

Assessing ethical complications concerning fetal genetic modification

In this Council, delegates will discuss the ethical implications surrounding genetic modifications on human embryos or fetuses. While gene therapy has been effective in treating diseases, modifying a person's DNA in a way that could be passed on to the offspring could reintroduce eugenics and undermine human equality. It is also illegal in many nations around the world.

Definitions of Terms

Embryo: Unborn offspring in the first 8 weeks after fertilization

Fetus: Prenatal human starting 8 weeks after fertilization.

Biomedical Ethics

- The analysis of moral and ethical implications of biological and medical studies and applications.

Gene

- A set of nucleotides forming an operational unit of the DNA that has a specific function thereby determining specific characteristics including disorders
- Genes are passed to offspring by their parents
 - o Sometimes an entire gene is passed on from one parent or another
 - o Other times there is a combination of both which make up the new gene of the child

Germline

- The germination cells (egg and sperm) are the in sexually reproductive organs. The DNA of these cells are passed on to successive generations¹

Gene Therapy

- The procedure of modifying a person's DNA likely in order to treat a genetic disorder or disease. The process is risky and still under study, only being used when there are no other treatment options. Versions of gene therapy include:
 - o Replacing a mutated, disease-causing gene with a healthy version
 - o Inactivating mutated dysfunctional genes or turning on under expressed genes
 - o Introducing new genes to help fight diseases²

Epigenetics

- The addition or removal of molecules that are located on top of certain DNA regions regulating how the DNA is expressed. The environment including food and smoking influences these modifications. Even identical twins with 100% identical DNA have a different epigenetic profile and have, for example, different finger prints.

Eugenics

- Improving a population or species by selective breeding. Encouraging the reproduction of people with desirable traits and discouraging reproduction of those with undesirable traits³ in order to eliminate certain genes from the general population

Reproductive cloning

¹ "Germ Line Definition." *Merriam-Webster*. Merriam-Webster, n.d. Web. 08 Jan. 2017.

² "What Is Gene Therapy? - Genetics Home Reference." *U.S. National Library of Medicine*. National Institutes of Health, 3 Jan. 2017. Web. 08 Jan. 2017.

³ "Eugenics." *Dictionary.com*. Dictionary.com, n.d. Web. 08 Jan. 2017.

- Cloning of an organism's DNA into an enucleated egg with the goal of creating an identical organism by implanting the new embryo into an adult female animal.⁴
- This has been done successfully with many animals and started with Scottish sheep (Dolly) provoking debate.

Therapeutic cloning

- Designed as therapy for disease
- Removing the nucleus of a cell and introducing it into a fertilized egg whose nucleus has been removed. The fertilized egg is allowed to develop for a few days and then some inner cells are removed for stem cell therapy and implanted into the patient to treat a disease⁵

Background Information

Although Mendelian genetics dates back to the late 1800s, the beginning of modern molecular genetics involves the discovery of chromosomes in 1913, the discovery that DNA is the molecule responsible for inheritance in 1928 and the determination of the structure of DNA in 1953 by Watson and Crick.⁶ With these and later discoveries about the function of DNA in cells, the biological problems concerning inheritance and genetics were able to be explored including the commencement of gene therapy in 1990. The first instance of human gene therapy involved inserting a therapeutic gene into a specially engineered virus which would not cause disease or reproduce but would, as regular viruses do, inject its genetic material, in this case the healthy gene, into the patient's cells.⁷ For example, cells from the target tissue are removed from the patient; the cells are grown in culture and then mixed with the virus and returned to the patient to replace the dysfunctional cells. Gene therapy is still under study as it does not always work and is risky. However it seems to be a viable procedure for future therapies. Extensive research is invested in improving techniques and applications all over the world, and many nations endorse the idea. UNESCO International Bioethics Committee released a statement in 2015 stating, "Gene therapy could be a watershed in the history of medicine and genome editing is unquestionably one of the most promising undertakings of science for the sake of all humankind."⁸ For example, China modified a non-viable human embryo in 2015, attempting to alter a gene related to HIV resistance. As we find more genetic anomalies that might be corrected with insertions, or turning genes on or off, many life saving treatments have become available.

Especially since the completion of the Human Genome Project, an international effort to map and determine the DNA sequences all of the genes in the human body, in 2003, there have been questions regarding the use of this new technique. Gene therapy and modifications are made much easier when scientists can know the details of every gene in a person's body and identify precisely which genetic malfunction is causing an issue. A person's DNA is very revealing, particularly in medicine. The UN has made statements in the International Declaration on Human Genetic Data, which consider the extremely sensitive data of genetic testing. There needs to be

⁴ "Reproductive Cloning." *Dictionary.com*. N.p., n.d. Web. 8 Jan. 2017.

⁵ "Definition of Therapeutic Cloning." *MedicineNet*. N.p., 19 Mar. 2012. Web. 08 Jan. 2017.

⁶ "Genetics." *Wikipedia*. Wikimedia Foundation, 6 Jan. 2017. Web. 08 Jan. 2017.

⁷ "Gene Therapy." *National Institutes of Health*. U.S. Department of Health and Human Services, n.d. Web. 08 Jan. 2017.

⁸ "UN Panel Warns against 'designer Babies' and Eugenics in 'editing' of Human DNA." *United Nations News Centre*. United Nations, 5 Oct. 2015. Web. 8 Jan. 2017.

extreme confidentiality to protect an individual's privacy given possible widespread discrimination that could occur if others learned of a person's genetic information, and thereby partly about its offspring too. If alterations were made to a fetus's genome, their genetic privacy could be in jeopardy.

Stem cells are widely used in research and investigated for therapeutic purposes, and to this end, therapeutic cloning is well established. However, using this treatment on embryos where the corrected gene will be passed on to the next generation is a point of contention. Is this the right thing to do, i.e. is it ethical? Do we allow nature to go its course or do we allow science to step in and improve or change the DNA of a to-be human and all of that human's descendants?

The UNESCO International Bioethics Committee followed up its previous statement about gene therapy by saying; "Interventions on the human genome should be admitted only for preventive, diagnostic or therapeutic reasons and without enacting modifications for descendants." The alternative would "jeopardize the inherent and therefore equal dignity of all human beings and renew eugenics." This is the heart of the controversy. Experts agree that gene therapy could be incredibly effective and has already been in certain cases. All of the patients were, however already born. In the very early developmental state of the embryo, the reproductive organs and germination cells are still in development. Therefore, any genetic modification at this stage would effectively be germ line editing and have effects on descendants. The fetus and any later generations would be cured of the genetic disorder but question is whether or not this benefit outweighs societal implications when modifications become inherited.

At first, it may even seem desirable; it means, after all, more people would be borne without genetic disorders. Such change would not only alleviate human pain, but would also benefit society as there will be less money spent on researching, diagnosing and treating diseases, which stem from disadvantaging genetic errors. However, as has been brought up by the International Bioethics Committee, genetic modifications that can be passed on to future generations could lead to a new kind of eugenics. Previously, eugenics meant selective breeding to eliminate a gene in future generations, but early embryonic gene therapy can eliminate a gene much easier and simpler. This could be a good thing as the genes that would be eliminated are usually "bad" genes, which cause medical issues. However, regardless of whether the gene is "bad" or not, the process would limit diversity and implies that not all people are equal anymore as some have been engineered to be improved "designer babies."

This is particularly applicable when we consider socioeconomic status. Prenatal gene therapy would undoubtedly be very expensive, thus giving a heritable genetic advantage to those who are rich and thereby, inadvertently promoting their genes as well. People who could pay for prenatal gene therapy would be genetically advantaged instead of only economically advantaged. Albeit, there is already some of this, as people who have money can pay for operations and medicine that others cannot, but this is a new level of advantage that would also ensure that this benefit continues on for generations. This imbalance would create an inherent inequality of genetic haves and have-nots, which are determined by economic status of the individual or of the state in which they live. While, in practice, regular post-natal gene therapy and other medical treatments would prevent total eugenics from happening because the enhancement would not be passed on to the children meaning that the original genes would continue on to future generations, the societal implications of even starting to eliminate certain genes completely from the gene pool, is of great concern. Inherited improvements could also create prejudice against

those who are not improved, who could be deemed as having less potential because of the possibility of medical complications.

Discrimination is already discussed as a result of genetic testing i.e. just knowing which genes someone has. It is therefore reasonable to assume that changing genes for certain members of society to be more desirable will extrapolate discrimination against those who have not had improvements.⁹

Additionally, when starting to change the characteristics of an unborn human, changes could soon move from solely medical alterations to modifying other elements of person's DNA. For example, while there is not one "smart" gene and it has been found that education, nutrition and the environment in which someone matures have a big influence on someone's intelligence, there are also components, which are founded in genetics. It is a similar story with strength and athletic and artistic ability, while beauty is almost entirely genetic. The question arises: can these things be changed as well? When there is no medical reason to make alterations, should other desirable characteristics be enhanced? These questions will all need to be answered by the Council.

There is inherent inequality in genetics. There will always be some who are naturally smarter, prettier, faster, stronger, more talented, less disposed to illness etc. And there is natural prejudice, favoring these groups. Gene therapy begins to upend the natural state of things, and prenatal gene therapy will guarantee that certain advantaging trends continue, possibly enhancing the aforementioned prejudice and eliminating the relative genetic equality that exists now. Each of these qualities perpetrates anyway as intelligent people, attractive people, athletic people many times have children with people of similar characteristics, but being able to guarantee certain characteristics would abolish all equal luck involved.

Notable Developments 2015-2016¹⁰

- April 2015- China is the first to make modifications on non-viable human embryos
- April 2015- US National Institute of Health (NIH) releases statement that it will fund research on prenatal gene-editing
- October 2015- International Bioethics Committee updates its position proposing a temporary prohibition on human germ line gene editing until further research is done on the safety and efficacy of procedures.¹¹
- December 2015- International Summit on Human Gene Editing (US, UK and China primarily involved) issues a statement that it would be "'irresponsible to proceed' with human germ line gene editing in the absence of 'broad societal consensus.'"
- December 2015- Barack Obama signs into law a bill preventing the Food and Drug Administration from using funds for research involving modification of human embryos
- February 2016- UK Human Fertilization and Embryology Authority (HFEA) makes the UK the first country to authorize editing of human embryos in research¹²

⁹ Genetic Testing." *World Health Organization*. World Health Organization, n.d. Web. 08 Jan. 2017.

¹⁰ "CGS : About Human Germline Gene Editing." *CGS : About Human Germline Gene Editing*. Center for Genetics and Society, 2016. Web. 08 Jan. 2017.

¹¹ "Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights." *UNESCO*. IBC of UNESCO, 2 Oct. 2015. Web. 8 Jan. 2017.

- February 2016-Director of US national intelligence deems genome editing to be part of the list of weapons of mass destruction and proliferation despite current technical limitations
- April 2016- Guangzhou University publishes second report on editing of non-viable human embryos
- May 2016- UK royal society advocates for debating risks and benefits of human germ line engineering¹³
- May 2016- Far right party in France initiates Stop Béb  OGM opposing all genome editing in human embryos

Major countries and organizations involved

- International Bioethics Committee (IBC) of UNESCO
 - o Experts in life sciences, social and human sciences, law, human rights, philosophy, education and communication who are diverse in geographical and cultural background and study ethical complications of progression in life sciences to ensure freedom and human dignity¹⁴
- WHO Human Genomics in Global Health initiative
 - o Promoting education and awareness in governments, the public and the health sector of challenges and opportunities in human genome science¹⁵
- 2014 Map¹⁶



¹² Callaway, Ewen. "UK Scientists Gain Licence to Edit Genes in Human Embryos." *Nature: International Weekly Journal of Science*. Macmillan Publishers, 1 Feb. 2016. Web. 08 Jan. 2017.

¹³ Sample, Ian. "Genetic Engineering of Humans Has Great Potential, Says Nobel Winner." *The Guardian*. Guardian News and Media, 23 May 2016. Web. 08 Jan. 2017.

¹⁴ "International Bioethics Committee | United Nations Educational, Scientific and Cultural Organization." *International Bioethics Committee | United Nations Educational, Scientific and Cultural Organization*. UNESCO, n.d. Web. 08 Jan. 2017.

¹⁵ "Human Genomics in Global Health." *World Health Organization*. World Health Organization, n.d. Web. 08 Jan. 2017.

¹⁶ Friedman, Lauren F. "These Are the Countries Where It's 'legal' to Edit Human Embryos (hint: The US Is One)." *Business Insider*. Business Insider, 23 Apr. 2015. Web. 08 Jan. 2017.

- Canada, Mexico, Brazil, Australia, Spain, France, Italy, Germany, UK, Sweden, Finland and most of Western Europe have legal bans set in place
- Countries in green have ambiguous regulations
- China, India, Ireland and Japan have bans that are not reinforced by legislation
 - o China was the first country to have edited human embryos in 2015. They were able to do so primarily because the work was done with non-viable human embryos that would not have become actual human beings. No modifications have been done on viable embryos up to this point.¹⁷
- UK
 - o In 2015 the UK legalized “three person babies.” The technique, developed in Newcastle, uses a modified version of IVF to combine the healthy mitochondria of a donor woman with DNA of the two parents.¹⁸
 - o UK agencies have promoted research and advocated for debate in germ line editing
- The US had no outright ban but has restrictive rules set in place by the Food and Drug Administration and National Institute of Health¹⁹
 - o 2015 law described above prevents funding for embryonic gene editing research
 - o Poles indicate the American public is largely opposed to human embryo gene modification²⁰

Relevant UN Resolutions and/or Statements

- International Declaration on Human Genetic Data
- United Nations Declaration on Human Cloning 2005
 - o The UN General Assembly recently passed a resolution that addressed the topic of human cloning. In a split vote, the United Nations Declaration on Human Cloning was adopted, which calls upon member states to prohibit all forms of human cloning *and* applications of genetic engineering, which violate human dignity and the protection of human life. According to the UK, this addition of “human life” prompted many countries to vote against the declaration because they did not want to discount the beneficial discussions about therapeutic and reproductive cloning. Reproductive cloning, as defined above, actually takes existing nuclei from an organism, implants it into a fertilized egg without a nucleus in order to make a second identical organism. Therapeutic cloning takes nuclei from an organism, usually skin cells in humans, takes those nuclei to make stem cells and then uses those stem cells as therapy in the original patient. Therapeutic cloning would be a method of fetal genetic modification, as it is already used in gene

¹⁷ Friedman, Lauren F. "These Are the Countries Where It's 'legal' to Edit Human Embryos (hint: The US Is One)." *Business Insider*. Business Insider, 23 Apr. 2015. Web. 08 Jan. 2017.

¹⁸ Gallagher, James. "UK Approves Three-person Babies." *BBC News*. BBC, 24 Feb. 2015. Web. 08 Jan. 2017.

¹⁹ Loria, Skye Gould and Kevin. "This Map Shows Where Researchers Might Design the First Genetically Engineered Baby." *Business Insider*. Business Insider, 20 Oct. 2015. Web. 08 Jan. 2017.

²⁰ Begley, Sharon. "Harvard Poll: Americans Say No to ‘designer Babies’." *STAT*. STAT, 09 Mar. 2016. Web. 08 Jan. 2017.

therapy today. The United Nations Declaration on Human Cloning is very vague however. "Member States are called upon to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life;" This could be interpreted in many ways in multiple ways and according to the UK many countries were worried that it would eliminated therapeutic cloning as well as reproductive cloning thereby putting unforeseen limitations on embryonic modifying research and future application.²¹

- IBC report: *Updating its Reflection on the Human Genome and Human Rights*
 - o Calls for temporary ban of genetic editing of the human germ line- which implies embryonic genetic modification

Previous Attempts to Resolve the Issue

As the technology for germ line engineering and fetal genetic modification is still relatively new, there have been few international meetings except for the International Summit on Human Gene Editing and the IBC report (both described above) to form an international consensus on these topics. As of yet, many countries are making their own decisions.

Possible Solutions

The Universal Declaration of Human Rights does not include an embryo in its definition of "human" and therefore it is not an official *human* right for them to be medically treated. However, the ethical question revolves around the following choice. On one hand, by administering therapeutic gene therapy to embryos, the future human being will have the chance to be effectively cured of a genetic disorder or disease, thereby curing any descendants they may have as well and securing their medical quality of life. On the other hand, the same genetic modification at this early stage would lead to social and ethical dilemmas of equity, injustice and discrimination, particularly when modification is extrapolated beyond medical needs.

In this Council, countries should discuss the ethical implications of each decision and decide on strict guidelines of if, how and when early genetic modification may be performed. Additionally, delegates must determine a way of monitoring and ensuring that restrictions and regulations are met, otherwise risking the possibility of terrible discrimination and -propagating genetically advantaged classes of society.

Repercussions from using this technology without clear regulations could result in a fundamental genetic shift in the global society.

Questions to consider include:

How much should the luck of genetics be respected?

Is it a right to select what your offspring will be like?

Must we respect nature?

Should we always use what science has to offer?

How is economic inequality accounted for?

²¹ "GENERAL ASSEMBLY ADOPTS UNITED NATIONS DECLARATION ON HUMAN CLONING BY VOTE OF 84-34-37 | Meetings Coverage and Press Releases." *United Nations*. United Nations, 5 Mar. 2005. Web. 08 Jan. 2017.

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