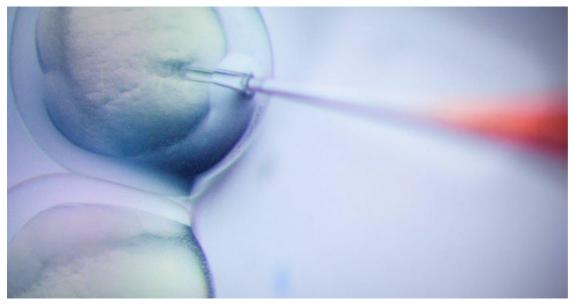


Covid-19 and gene editing: ethical and legal considerations

By <u>Sheetal Soni</u> 25 May 2020

Researchers are racing against time to find ways to treat and prevent Covid-19. There is currently no treatment for the disease, and the World Health Organisation has created <u>Solidarity</u>, a global clinical trial which is testing four drugs as possible treatment. There are also more than 90 <u>vaccine trials</u> being undertaken worldwide, but it may take more than a year before a vaccine is developed. And there is currently a <u>global shortage</u> of Covid-19 testing kits.



A researcher performs a CRISPR/Cas9 process at the Max-Delbrueck-Centre for Molecular Medicine in Germany . Gregor Fischer/picture alliance via Getty Images

One of the methods researchers are exploring to combat Covid-19 is gene editing. Gene editing could potentially be used on the genome of the virus that causes Covid-19, to make it harmless. It could be used to develop better testing kits, and could even be used to edit the human genome to prevent people from being infected by the virus.

But gene editing is associated with a range of ethical issues such as safety, equal access and consent. Bioethicists and researchers believe that gene editing in humans <u>must be proven to be safe</u> before it can be offered as a treatment option. There is also the issue of equal access to treatment, which must be considered.

To ensure that an ethical approach to research for a cure for Covid-19 is taken, the International Bioethics Committee and the World Commission on the Ethics of Scientific Knowledge and Technology issued a joint statement calling for an interdisciplinary dialogue among scientific, ethical and political stakeholders. The joint statement does not describe specific treatment options, but it calls on the research community to work together to find a cure using a bioethics and ethics of science and technology perspective which is rooted in human rights.

Scientists have considered the possibility of CRISPR (or clustered regularly interspaced short palindromic repeats) technology being used to address the Covid-19 pandemic. CRISPR is a mechanism that arose in bacteria millions of years ago to fight off disease. The CRISPR protein can be used to target specific sequences of DNA, which it then cuts like a pair of scissors. The cut DNA strand can then repair itself, or a new DNA sequence can be inserted. It has now been turned into a biological tool for editing genomes of biological organisms in order to modify them or target disease. It therefore has a number of different uses, from improving crop quality to correcting genetic conditions.

CRISPR gene editing

Using CRISPR to edit the SARS-CoV-2 genome

CRISPR has the potential to <u>disable the virus</u> that causes Covid-19 by editing its genome so that it is, in effect, made harmless. Using an approach called PAC-MAN (Prophylactic Antiviral Crispr in huMAN cells), <u>researchers at Stanford University</u> have shown that CRISPR has the ability to attack the SARS-CoV-2 genetic makeup and reduce the amount of virus in a test solution by 90%. Research is ongoing, but it's thought that this approach is so effective, it might have the potential to stop the disease in people. There would be no barrier to this research as long as researchers abide by the ethical and legal guidelines that apply to their institution and country.

CRISPR-based Covid-19 tests

Gene editing tools have the potential to improve testing rates and could be an answer to the global shortage of COVID-19 tests. Apart from being a gene editing tool, CRISPR is also a <u>diagnostic tool</u>, and can be used to detect infection in cells. Scientists are hopeful that <u>CRISPR based testing</u> will alleviate the global testing burden. While many of these tests are still in the development stage, the <u>Food and Drug Administration</u> approved a CRISPR-based Covid19 diagnostic test by a <u>Cambridge biotech start-up</u> on 8 May 2020. The test can provide results within an hour, and the company making it claims that more than 1 million tests can be performed in a week. In order for these tests to be legally made available for use, they would need to be approved by the appropriate regulatory authority, such as the Food and Drug Administration in the US, or <u>South Africa's Health Products Regulatory Authority</u>.

Using CRISPR to make people resistant to infection

CRISPR creates the potential to <u>edit people's genes</u> to make them resistant to infection. So, if we can't stop the virus, can we stop ourselves from getting infected? Gene editing in humans takes one of <u>two forms</u>: somatic cell editing and germline editing.

Somatic cell editing affects a person's body cells, while germline editing involves editing the DNA in sperm, eggs or embryos, resulting in genetic changes in an individual's descendants. There are a number of somatic cell CRISPR clinical trials being undertaken and <u>some treatments</u> have been successful. But germline editing is more controversial and over <u>40 countries</u> prohibit it in their law.

When the Chinese scientist He Jiankui used CRISPR to edit the genomes of <u>two children</u>, he was criticised as acting unethically, since the safety and efficacy of germline editing has not been established. Scientists around the world called for a five-year <u>moratorium</u> on it. He Jiankui was sentenced to <u>three years in prison</u> in 2019.

There are also laws which will obstruct this potential use of CRISPR. Article 3 of the <u>Oviedo Convention</u> states that "an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic, or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants". This has been interpreted as expressly forbidding germline gene editing.

National law can also prohibit this. Section 57 of South Africa's National Health Act states that "a person may not manipulate any genetic material, including genetic material of human gametes, zygotes or embryos". Section 57 is enacted to prohibit human reproductive cloning. But this law was enacted before CRISPR even existed and it mimics the approach taken in international law against genetic manipulation of gametes and embryos. There are licensed somatic cell CRISPR therapies available. But there are potential legal barriers to the lasting protection which germline CRISPR intervention would give us.

Way forward

There is pressure on researchers to develop safe and effective treatment and vaccines. CRISPR technology has been used in a variety of ways, but it raises a series of ethical and legal issues with regard to its potential use in humans.

So far, scientists have been cautious about putting CRISPR technology to use in humans. But should CRISPR be considered as a legitimate weapon in the fight against the pandemic, knowing that <u>time is of the essence</u>? While we all act together in the fight against Covid-19, it cannot be at the expense of ethical and legal <u>standards</u>.

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