

Gene-edited babies and cloned monkeys: China tests bioethics

November 27 2018, by Catherine Lai



CRISPR technology has opened up enormous potential to battle genetic faults and diseases

A Chinese scientist's claim that he created the world's first genetically-edited babies has shone a spotlight on what critics say are lax regulatory

controls and ethical standards behind a series of headline-grabbing biomedical breakthroughs in China.

University professor He Jiankui on Sunday said the DNA of twin girls had been altered to prevent them from contracting HIV, but his claims prompted a fierce backlash from the scientific community who not only cast doubt over the breakthrough, but also questioned its morality.

China is seeking to become a leader in the fields of genetic research and cloning, forging ahead even as others hesitate over ethical issues.

Scientists in the country were the first to carry out gene editing on human embryos in 2015, although with mixed results, the British journal *Nature* reported in 2017. And earlier this year, Chinese scientists unveiled monkeys that were cloned using the same technique that produced Dolly the Sheep two decades ago.

While the procedure could boost medical research into human diseases, it also raised ethical questions about how close scientists have come to one day cloning humans.

'Head transplant'

Italian surgeon Sergio Canavero sparked controversy last year when he claimed to have conducted the world's first head transplant on a corpse at a Chinese hospital, the state-run *Global Times* reported at the time, though other scientists have called his claims overblown.

On Sunday He, who was educated at Stanford University, announced in a YouTube video he had used CRISPR, a technique which allows scientists to remove and replace a strand with pinpoint precision, to modify the twins' DNA.

The tool has not been used in human trials in the United States, though doctors in China have been applying it to treat cancer patients.

Qiu Renzong, former vice president of the Chinese health ministry's ethics committee, accused He of obtaining a "fraudulent" ethics review by going to another hospital for review as opposed to obtaining approval from his own university, adding he was destroying the reputation of China's scientists.

Qiu said a lack of regulation mean that scientists often face no punishments as they are only required to abide by the rules of their institutions, which may not stipulate punishments for misconduct.

"People say the ministry is without teeth, cannot bite people. So we try to provide the teeth to the ministry head, so they can bite people when people violate the regulations," he told reporters in English at a gene editing conference in Hong Kong.

"The mainland is very protective of scientists, if you make some small mistake, that's the end of it, there's no punishment. I suggest that they should be punished," he added.

'Crazy' experiment

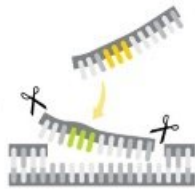
With a sceptical research community waiting for evidence of He's claims, the scientist is expected to speak at the same conference in Hong Kong on Wednesday and Thursday.

Evolution of genetic engineering

CRISPR/Cas9 vastly cuts down the time needed for genetic experiments

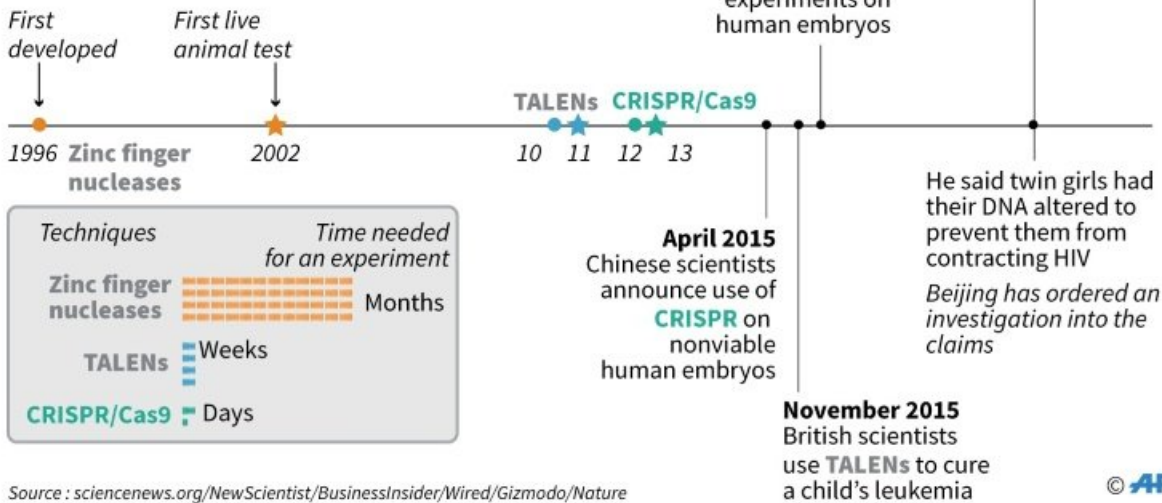
CRISPR/Cas9

Derives from snippets of viral DNA that bacteria have incorporated into their own genomes



The technique makes it possible to remove or insert sections of DNA in precise locations

Timeline of genetic techniques



Fact file on the development of the CRISPr gene-editing technique

He, who works from a lab in the southern Chinese city of Shenzhen, faces scrutiny on the mainland too, with the National Health Commission ordering an investigation into the case.

On Tuesday, Shenzhen Harmonicare Women and Children's Hospital said in a statement it suspected the signature on a document approving the experiment, specifically its adherence to ethical standards, was falsified and that it had asked police to investigate.

A group of 122 Chinese scientists signed a joint statement calling the

experiment "crazy" and said it was unfair to other scientists who stick to "the moral bottom line".

The Southern University of Science and Technology, where He works, said he had been on unpaid leave since February and his research is a "serious violation of academic ethics and norms".

A notice from Shenzhen's medical ethics authority said that all medical organisations must establish an ethics review committee before undertaking biomedical research concerning humans, and the ethics board of the hospital involved had not completed its registration as required.

He defended his research in another video, saying that he is trying to help families who carry genetic diseases.

"We believe ethics are on our side of history. Look back to the 1970s with Louise Brown. The same fears and criticisms then are repeated now," he said, referring to the first person to be born through in vitro fertilisation.

\$1 billion industry

China has the second-largest genomics market worldwide, according to UBS. Beijing-based CCID Consulting estimates the market's value will nearly triple from 7.2 billion yuan (\$1 billion) in 2017 to 18.3 billion yuan (\$2.6 billion) by 2022.

Looser regulations have allowed China to get ahead in the biomedical field, said Michael Donovan, the founder of Veraptus, a biotech company in China.

But other factors such as a larger population providing a larger pool of

potential patients, as well as regulatory support from the government also played a role, Donovan said.

"In many industries, the regulatory stance is that if there aren't laws for it, then they can proceed cautiously," he added.

"And that's the murky area that gene-editing is in right now."

While certain hospitals can approve certain procedures without it going to a national approval body, it was "very strange" that He did not get a national authority's greenlight for such a ground-breaking experiment, Donovan said.

"From the ethical side you don't have the religious pool that we do in the United States," he said. "But it is still life, so people are still concerned that we're moving forward too quickly with this."

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