



## **Over View Of Gene Editing Technology And Its Application To Produce Designer Babies**

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### **Abstract**

Genome editing<sup>1</sup> is a powerful new tool for making precise additions, deletions, and alterations to the genome—an organism's complete set of genetic material. In recent years, the emergence of highly versatile genome-editing technologies has provided investigators with the ability to rapidly and economically introduce sequence-specific modifications into the genomes of a broad spectrum of cell types and organisms.

### **Keywords**

Genome Editing, CRISPR, Genome Sequencing, Genetic Engineering, Designer babies.

### **Introduction**

The development of new approaches—involving the use of mega nucleases; zinc finger nucleases (ZFNs); transcription activator-like effector nucleases (TALENs); and, most recently, the CRISPR/Cas9 system—has made editing of the genome much more precise, efficient, flexible, and less expensive relative to previous strategies. With these advances has come an explosion of interest in the possible applications of genome editing, both in conducting fundamental research and potentially in promoting human health through the treatment or prevention of disease and disability.<sup>2</sup> The latter possibilities range from restoring normal function

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<sup>1</sup>Medicine and Biomedical and Behavioural Research Splicing Life: A Report on the Social and Ethical Issues of Genetic

Engineering with Human Beings 1982 [[http://www.bioethics.gov/reports/past\\_commissions/splicinglife.pdf](http://www.bioethics.gov/reports/past_commissions/splicinglife.pdf).]

<sup>2</sup> GCSE Religious Studies - Gene therapy and genetic engineering - Revision 7. (n.d.) Retrieved July 29, 2018,

in diseased organs by editing somatic cells to preventing genetic diseases in future children and their descendants by editing the human germ line. Like other medical advances, each of these applications poses unique benefits, risks, regulatory frameworks, ethical issues, and societal implications. A key question that has been raised in relation to genome editing involves how to balance potential benefits with the risk of unintended harm. how to control the use of these technologies; how to incorporate societal values into prominent clinical and policy considerations; and the culturally inescapable inevitability of a country that shapes the landscape of whether and how to use these technologies how to respect differences Many of the ethical, legal, and social issues associated with gene therapy and human reproductive medicine provide a context for considering important issues related to genome editing. When conducted carefully and under proper supervision, gene therapy research has gained support from many stakeholders. However, technologies such as CRISPR/Cas9 have made genome editing so efficient and precise that they have opened up applications that were previously considered mostly theoretical. One example is germ cell editing to prevent inherited diseases. The potential application of 'improvement' editing for changes beyond mere health restoration or protection is another. As genome editing has just begun to move from basic research to clinical research applications, now is the time to assess the full range of its potential human applications and how these scientific developments will drive forward. The speed at which science evolves is causing a great deal of excitement among scientists, industry, health advocates, and patient groups who are benefiting from these advances. Partly because of the above concerns, there is a debate among policy makers and other stakeholders about whether there are adequate systems in place to govern the technology and how genome editing will ultimately be applied in practice. I am concerned about whether the social value is reflected in the content.

### **What is genetic Engineering?**

Genetic modification or genetic engineering is the process of altering the DNA of an organism's genome. There are many ways to modify DNA, such as deleting portions of it, changing one or more base pairs, or inserting extra copies of genes. These eight changes lead to the expression of different phenotypes within the cell. According to The American Heritage Science Dictionary, a phenotype is the expression of a particular trait, such as height or blood type, based on genetic and environmental influences. Genetic engineering can be applied to any organism, from a virus to an elephant. Genetic modification is used in many areas of science including medicine, agriculture, technology, and scientific research. "Genetic modification" has many apparent synonyms in the literature: genetic engineering, genetic enhancement, germ line engineering, germ line enhancement, germ line therapy, germ line manipulation, genome

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rom <https://www.bbc.com/education/guides/zjw2fg8/revision/7>

manipulation, and so forth. In this paper, when we speak of "genetic modification" we mean the process of intentionally altering human genes for the purpose of producing offspring with those genetic changes.<sup>3</sup> We use the term "genetic modification" because it covers a wider range of cases than other terms, and because it does not assume a distinction between genetic therapy and genetic enhancement, one which is difficult to maintain and which may not be as morally significant as is often assumed.<sup>4</sup>

What is a designer child?

A "designer baby" is a child born after interventions have been carried out in the pre-implantation stage of the embryo with the aim of influencing the characteristics or traits that the child might have after birth.

Advances in genetic engineering and assisted reproductive technology (ART) have made it possible to screen embryos for genetic disorders before implantation during in vitro fertilization. Using preimplantation inheritable determination (PGD), medical practitioners can identify embryos that may carry the imperfect gene. A defective gene can be changed and the result is a genetically modified child. Such children are called designer children because they have been "designed" through genetic modification.

### **Applications of genetic engineering**

With the rapid advancement in technology, more information about genomes of different organisms is known today. With such information, the number of applications of genetic engineering is also increasing.<sup>5</sup> Applications of genetic engineering can be found in almost every field.

#### **For Research**

Genome editing can be used to change the DNA of cells or organisms to understand their biology and function.

#### **Treating Disease**

Genome editing is used to modify human blood cells, which are then put back into the body to treat diseases such as leukemia and AIDS. It may also be used to treat other infections and simple genetic disorders.

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<sup>3</sup>Frankel M, Chapman A, eds: *Human Inheritable Genetic Modifications: Assessing Scientific, Ethical, Religious, and Policy Issues*

Washington, DC: American Association for Advancement of Science; 2000.

<sup>4</sup>Resnik D: The moral significance of the therapy-enhancement distinction in human genetics. *Camb Q Healthc Ethics* 2000, **9**:365-77.

Dennett D: *Elbow Room: The Varieties of Free Will Worth Wanting* Cambridge: MIT Press; 1984.

<sup>5</sup>See Mary Todd Bergman, *Perspectives on Gene Editing*, HARV. GAZETTE (Jan. 9, 2019), <https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/> (discussing Dr. He's experiment, the resulting outcry, and general restrictions that have been placed on human germline editing)

## Biotechnology

Genome editing has been used in agriculture to genetically modify crops to improve yields, make them more resistant to disease and drought, and to genetically modify hornless cattle.

### Gene Editing Techniques: Tools to Change the Genome

Gene-editing technology is a process of versatile technologies that has motivated researchers and scientists to edit the genes to sequence genes according to the modified genome sequence. With the help of gene-editing technology, many researchers have initiated the modification of genes into the genome of those organisms that belong to a broad spectrum. One of the sequent technologies which are related to gene-editing technology is the CRISPR-Cas9 and TALEN. These two technologies are highly recommended and frequently used in the editing of genes. CRISPR-Cas9 which is called Clustered regularly interspaced short palindromic repeats which are associated with protein.<sup>6</sup> With the help of such innovative technologies, researchers can develop new genomes that can be used in the treatment of different kinds of diseases specially cancer. The process is executed by cutting the DNA sequence with specific enzymes and thus this phenomenon is referred to as nuclei engineering and through this process, the DNA can be modified and can be further inserted into the gene of interest.<sup>7</sup> However, targeted DNA can be induced to get desirable results and such a process breaks the DNA and later activates it through the help of DNA repair mechanisms, and such parts of DNA are inserted into site-specific areas in the genome of interest. However, in the process of gene-editing technology, the basic principle is related to the targeting of the gene of interest which can be incorporated through homologous recombination or the process of conditional targeting. Moreover, the double-strand breakage that occurs due to the cutting of the DNA of interest can be repaired with the help of the double-strand break repair mechanism which influences the joining of the double-stranded DNA and allows in further transcription and translation to produce targeted proteins and mRNA.

Gene editing might sound simple on paper, but it is far from easy. The history of genome engineering goes back almost 70 years, to the initial discovery of the DNA double helix. Since then, scientists have spent decades trying to uncover ways to edit the genome that balance specificity with time and cost.

#### 1. Restriction Enzymes

##### The Original Genome Editor

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<sup>6</sup>Buchanan A, Brock D, Daniels N, Winkler D: *From Chance to Choice* Cambridge: Cambridge University Press; 2000.

<sup>7</sup>President's Council on Bioethics *Human Cloning and Human Dignity* 2002 [http://www.bioethics.gov/reports/cloningreport/pcbe\\_cloning\\_report.pdf](http://www.bioethics.gov/reports/cloningreport/pcbe_cloning_report.pdf)].

The ability to edit genes became a reality with the discovery of restriction enzymes in the 1970s. Restriction enzymes recognize specific patterns in the nucleotide sequence and cut at this point, providing an opportunity to insert new DNA material at this point.

restriction enzymes are not widely used today for gene editing because they are restricted by the nucleotide patterns they recognize, but they are still widely used today for molecular cloning, plays an important role in DNA mapping, epigenome mapping, and DNA library construction.

## **2. Zinc Finger Nucleases**

### Improving Detection

As time goes on, the need for precision in genome editing has become more and more evident. Off-target effects can be detrimental, so scientists needed gene-editing techniques that recognize the site being edited. The discovery of zinc finger nucleases (ZFNs) in the 1980s solved this problem. The

ZFN consists of two parts: an engineered nuclease fused to a zinc finger DNA-binding domain. Zinc finger DNA-binding domains recognize 3-base pair sites on DNA and can bind to recognize longer sequences.<sup>8</sup> Additionally, ZFNs act as dimmers, increasing the length of the DNA recognition site and consequently increasing specificity. However, specificity was increased in her ZFNs, but not completely. A major hurdle in using the

ZFN was that the 3 base pair requirements made the design more challenging. Guanine-rich target sites appeared to result in more efficient editing than guanine-poor sites. Because the interaction between ZFNs and DNA is modular (that is, each ZF interacts independently with DNA), processing efficiency was also compromised. Therefore, scientists had to address these issues if they wanted to achieve more efficient genome editing.<sup>9</sup> His ZFN ofshowed real promise in the medical field. In particular, the scientist used his ZFN to inactivate her CCR5 in human T cells, a key receptor for HIV. After ZFN-mediated editing, scientists determined that CD4+ T cells are safe to use and have exciting potential for HIV treatment. Additionally, ZFNs have been used to edit tumour-infiltrating lymphocytes as a therapeutic strategy for metastatic melanoma.

## **3. Transcriptional Activator-Like Effector Nucleases: Single-Nucleotide Resolution**

In 2011, a new gene-editing technique emerged that represents an improvement over ZFNs. Transcriptional activator-like effector nucleases (TALENs) are structurally similar to ZFNs. Both methods he uses the nucleus to cleave DNA

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<sup>8</sup>What is genetic engineering? (2017, February 17). <https://www.yourgenome.org/facts/what-is-genetic-engineering>

<sup>9</sup>Bhakta MS, Henry IM, Oosterhout DG, Das KT, Lockwood SH, Meckler JF, Wallen MC, Zykov ich A, Yu Y, Leo H, etal. 2013. Highly active zinc-finger nucleases by extended modular assembly. *Genome Res*

and require dimerization to function, but the DNA-binding domains are different. TALENs utilize transcription activator-like effectors (TALEs), which are tandem sequences of 33-35 amino acid repeats. Amino acid repeats have single-nucleotide recognition, increasing targeting ability and specificity compared to ZFNs. Even at single-nucleotide resolution, using his TALENs as gene-editing tools was still time-consuming, expensive, and had certain design limitations. The structure of TALENs implied the requirement for 5'-thymine and 3'-adenine at the target site, which limited their target applicability.

Moreover, TALENs showed decreased editing efficiency in highly methylated regions. Delivery to cells has also been a challenge, as TALENs are much larger than ZFNs (~6kb vs. ~2kb), increasing the time and expense required for successful editing. TALEN demonstrated an improvement in genome-editing technology, but high research and financial costs still hampered its widespread adoption.

Like his ZFN predecessor, TALEN was used in agriculture as well as in the medical field.

#### **4. CRISPR-Cas9 Gene Editing: Revolutionizing Genome Editing**

One commonly used gene-editing technique involves the CRISPR-Cas9 mechanism. However, other mechanisms are associated with gene-editing processes. Gene editing is also known as genetic engineering because it allows you to cut and paste the desired gene to get the desired result. Using this process, we can randomly insert genes of interest into the alindromic sequences to understand the mechanisms of genes of interest. It helps to modify the DNA used in organisms to study the consequences of genes of interest.<sup>10</sup> This process involves three major steps, including insertion, deletion, and alteration of the gene of interest. With the help of this process, researchers and scientists are able to understand deadly diseases that occur in humans, and by altering the DNA of target organisms, researchers and scientists can help prevent such diseases. can be treated to understand the future extent and consequences. With the help of such technology, different types of drugs and vaccines can be developed to obtain different drugs to treat chronic diseases. Gene-editing techniques have led researchers to believe they can cure certain diseases such as HIV, cancer and haemophilia, and could help cure millions of people suffering from such diseases. there is

#### **Legislative and Regulatory Frameworks in Various Countries Related to Gene Editing**

##### **Positioning in India**

India has seen recent growth in technology but still does not have specific legislation regulating genetic modification or germ cell editing. According to

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<sup>10</sup> What is genome editing and CRISPR-Cas9? - Genetics Home Reference - NIH. (n.d.). Retrieved July 10, 2018, from <https://ghr.nlm.nih.gov/primer/genomicresearch/genomeediting>

guidelines issued by the Indian Council for Medical Research (ICMR), gene editing to create designer his babies is unethical and should be banned. The report also notes that scientists currently lack sufficient knowledge and understanding of germline editing.

However, in vitro studies can be performed on substitute embryos that cannot be placed in utero. In March 2018, a Memorandum of Understanding was signed between ICMR and the French National Institute of Hygiene and Medicine (INSERM) to identify potential research areas focused on gene editing. Now is the time for India to need clear legislation to facilitate the safe use of modern gene-editing technologies.

### **Position in the United States**

Although the United States more or less accepts the practice of germline editing, there are no specific laws regarding genetic engineering. In 2016, the National Institutes of Health (NIH), part of the U.S. Department of Health and Human Services, issued several guidelines that do not support genetic modification.

A report was subsequently published advising the U.S. government on the benefits and necessity of germ cell editing. The report highlights the conditions under which this technology can be practiced. Also, the U.S. Food and Drug Administration has authorized the use of embryos to solve infertility problems. I came.

### **UK position**

The UK has taken a restrictive approach to genetically modified organisms (GMOs) but is gradually embracing the technology.

Embryonic research is regulated by the Human Fertilization and Embryology Act 1990. The law allows research on human embryos after obtaining a license. There are certain requirements that must be met by law. In 2011, the Human Fertility and Embryology Agency (HFEA) approved mitochondrial gene replacement therapy (MRI) for the treatment of terminal disease and infertility.

The UK is more open to germline modification than other major countries. The agency has licensed scientists to modify genes in living human embryos. These practices clearly show that the UK is embracing the designer's baby age.

### **Positioning in Japan**

Currently, there is no legal framework for genome editing in Japan. Following an experiment conducted in China in 2015, the Cabinet's Life Ethics Study Group issued a report accepting gene editing research. However, the report was strictly against the reproductive manipulation of embryos and the insertion of modified embryos into a woman's uterus. In Japan, legislation to regulate gene editing is underway. Japan takes a neutral approach to germline gene editing research, but strictly prohibits the reinsertion of embryos into a woman's uterus.

## **Positioning in China**

Recently, Chinese scientists claimed to have conducted experiments on live human embryos. As a result, twin girls have given birth and are less susceptible to HIV. This experiment laid the foundation for the history of genetic engineering

China is now planning to introduce "Gene Editing Regulations" to regulate all issues related to genetic engineering. Recently, when China amended its civil law, it included provisions for gene editing in the latest draft.

## **Germline Gene Editing Advantages and Disadvantages**

### **Advantages**

1. Reduces the risk of genetic diseases by making it possible to cure intractable diseases.
2. Helps reduce the chance of inherited diseases.
3. Children may be born with higher intelligence and obedience, which makes them more likely to succeed in life.
4. New generations can be endowed with new qualities that lead to the development of society  
As a whole

### **Disadvantages**

1. Failure of the procedure can lead to termination of the embryo.
2. Has the ability to create people with perfect or desirable qualities who are likely to create a gap in society.
3. Limits the choice of children as individuals.
4. Altered traits are unique and can damage the gene pool.

### **Conclusion**

It is very clear that there is great potential for germline gene editing and its application in improving humanity. At least in India, the current situation is not conducive to reproductive gene editing, but innovative legal and policy 'plans' could change the same. Human genome editing is prohibited by guidelines, laws and regulations in most countries. However, the first criminal case involving genome-edited babies was issued in China in 2019. Genome editing of healthy human embryos can cause irreversible mutations and severe consequences for heredity in future generations, but its long-term safety is unpredictable. A set of laws, regulations and guidelines should be created to penalize genome editing practices and prevent similar negative events in the future. A more effective and binding mechanism should be established and implemented among countries. To improve global registration and monitoring of human genome editing technologies and research, collaborative networks should be strengthened.



In this way, genome editing is prohibited in many countries, but necessary and practical laws, regulations and guidelines should be developed and appropriate penalties should be applied based on violations. Precautionary measures should also be provided by a special law.

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