

WHY IS CHINA LAYING DOWN GENE EDITING RULES?

Relevant for: Science & Technology | Topic: Biotechnology, Genetics & Health related developments

The story so far: In a bid to make babies immune to infection by the human immunodeficiency virus (HIV), He Jiankui, a researcher from the Southern University of Science and Technology in Shenzhen, China, used a clinically untested gene editing tool (CRISPR-Cas9) to modify a particular gene. The tool has also been used on another woman to make a gene-edited embryo; the pregnant woman is expected to deliver in August. The announcement of the birth of gene-edited twin girls late last year set off an international furore.

Unusual but repeated DNA structures that scientists had been observing for some time were given a name — Clustered regularly interspaced short palindromic repeats or CRISPR. In 2012, scientists discovered that CRISPR is a key part of the “immune system”. For instance, when a virus enters bacteria, it fights back by cutting up the virus’s DNA. This kills the virus but bacteria store some of the DNA. The next time there is an invasion, bacteria produce an enzyme called Cas9 which matches the stored fingerprints with that of the invader’s. If it matches, Cas9 can snip the invading DNA. The CRISPR-Cas9 gene editing tool thus has two components — a short RNA sequence that can bind to a specific target of the DNA and the Cas9 enzyme which acts like a molecular scissor to cut the DNA. To edit a gene of interest, the short RNA sequence that perfectly matches with the DNA sequence that has to be edited is introduced. Once it binds to the DNA, the Cas9 enzyme cuts the DNA at the targeted location where the RNA sequence is bound. Once the DNA is cut, the natural DNA repair mechanism is utilised to add or remove genetic material or make changes to the DNA.

Dr. He used the CRISPR–Cas9 gene editing technique in the twin girls to disable a gene called CCR5, which encodes a protein that allows HIV to enter and infect cells.

Though no guidelines have been drawn up so far, there is a general consensus in the scientific and ethics communities that the CRISPR–Cas9 gene-editing technique should not be used clinically in embryos. There is also consensus that gene editing can be potentially used only to prevent serious genetic disorders that have no alternative treatment. While HIV cannot be cured, medicines can keep the virus under check.

Importantly, human clinical trials have not been carried out anywhere in the world to test whether disabling the gene completely prevents HIV infection and what the side-effects of doing so would be. In the absence of any clinical trial data as well as consensus to use this tool to prevent HIV infection, performing it on babies as a form of medical intervention is unethical.

According to *Nature*, the hospital that had supposedly given Dr. He ethical approval to use the technique on pregnant women issued a press statement denying this. The hospital also “questioned the signatures on the approval form” and said no committee meeting had been held related to his research work.

Apparently, information on the consent form suggests that the parents who had participated in the experiment were never told about the problems of disabling the gene.

While it is generally believed that babies without a functional CCR5 gene will become resistant to HIV infection, certain other strains of HIV use another protein (CXCR4) to infect cells. Hence, even people who are born with two copies of the non-functional CCR5 gene are not completely protected or resistant against HIV infection.

There is also the possibility that the gene editing tool could have caused unintended mutations in other parts of the genome, which may lead to unpredictable health consequences.

Most importantly, medicines and delivery through caesarean section and avoiding breast feeding can prevent vertical viral transmission from mother to foetus. While women with HIV have greater chances of passing the virus to the foetus, in this case, the mother was HIV-free; the father was HIV positive.

The CCR5 gene's protective role against the West Nile virus is well established. According to *Nature*, the CCR5 gene also helps to protect the lungs, the liver and the brain during certain serious infections and chronic diseases. The gene is known to prompt the immune system to fight the influenza virus in the lungs. Without this gene the defence system would fail. In the case of people with multiple sclerosis, absence of this gene makes them twice as likely to die early.

Was the gene removed in both the babies?

There are two copies of the gene in every person. In the case of one baby girl both the copies of the gene were disabled but in the other baby, only one copy was disabled. So the baby with one functional copy of the gene might still be susceptible to HIV infection. The decision to implant the embryo with only one disabled copy makes the work all the more unethical. Though Dr. He claimed the babies were born in early November last year, *The New York Times* reported that the babies were born premature in October.

The day Associated Press broke the story, the Chinese national health commission asked the Guangdong health commission to start an investigation. On January 21 this year, Dr. He was fired from the university where he worked after a probe by the Guangdong health commission found that he had violated the national regulations against using gene-editing for reproductive purposes.

According to *The Scientist*, Dr. He's experiment violates the 2003 guidelines that prohibits the use of gene-manipulated embryos for reproductive purposes. On February 26, China posted the draft regulation requiring researchers to obtain prior approval from the government before undertaking clinical trials. Those found violating the rules will be punished and this includes a lifetime ban on research. China is now all set to introduce gene-editing regulation.

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