SUZMUN XII
Suzhou Singapore International School, SIP, China

Forum: United Nations Commission on Science and Technology

Issue: Implementing measures to address the legal and ethical concerns of gene-editing technology

Student Officer: Millie Lee

Position: Deputy President

Introduction

With an increase in the use of biotechnology, the boundaries of gene-editing technology is becoming a controversial issue. The ability to modify human raises both legal and ethical questions about the extent of genetic enhancement and the potentials for genetic alterations.

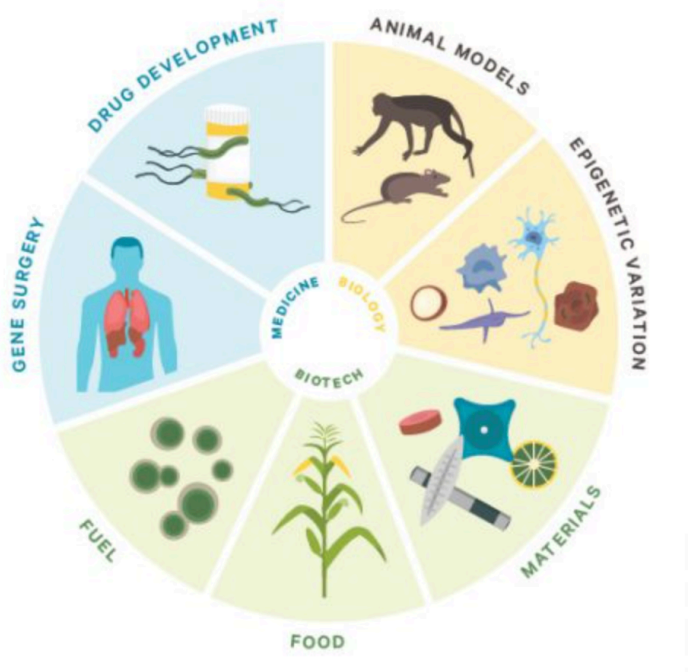

Figure 1: Diverse applications of gene-editing technology (Royal Society)

Recent advancements in this type of technology has been researchers developing new ways to convert these gene-editing technology into medicine, fuel, food and other various parts of our lives. According to Science Daily News, “Researchers in Japan have developed a novel

GEd technique known as NICER, which results in significantly fewer off-target mutations than that of previous CRISPR editing." Following the decade of research on the CRISPR editing, new technologies are pushing the boundaries for new gene-editing technological developments.

Gene-editing technology is considered as a revolutionary change, considering the breakthrough of previous work on yeast and mice. The human GEd technology has been mainly utilized for two purposes: reproductive gene editing and eradicating genetic diseases. The reproductive gene editing technology modifies enzymes to target gene modifications in human embryos and gametes, to produce an ideal baby by altering its genes before they are born. The GEd technology has also been used to eradicate genetic diseases by modifying the cells that are involved, such as the sickle cell disease. While this may seem like one of the major steps that the society will take to reach the future, the increase in development and utilization of gene-editing technologies strongly encourages the discussion on legal and ethical boundaries.

Key Terminology

Genome-editing/Gene-editing (GEd)

A method for making specific changes to the DNA of a cell or organism, essentially customizing its genetic makeup

Deoxyribonucleic acid (DNA)

The molecule that carries genetic information for the development and functioning of an organism, made of two linked strands that wind around each other in the shape of a double helix.

Germline gene-editing (GGE)

An inherited process where DNA is inserted into the reproductive cells in the human body to correct the genetic variants of the reproductive cells of an individuals.

Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)

A technology of repetitive DNA sequences that research scientists use to selectively modify the DNA of living organisms, adopted for use in the laboratory for the purpose of gene-editing.

Somatic Cell Editing

A technology utilized to edit disease-causing DNA within the body's non-reproductive cells, so the effects of modification is limited to the individual, and not passed down to future generations.

Background

After Mendel's laws showed the genetic processes of plant breeding and a combination of preferential traits, further advancements in technology revealed that variations in the genome could be created and altered. The flaw of the gene-editing technology was the randomly occurring variations and undirected possibilities. Gene editing technology was first performed on yeast and mice during 1980s and 1990s. During the decade of 2010, the emerging of developments of new breeding technologies (NBTs) such as GEd opened the possibility for plant breeding. Some of the systems of GEd include Somatic Cell GEd (SCGE), and CRISPR.

Shedding light on multiple systems of GEd has encouraged researchers to implement these systems into making a positive impact on the biological medical factors, for example, changes in DNA that causes disease (i.e. cancer, cell disease, genetic disorder), searching for a way to manipulate the DNA into correct the specific elements. However, these actions of fast-paced developments over the past few decades have raised various concerns on the ethical factors of GEd systems. Following the discoveries that these systems, especially the CRISPR has the potential to make GEd more accurate and efficient in comparison to older technologies, many bioethicists and researchers believe that human GEd for reproductive purposes should not be attempted in the status quo.

In 2014, around 40 countries did not support or banned research on GEd because of the ethical and safety concerns. Previous efforts were also led by the U.S., United Kingdom, and China to unite the regulation of the application of GEd technologies in the International Summit on Human Gene Editing (ISHGE).

GEd has been surrounded by ethical dilemmas after China released news about the genetically editing twins in 2018, and scientist He Jian Kai and other researchers are attempting a comeback after 3 years in prison. A large majority of the countries (96 out of 106) have political documents and legislations addressing the issue of gene editing in the early stages of human cells, and 75 countries out of the 96 prohibit the use of genetically modified embryos to initiate a pregnancy, also known as heritable GEd. Additionally, there are summits, organizations that are in effect and encompasses multiple countries, such as the ISHGE and the Oviedo Convention. However, despite these efforts, no country or organization explicitly permits human GEd .

As regarding the ethical concerns of this technology, two major points have risen to the surface: informed consent and justice and equity. Firstly, many GEd are being utilized for embryos and for reproduction systems. However, it is impossible to obtain informed consent from these embryos, and they will solely be affected by the parents' decision. On the other hand, some argue that some embryos may benefit greater from these technologies, such as preimplantation genetic diagnosis (PGD) or in-vitro fertilization (IVF). Secondly, GEd 's cost would increase the gap of accessibility and disparity, preventing many Less Economically Developed Countries (LEDCs) to not be able to access these resources. Furthermore, some countries have moral and religious objections against these actions, which could potentially lead to greater conflicts between countries, organizations, or individuals. Genome privacy can also become an issue, needing systematic protection of clinical genomic data while utilizing the technology. Linkages between multiple institutions leads to exchanges in sensitive individual identifiers. The accessibilities of this technology is both an ethical and legal concerns, because the cost of using these technologies are very high and the accessibility of these technologies to certain vulnerable groups and individuals. The differences in governments' perspectives and ideas alongside with undefined standards and principles does not provide transparency in the solutions to legal and ethical concerns regarding the utilization of GEd technology.

Major Parties Involved

United Nations World Health Organization Expert Advisory Committee (EAC)

Established in December 2018, the Expert Advisory Committee was established by the World Health Organization (WHO) with the purpose to examine the scientific, ethical, social and legal challenges associated with human GEd. The role of this Committee was the give advice and recommendations on institutional, national, regional, and global governance mechanisms for human GEd. Throughout this work, the Committee conducted a comprehensive review of current research and applications of gene-editing, examined existing proposals and initiatives, and gathered information on the use of the gene-editing technology. Furthermore, the Committee consults and builds on existing initiatives to develop a governance framework and recommendations on the governance and oversight of human GEd. The panels in the EAC consists of experts, appointed by the Director-General, to correspond to meetings to achieve such goals mentioned above.

United States of America (USA)

The United States of America (USA)'s federal law prohibits the use of federal funds for research on human germline gene therapy. GGE is banned in the USA, although there are no federal legislation that dictates protocols or restrictions regarding human genetic engineering after the passing of the Dickey-Wicker Amendment in 1996. However, the USA has many institutions and organizations regarding this issue. Firstly, the Food and Drug Administration (FDA) provides recommendations to institutions developing the human genome-editing technology, through applying the information from the Investigational New Drug (IND) application for any drugs related technologies. These processes help with product manufacturing and testing, nonclinical safety assessment and clinical trial designs. The USA and other Majorly Economically Developed Countries (MEDCs) have major influence in the perspective and

actions of smaller countries, so these attempts from governmental organizations set a standard for other countries.

World Medical Association (WMA)

The World Medical Association (WMA), founded in 1947 on September 17th, is an international organization representing physicians with meetings between 27 different countries. This committee ensures the independence of physicians with ethical standards at all times. They provide ethical assistance and guidance to physicians, considering the right of patients, and research on human subjects etc.

Timeline of Events

Date	Description/Note
1974	Viral DNA injected to integrate genome of mice (first transgenic animal)
1987	First discovery of CRISPRs in E.coli (mechanism first published)
1999	First Human Chromosome is Sequenced
2001	First Gene-Targeted Drug Therapy is Approved
2003	Completion of the Human Genome Project
May 2005	Discovery of CAS9 Protein and the protospacer adjacent motif (PAM)
August 1st, 2005	Suggestion in CRISPR spacer sequences can provide cell immunity against phaGEd infection and degrade DNA
2006	Food and Drug Administration (FDA) Approval of the First Preventative Cancer Vaccine
2006	First Induced Pluripotent Stem Cells (iPSCs)
March 23, 2007	Experiments demonstrate for the first time the role of CRISPR together with Cas9 genes in protecting bacteria against viruses
2008	DNA demonstrated to be the molecular target of most CRISPR-Cas systems
2015	A Human Embryo is Edited with CRISPR
December 2015	International Summit on Human Gene Editing
2020	CRISPR/Cas GEd technologies recognized with 2020 Nobel Prize in Chemistry

Previous Attempts/Solutions

The Human GEd (HGE) Registry is a “central database that collects information of clinical trials using human GEd technologies.” They focus on making information of clinical trials of HGEd easily accessible for all stakeholders. 2 meetings were held by the Committee of the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human GEd . They focus on two issues - the first being the somatic and germline clinical trials and the second being research using GEd technologies on human embryos and germline cells.

The International Summit on Human GEd (ISHGE) was led by the United States, United Kingdom and China in 2015 and was held in Washington D.C. After the second summit in 2018 at Hong Kong, the London summit in 2023 continued the global dialogue on GGE, sharing information on developments of clinical trials and the CRISPR. Through the third summit, researchers were able to offer the conclusions that despite the remarkable progress, human GEd remains unacceptable, and research is needed to expand the ranGEd of diseases to better understand risks and unintended effects. Furthermore, equitable access to these treatments is urgently needed. They also stress the importance of needing a governance framework and ethical principles for the responsible use of heritable GE. This Summit advocates for continued research to expand upon the ranges of diseases that could be treated using this technology, and to better understand risks and unintended effects.

The Declaration of Helsinki is a statement of ethical principles for medical research involving human subjects that was adopted by the General Assembly of the World Medical Association in June 1964. This statement was constantly amended until October 2013, but there has not been any progress since. Despite the limits, the declaration addresses multiple aspects of the issues of gene-editing technology.

Potential Solutions

1) Government + Collaborative Network

As the issue of legality of gene editing technology rose from the criminal case in China of 2018-2019, many believe that a full set of laws and regulations along with the guidelines should be formulated to penalize GEd behaviors and prevent these issues happening in the future. A collaborative network should be strengthened for better global registry and surveillance of human genome-editing technology and research. Preventing too much subjectivity of the government in this issue should also be permitted.

2) Standardization

The blurry line of restriction between legal and illegal use of CRISPR and other forms of gene editing technology strongly advocates for more effective and binding mechanisms to be constructed and implemented among different countries. The wide ranGEd of differentiation between the legislations of each country would make it impossible for the legal and ethical concerns of gene-editing technology to be addressed, and therefore: even if the country needs specific adjustments, the standardization of the guidelines and basic legislation should be set.

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