Accessed March 1, 2019).

Yicai (2018) 122位科学家发联合声明：强烈谴责“首例免疫艾滋病基因编辑”. Yicai. 26 November. [online]. Available from: https://www.yicai.com/news/100067069.html (Accessed March 1, 2019).

Zhishifenzi (2018) 140名艾滋病研究专家针对“基因编辑婴儿”再度联名公开信. 27 November. [online]. Available from: http://www.zhishifenzi.com/news/multiple/4681.html (Accessed 1 March 2019).

国家自然科学基金委员会关于“人类胚胎基因编辑婴儿”事件的公开信,

<http://www.nsfc.gov.cn/publish/portal0/tab442/info74655.htm> (Accessed Feb.20, 2019)

Fan Yuelie, Wang Huiyuan, Yu Jianrong,The ethical debate on gene-editing, Science Technology China，Issue 6, 2018.

Pam Belluck, How to Stop Rogue Gene- Editing of Human Embryos? The New York Times, Jan. 23, 2019

[Antonio Regalado](https://www.technologyreview.com/profile/antonio-regalado/), Stanford will investigate its role in the Chinese CRISPR baby debacle, February 7, 2019. Available from:

https://www.technologyreview.com/s/612892/crispr-baby-stanford-investigation/(Accessed Feb. 26, 2019)

[Antonio Regalado](https://www.technologyreview.com/profile/antonio-regalado/), February 21, 2019, China’s CRISPR twins might have had their brains inadvertently enhanced, MIT Technology Review. Available from:

[https://www.technologyreview.com/s/612997/the-crispr-twins-had-their-brains-altered/ (Accessed](https://www.technologyreview.com/s/612997/the-crispr-twins-had-their-brains-altered/%20(Accessed) Feb.27, 2019)

Call for suggestion/recommendations on “Regulation on clinical us of new biomedical technology”, National Health Commission, Available from: <http://www.nhc.gov.cn/yzygj/s7659/201902/0f24ddc242c24212abc42aa8b539584d.shtml> (Accessed Feb.27, 2019).

News, Nature子刊报道我校贺建奎副教授研发的基因测序仪, Southern University of Science and Technology, Available from:

http://www.sustc.edu.cn/biology\_news/1989 (Accessed Feb.26, 2019).