

COMMUN IX UNITED NATIONS GENERAL ASSEMBLY (UNGA)

GENOME EDITING

Background Guide

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INTRODUCTION

Dear Delegates,

Thank you for participating in this General Assembly on gene editing at COMMUN IX. The United Nations General Assembly (UNGA) is the main policy-making body of the United Nations, where member states meet in sessions, such as this one, to discuss international issues presented before the delegates. The purpose of this assembly is to discuss the ethical, social, and scientific consequences of genome editing.

This committee is run by two co-chairs. Our names are Andrew Carter and Peyson Bilimoria, and we are both juniors at Commonwealth School. This is our second year chairing a committee at COMMUN, and we have both participated in Model UN and Model Congress for over two years.

According to the WHO, genome editing is defined as "a method for making specific changes to the DNA of a cell or organism," in order to change certain traits.¹ With the rapid breakthroughs in biotechnology of the 21st century, the ethical, social, and scientific consequences of genome editing have emerged as major worldwide issues. Largely due to the speed of this technological advancement, regulations have often not kept pace with advancements in the field of genome editing and vary wildly in both content and enforcement from country to country. There is widespread fear that genome editing could result in the creation of unintended illnesses and bioweapons that could come with long-term, unforeseen issues that would only appear after generations. Some have suggested that regulations be put in place to combat this, whereas others have hoped to put an end to genome editing altogether.

Cases of possibly immoral and non-consensual collection, replication, and editing of human genomes, such as the unregulated creation of "designer babies," have raised concerns for many ethicists and policymakers.² Others argue, however, that gene editing could be a net benefit for humanity. Many studies suggest that research into gene editing could allow for major breakthroughs in preventing and combating diseases such as HIV, in breeding highly resilient and high-yielding crops, and in preventing severe genetic diseases.³ That the business of gene editing can be incredibly lucrative only makes the debates surrounding its application more vehement.

Over the course of this conference, it is your job to represent one of a diverse group of nations and to build regulations and a worldwide consensus on the future of biotechnology. The conference will focus on two topics. You will first consider human genome editing, both for medical treatment and in embryonic "designer babies." You will then turn to how to apply

¹ <u>https://www.who.int/health-topics/human-genome-editing#tab=tab_1</u>

² <u>https://embryo.asu.edu/pages/ethics-designer-babies</u>

³ https://www.leopoldina.org/en/topics/genome-editing/genome-editing-pros-and-cons/

editing of viruses' genetic materials and how biological hazards such as lab leaks could change the future of biosecurity. We look forward to seeing how you address each of these topics!

In order to be eligible for awards, and, more importantly, to make your experience at COMMUN as fun and rewarding as possible, **this committee requires each delegate to submit a position paper** detailing their country's position on the topics before the committee. For examples of previous position papers and other resources to aid your research, please visit <u>COMMUN's Resources Page</u>.

We can't wait to read and learn more about your country's position! If you have any questions, please feel free to email us!

Sincerely,

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IMPORTANT DEFINITIONS

The following words appear throughout this guide and are important for your understanding of biowarfare and genome editing:

• <u>Biodefense</u>: Measures put in place to prevent and respond to biothreats, both from bioweapons or unintentional spreading of diseases such as COVID-19.

- <u>Bioweapons:</u> Weaponized forms of microorganisms such as viruses and bacteria deliberately released to inflict harm on human beings, plants, or any other living organisms.⁴
- <u>CRISPR</u>: (short for "clustered regularly interspaced short palindromic repeats") is a technology that research scientists use to selectively modify the DNA of living organisms. CRISPR was adapted for use in the laboratory from naturally occurring genome editing systems found in bacteria.⁵
- <u>"Designer Babies"</u>: Term used to describe babies who have been subject to embryonic genome editing.
- <u>Human Embryonic Genome Editing</u>: Using technology such as CRISPR to edit the genomes of human embryos (before they are born). Often done as an attempt to prevent genetic disorders and decrease their chances of sickness.
- <u>Human Genome</u>: 23 pairs of chromosomes located in the cell's nucleus, as well as a small chromosome in the cell's mitochondria. A genome contains all the information needed for an individual to develop and function.⁶
- <u>Human Therapeutic Genome Editing / Gene Therapy:</u> Using technology such as CRISPR to edit genomes for the purpose of addressing an individual's medical condition. Often in the form of inserting edited genes into or removing genes from a patient's genome.⁷
- <u>Precision Medicine</u>: A healthcare approach that utilizes molecular information (genomic, transcriptomic, proteomic, metabolomic, etc), macroscopic examination, and health data from individual patients to generate specific care insights to prevent or treat their diseases.⁸

PROBLEM STATEMENTS

On October 2, 2015, the United Nations International Bioethics Committee (IBC) published a report "Updating Its Reflection on the Human Genome and Human Rights." In this update, the committee took into account many past declarations on the topic of genome editing, including the Universal Declaration on the Human Genome and Human Rights, the International Declaration on Human Genetic Data, and the Universal Declaration on Bioethics and Human Rights. The possible ethical and consensual problems of human genome editing are discussed in great detail in this report.⁹ In addition to discussing such topics, the report also describes the changing nature of genome editing, highlighting the need to update the restrictions and modernize the universally accepted practices regarding human genome editing. With the extreme technological advances of the 21st century and with precision medicine becoming more

⁴ <u>https://www.who.int/health-topics/biological-weapons#tab=tab_1</u>

⁵ https://www.genome.gov/genetics-glossary/CRISPR

⁶ <u>https://www.genome.gov/genetics-glossary/Genome</u>

⁷ CRISPR Interpretation: <u>https://crisprtx.com/gene-editing/therapeutic-approach</u>

⁸ <u>https://www.efpia.eu/about-medicines/development-of-medicines/precision-medicine/</u>

⁹ For information on this report, see <u>https://unesdoc.unesco.org/ark:/48223/pf0000233258/PDF/233258eng.pdf.multi</u>

common, such restrictions will be crucially important to preserve ethical standards around the world. The goal of this committee's first session is to develop legally binding resolutions on the topic of human genome editing that tackle fears associated with the rate of genome editing advancement and concepts such as the "designer babies," as well as hopefully allow for the medical advancement of such an important scientific field.

The topic of viral and bacterial genome warfare is also extremely important to global security. In 1975, the Biological Warfare Convention was passed by the UN, detailing preventions and restrictions against biowarfare and bioweaponry.¹⁰ While this convention agrees to never purposely produce bioweapons, the risk of accidental genome-edited viral outbreaks or response to biothreats is not detailed. Biological weapons have become an increasingly common and alarming threat to global safety, as seen in the 2001 anthrax attacks in the United States, where the mailing of anthrax-laced letters resulted in five deaths and a widespread bioterrorism scare.¹¹ As more and more research is done on viral genomes and pathogens in containment facilities across the world, there is an increasing possibility of bio-leaks and the accidental spread of such pathogens. The effects of an accidental lab leak could be deadly. The goal of this committee's afternoon session is to develop legally binding resolutions that minimize the risk of lab leaks and the production of bioweapons, as well as plans to defend against such threats.

BACKGROUND

Genome Editing

A Brief History of Genome Editing

Genome editing is a very new field of scientific research. Until the mid-20th century, a majority of research on genomes came from analyzing natural and random mutations, until scientists realized that they could manipulate the speed of mutations through radiation treatment. However, they were unable to target specific genes until the late 20th century, when scientists were able to focus mutations on specific genes within mice. Unfortunately, the process was tedious, the mutations were still varied, and human genome questions were still far away.¹²

The building blocks of modern gene editing arose during the late 20th century, though they were not yet applicable to human genomes. Scientists were able to recognize the process by which mutations frequently occurred during reproduction and were thus able to start identifying the "molecular mistakes" that caused certain diseases. It was this process of identification that paved the way for modern targeted genome therapy.¹³

¹⁰ https://front.un-arm.org/wp-content/uploads/2020/12/BWC-text-English-1.pdf

¹¹ https://www.fbi.gov/history/famous-cases/amerithrax-or-anthrax-investigation

¹² https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5733845/

¹³ <u>https://www.britannica.com/science/gene-editing</u>

The biggest breakthrough in modern genome editing practices happened in 2009 with the release of the genome editing tool CRISPR, specifically CRISPR-Cas9. CRISPR has been significantly easier to use, cheaper, and more accurate than any other methods of genome editing preceding it. Most modern research and usages of genome editing partially, if not fully, utilize and rely on CRISPR.¹⁴

International Summit on Human Gene Editing, 2015¹⁵

In 2015, The National Academy of Sciences, the National Academy of Medicine, the Chinese Academy of Sciences, and the Royal Society of the UK organized an International Summit in Washington, D.C, in order to address a wide range of ethical and governance issues associated with modern genome editing. Following the summit, they broke down their conclusions into the following key realizations:

Firstly, modern genome editing tools, specifically CRISPR, were far from perfect. While CRISPR excelled compared to previous methods of genome editing at an incredibly cheap price, it was far from perfectly accurate. There was little way to ensure that CRISPR would not generate unwanted immune responses, trigger cancer activation, or result in genome rearrangement. However, they did acknowledge that CRISPR had continued to improve in these regards since its release and predicted these issues would become negligible in the coming years.

Despite its current limitations, the scientists at the summit believed that there was already a wide range of positive genome-editing applications. Applications of therapeutic genome editing have been able to reduce the effects of HIV and hemophilia B, and they predicted that in the near future, with continued research, they would be able to combat sickle cell anemia, thalassemia, and other blood disorders; hepatitis and other infections; immune deficiencies; infertility; and cancer. In recent months, these predictions have become reality, with the United States's FDA approving two CRISPR-based treatments for sickle cell diseases in late 2023.¹⁶ The summit also highlighted the possibility of using genome editing to end inheritable diseases and "enhance[] human traits."

Despite its promising future and endless capabilities, some scientists shared their concerns over the ethical, legal, and social issues surrounding human genome editing, including many that proposed a ban on all research until the UN banned all embryonic editing for reproductive purposes. However, there were others who proposed that these advancements were simply part of human nature to continue to succeed and advance, and some even believed that in order to get the most out of such technology, there should be little to no regulations. That being said, most of the scientists acknowledged the possibility of eugenic-type ideals returning with the

¹⁴ https://www.genome.gov/about-genomics/policy-issues/what-is-Genome-Editing

¹⁵ https://nap.nationalacademies.org/read/21913/chapter/1#4

¹⁶

https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-d isease

implementation of widespread genome editing, especially without any cohesive plan to ensure equal access to treatment.

2018 Chinese CRISPR Twins

In November of 2018, word of embryonic-edited twins from China took worldwide media by storm. Using CRISPR technology, Chinese doctor He Jiankui genetically engineered a pair of embryonic twins in an effort to experiment with preventing HIV from being passed down to children. The experiment lacked proper and sufficient evidence and had no legal basis under Chinese law. However, many, including He Jiankui, deemed the experiment a success.

The event became a central piece to the discussion of the possibilities and ethics of human genome editing. While it partially proved the capabilities of CRISPR and embryonic genome editing, it raised many concerns about regulations and restrictions surrounding the practice. Many of He Jiankuis's experiments had gone unmonitored, and, when inspected, showed major flaws and places of incomplete or improper editing, which could possibly lead to health issues in the twins later in their lives. Scientists and the public alike began questioning who should have access to genome editing technology. Many were left wondering how illegal experiments like these could go as far as they did. Another issue raised was how experiments like this could unfairly target one group over another. While both of the twins' genomes were genetically edited, only one had both copies of their HIV-prone genomes edited, while the other had just one, leaving the second child still partially susceptible to the virus. According to the doctors involved, this was in order to monitor the reactions of both children to their environments, leaving one child at a significant disadvantage compared to the other, even though neither of them were able to choose or prevent being genetically modified to any degree. Not to mention, both embryos were healthy before being modified, meaning their modifications were purely enhancements.¹⁷

In 2019, He Jiankui was arrested and sentenced to three years in prison for knowingly breaking Chinese genome editing law. He Jiankui defended his work, claiming, "I believe families need this technology. And I am willing to take the criticism for them."¹⁸

Biowarfare, Terrorism, and Security

Brief History of Biowarfare:19

After the tens of thousands of biowarfare-related deaths during World War II, countries came together in an effort to fully eradicate biowarfare through the 1972 Biological Weapons

¹⁷ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6724388/

https://www.npr.org/2019/12/30/792340177/chinese-researcher-who-created-gene-edited-babies-sentenced-to-3-year s-in-prison

¹⁹ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1326439/

Convention disarmament treaty. However, this treaty, and treaties like it, have largely been ineffective in stopping both research and usage of biowarfare and bioweapons, which only increases as human understanding of viruses and bacteria continues to grow.

The major issue of these treaties, going as far back as the 1874 Brussels Convention, which outlawed the use of poison in war, was that they were entirely based on good faith and lacked any means of control, enforcement, or punishment. Following the effectiveness of bioweapons in World War II, many European countries have since continued research into bioweapons despite being the frontrunners in drafting and signing said treaties.

In the last 100 years, many countries have pointed fingers at others, with claims of using biowarfare, but these cries often fall on deaf ears. Powerful countries such as the US, the old Soviet Union, and Germany have been accused of using biowarfare despite signing the same treaties as everyone else. They have largely been able to get away with it due to the disparity between the sophistication of their attacks and the weak biodefenses of the affected countries.

There are many current fears over Russia and its lack of transparency in its development of biowarfare. However, according to US intelligence, South Africa, Israel, Iraq, and several other countries have also developed or are still developing biological weapons.

2001 Anthrax Attacks

In the days following the 9/11 attacks, multiple letters laced or filled with anthrax were sent to United States congressional offices and news outlets. Anthrax is a very rare but also incredibly dangerous A-level bioterrorism threat bacterial spore which, when inhaled, is almost untreatable. Being a bacteria, Anthrax is spread through spores which, when inside the body, can be "activated" and multiply, overwhelming the body's immune system. Anthrax can enter the body through exposure from cuts or wounds (cutaneous), eating contaminated food (gastrointestinal), or, as in the case of the Anthrax Attacks, breathing in the spores (inhalation).²⁰

Even though the idea of such a bioattack had been considered before, it had only really been discussed in theoretical terms. After the first confirmed case in Palm Beach County Florida, it was reported that hospitals and administration had large amounts of difficulty contacting local, state, or federal agencies. Federal officials initially believed that the case was isolated and not a result of bioterrorism, although, within the next seven weeks, 22 cases were reported across four states.²¹ Other issues allowed for the effectiveness of the Anthrax Attacks, such as the fact that few doctors had experience dealing with Anthrax and that processes of cleaning contaminated areas were highly inefficient, for example, decontaminating the buildings where the letters were sent cost almost one billion dollars. The United States was completely caught off guard, and major holes in biodefense, both nationally and internationally, began to show.²²

²⁰ https://www.cdc.gov/anthrax/pdf/evergreen-pdfs/anthrax-evergreen-content-english.pdf

²¹ https://www.acpjournals.org/doi/10.7326/0003-4819-155-12-201112200-00373

https://nihrecord.nih.gov/2022/05/13/2001-anthrax-attacks-revealed-need-develop-countermeasures-against-biologic al-threats

However, the Anthrax Attacks also revealed how countries could respond to such threats. Using modern technology, laboratories were quickly able to study and find ways to contain the spread of anthrax spores and have since been studying other similar bio-weaponable bacteria and viruses in order to have pre-prepared responses. The genetic nature of the anthrax used was also traceable to particular labs, even allowing the FBI to conclude who was responsible for the attacks, proving how close regulation and documentation of possible bio-weapons can allow for a swift response.²³

2019 Langzhou Brucella Leak

In order to combat Brucella's main form of transmission through wild animals, the Zhongmu Lanzhou biopharmaceutical plant of Gansu, China was attempting to perfect an effective vaccine. However, in failing to adequately decontaminate their facility, contaminated aerosol leaked into the air, infecting over 10,000 people in nearby towns and cities. Brucella is a B-level bioterrorism threat and is spread mostly through animals, affecting humans similarly to a common fever. It is also especially prevalent in countries that lack effective forms of combating and maintaining animal health programs. Many countries from Asia and Africa, as well as the Middle East, are deemed high-risk regions for Brucella.²⁴

According to investigations, there were a large number of severe risk factors that contributed to the leak. Many of the procedures used to produce and study the vaccine were performed in open conditions without protective coverings, despite the strict national and international restrictions surrounding veterinary vaccine production. Studies suggest that standardized procedures, enforcement of wearing of personal protective equipment (PPE), and automation of labor where possible could have prevented such a leak. Improper lab conditions and precautions relating to Brucella have also been reported around the world, such as in Argentina, where traces of Brucella were found in over 70% of workers in vaccine manufacturing plants.²⁵

QUESTIONS TO CONSIDER

While reading your country's positions below, performing your own research, and writing your position paper, consider these questions as guides to understand your country's stances and where you can collaborate with other delegates.

Genome Editing:

²³ https://www.acpjournals.org/doi/10.7326/0003-4819-155-12-201112200-00373

²⁴ https://jglobalbiosecurity.com/articles/10.31646/gbio.108

²⁵ <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9621275/</u>

- What does your country think is the appropriate balance between promoting scientific advancement through genome editing and establishing guidelines to prevent misuse or unethical practices?
- What does your country think the role of international cooperation should take in establishing or enforcing guidelines? Should each country choose its own regulations?
- What regulations and guidelines does your country envision for the rest of the world, and how can you work with other countries to communally agree on these rules?
- How should your country and others approach the disparity of access to state-of-the-art genome editing technology? Does your country envision itself having a strong role in genome therapy or embryonic editing research, or maybe becoming a leader in regulating genome editing? How do other countries impact your view?
- What does your country believe the UN's reaction to breaking guidelines should be; is it the job of all countries to enforce and condemn the breaking of regulations?

Biowarfare:

- What does your country see as the role of the United Nations in establishing a framework for biowarfare protection and regulation? Should each country have its own regulations, and should the UN have a say?
- What does your country see as the United Nations' role in supporting smaller nations in defense against bio scares and biowarfare? Should every country have to contribute? Does your country want more aid?
- What measures, if any, should the UN put in place to promote transparency between countries on biowarfare development and usage? Does your country want to share its developments?
- In the event of a biowarfare attack, how should the United Nations respond in a time-effective and productive manner? Do certain countries take a stronger role? What consequences, if any, does your country think should be established for those who use biowarfare?
- What is the United Nations' role in addressing non-state biowarfare? Will the framework for protection be enough, or do the countries affected need extra support from the UN?

COUNTRY POSITIONS

ISRAEL

Most human gene editing in Israel is allowed and only lightly regulated. All gene therapy must be approved by an advisory council and must follow all guidelines outlined in the 2000 Genetic Information Law.²⁶ However, gene editing for the purpose of creating "designer babies" is completely prohibited. Genome editing cannot be used to "cause the creation of a person"

²⁶ Law can be found at https://www.jewishvirtuallibrary.org/jsource/Health/GeneticInformationLaw.pdf

unless explicitly allowed by the Minister of Health.²⁷ In terms of viral genome editing, Israel has made significant advances in the past years. Scientist Dr. Adi Barzel, from a study testing gene editing technology on AIDS in Tel Aviv University, expects that "over the coming years we will be able to produce a medication for AIDS, additional infectious diseases and certain types of cancer caused by a virus."²⁸ Since Israel is a religious state, there are also many ethical considerations that relate to Judaism and Jewish religious law.²⁹ Israel's stance on biowarfare is largely unknown to the public. While Israel does possess advanced chemical and biological weapons, the types of agents and in what quantities are unknown.³⁰ Despite its definite positive effects on the political stability and confidence of the region, Israel has never made public statements on their usage of biowarfare and has not signed the 1972 Biological and Toxin Weapons Convention.³¹

<u>MEXICO</u>

There is no specific legislation restricting human gene editing in Mexico. However, all new biotechnology medicine must be in accordance with La Ley General de Salud, the General Health Law.³² Furthermore, it must undergo approval by a variety of health committees to be produced for widespread use. Due to its lack of specific legislation surrounding gene editing, Mexico has become somewhat of a safe haven for other countries who want to perform gene editing procedures without the restrictions of their home country. In 2016, American scientists traveled to Mexico to create a child through genome modification, as the laws in their home country would not allow it.³³ Due to this, concerns have been raised about Mexico's lack of specific genome editing regulations. There is also no widespread viral genome editing in Mexico, but such a field may become useful in the coming years as it continues to evolve. The vulnerability of the Mexican population to biothreats has been discussed, yet national government budgets have yet to permit sufficient research and procedures needed to respond to such threats. Current public health policies are also outdated and inadequate.³⁴

<u>INDIA</u>

Human genome editing in India is allowed for research but banned in other forms. However, there is little specific language around these bans. Due to this, there are many questions about the country's genomic security. In research, genome modification on embryos is

²⁷ <u>https://www.nuffieldbioethics.org/wp-content/uploads/Report-regulation-GEHR-for-web.pdf</u>

²⁸ https://english.tau.ac.il/combating_AIDS

²⁹ Concerns can be found at <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9622389/</u>

³⁰ https://carnegieendowment.org/2002/04/16/chemical-and-biological-weapons-in-middle-east-pub-11745

³¹ https://www.nti.org/analysis/articles/israel-biological/

³² Information on this Law can be seen at <u>https://www.diputados.gob.mx/LeyesBiblio/pdf/LGS.pdf</u>

https://www.technologyreview.com/2016/09/28/157310/a-three-parent-child-was-conceived-in-mexico-because-the-us-wont-allow-it/

³⁴ <u>https://www.scielo.org.mx/scielo.php?pid=S0036-36342001000600012&script=sci_abstract&tlng=en</u>

allowed under certain parameters, such as the rule that as long as an embryo is not carried to term, its genome modification is allowed.³⁵ There are also many fears of the misuse of genome editing in Indian society, especially in the hands of the elites, a question that also translates into the viral editing field.³⁶ If genome-edited viruses got into the hands of the wrong person, especially in such a populous country, the effects could be devastating. Due to the lack of widespread hygiene and sanitary facilities, India is considered vulnerable to all forms of biological agents. In terms of bioterrorism, India lacks the organization needed to properly identify, collect, and control specimens before they grow beyond control. Preparedness and long-term strategies are needed to continue to prevent and combat bio-threats and weapons. Since signing its name at the 1975 BWC, India has agreed to prohibit any production or stockpiling of bioweapons.³⁷

AUSTRALIA

Human genome editing in Australia is prohibited, carrying a 15-year jail sentence for anyone who edits the human genome to create heritable traits. It is, however, possible for research, as long as the researcher has a license and its purpose is ethical.³⁸ Australia is also one of the global hubs for advancement in the field of viral genome editing, producing a specialized version of CRISPR that can quickly target the Mpox virus.³⁹ With these rapid advancements, Australia may soon become a model country when it comes to viral genome editing.

THE UNITED KINGDOM

Human genome editing for therapeutic and research applications is highly regulated in the United Kingdom, yet possible.⁴⁰ While genome modification with the goal of reproducing is strictly illegal, genome editing for research is permitted (although it requires a hard-to-obtain license, given based on the proposal's ethics.)⁴¹ In recent years, there has even been an increase in allowed medical applications of CRISPR-edited genomes. In 2021, the UK Government lowered its regulation on medical and therapeutic post-embryonic genome editing, permitting the approval of treatment of sickle cell disease with CRISPR-edited genome therapy in November

³⁵ https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/india-germline-embryonic/

³⁶ https://carnegieendowment.org/2019/04/09/can-world-keep-lid-on-pandora-s-box-of-gene-editing-pub-78798

³⁷ Krishan, Kewal, et al. "India's Preparedness against Bioterrorism: Biodefence Strategies and Policy Measures." *Current Science*, vol. 113, no. 9, 2017, pp. 1675–82. *JSTOR*, http://www.jstor.org/stable/26493307. Accessed 4 Jan. 2024.

³⁸ <u>https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/australia-germline-embryonic/</u>

³⁹ https://www.doherty.edu.au/news-events/news/unveiling-australias-fastest-next-gen-mpox-diagnostic-tool

⁴⁰ https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/united-kingdom-germline-embryonic/

https://www.hfea.gov.uk/about-us/news-and-press-releases/2016/hfea-approves-licence-application-to-use-gene-editing-in-research/

2023, which received great support from doctors and patients alike.⁴² The relaxing laws have also proven to be financially beneficial for the pharmaceutical industry, yet there has been a push from within the UK and other parts of Europe to pause any decisions until regulations can catch up.⁴³ After the COVID-19 outbreak, the UK Government has pledged itself to improve its defenses against all forms of biological risks, including bio-warfare. By 2023, the UK also plans to position itself as a leader in establishing the framework for international regulations on biological threats and defense against biowarfare and leaks.⁴⁴

GUINEA

Guinea does not have much experience with genome editing, both human and viral. There is a lack of research into its effects and no products are being developed with its use.⁴⁵ However, as seen in the Ebola crisis, West African countries such as Guinea can be extremely prone to new diseases.⁴⁶ While Guinea may not have extensive legislation on the topic, it houses and represents the fears of many of the developing nations around the globe.

SOUTH AFRICA

Many South Africans have recently expressed a push for advanced and widely available genome editing research and medicine. As seen in a 2022 study, most South Africans supported the use of genome editing technology to prevent genetic health conditions and protect against viruses such as HIV/AIDS. Such applications would be done on the fetal level, effectively creating designer babies. Furthermore, since the South African constitution deems the "right to access healthcare services," many South Africans would not stand for encroachment on their access to such services if they are created.⁴⁷ South Africa also has a long history of biowarfare, having an extensive bioweapons program that lasted from 1981 to 1993.⁴⁸ While the program was abandoned and bioweaponry was agreed against, the country still has many people who helped produce these bioweapons, and could provide insight and expertise into the weapons' potential uses and dangers.

⁴²

https://amp.theguardian.com/society/2023/nov/16/uk-medicines-regulator-approves-casgevy-gene-therapy-for-two-b lood-disorders-sickle-cell

⁴³ <u>https://perma.cc/HZ66-GW9H</u>

⁴⁴ https://www.gov.uk/government/publications/uk-biological-security-strategy/uk-biological-security-strategy-html

⁴⁵ https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/africa-germline-embryonic/

⁴⁶ <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9759305/</u>

⁴⁷ For information on this study, see

https://blog.petrieflom.law.harvard.edu/2022/12/02/human-genome-editing-south-africa/

⁴⁸ https://www.nti.org/analysis/articles/south-africa-biological/

<u>RUSSIA</u>

Russia currently has a lack of regulation of and a lack of interest in editing the human genome. There are no official laws against it, but the country generally supports the idea that the field of human genome editing, being so ever-evolving, is not safe enough yet for widespread use. However, some Russians do not hold this same sentiment, and scientists such as Denis Rebrikov have intended to work on creating designer babies and editing the human genome.⁴⁹ While there are also no policies on viral genome editing in Russia, the field may become important in the coming years. Due to Russia's current active military status and position as a large global power, the use of bioweapons and edited viral genomes could prove tactically advantageous in their global endeavors. In 2022, Russia falsely claimed, during its ongoing invasion of Ukraine, that Ukraine was housing US bioweapons facilities, showing the importance of global monitoring and consensus around these programs.

ARGENTINA

Argentina has been known to have a lack of interest in the editing of genomes, both human and viral, and has currently made no efforts to change this sentiment.⁵⁰ However, with the election of new president Javier Milei, this may quickly change. Milei, who cloned his pet dogs, has described the field of cloning as "the future."⁵¹ While this view currently only applies to animal cloning, Milei's practice of quickly changing many parts of the Argentinian government could lead him to emphasize the editing of both human and viral genomes. His right-wing libertarian views, furthermore, may allow for future unregulated genomic ventures in Argentina. With Milei's election, Argentina could quickly become one of the largest global hubs for gene editing.

UNITED STATES OF AMERICA

Therapeutic and medical application of genome editing, as well as embryonic editing, is highly regulated in the United States. This is largely due to its controversial nature and unpredictable side effects. However, there are ways to get around these regulations. Privately funded research lacks almost all restrictions placed on government-funded trials.⁵² In the near future, in whole or state-by-state, there is a likely chance that the United States will ban or largely prohibit human embryonic editing.⁵³ However, in 2020, the Food and Drug Association

⁴⁹ For information on the human genome in Russia, see

https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/russia-germline-embryonic/

⁵⁰ <u>https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/argentina-germline-embryonic/</u>

⁵¹ https://www.nytimes.com/2023/10/19/world/americas/argentina-election-javier-milei.html

⁵² https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/united-states-embryonic-germline-gene-editing/

https://www.cambridge.org/core/books/abs/human-germline-genome-modification-and-the-right-to-science/regulation-of-human-germline-genome-modification-in-the-united-states/D9A1C0BFACC0683E97141B27DD79278D

released new guidelines that were in strong support of the development of therapeutic applications, in which they notably pushed for the idea of post-market regular evaluation of these treatments.⁵⁴ In response to the COVID-19 outbreak, the United States has released an in-depth strategy preparing against future biothreats, although this strategy does not mention aiding other countries.⁵⁵ According to the US Department of Justice, "Bioweapons has been singled out as the greatest threat that the United States (U.S.) might face in the next century."⁵⁶

GERMANY

Germany's current regulations on genome editing match those set by the European Union (EU). The EU is highly regulatory of all human genome editing, with therapeutic applications being highly regulated by EU agencies, and all embryonic editing is strictly prohibited. However, it is notable that current regulations are vague and misleading, especially with regard to the line between therapeutic editing and all other forms.⁵⁷ Germany is one of the strongest enforcers of the regulations, leading to little German gene-editing innovation despite recent technological advancements.⁵⁸ The EU's current regulations on biodefense are vague.⁵⁹ Germany has recently believed strongly in revamping both domestic and international biosecurity measures.⁶⁰ They see aiding other countries in their efforts in biosecurity as critical for both their own and international biodefense.⁶¹

FRANCE

France's current regulations on genome editing match those set by the European Union (see "Germany" above). While abiding by the EU's strict prohibition against embryonic gene editing, there have been many recent therapeutic application advancements from France.⁶² Recent changes in French laws relating to genome editing have also combated and opposed EU laws, although they have yet to demand or push for changing of regulation.⁶³ The EU's current regulations on biodefense are vague.⁶⁴ France actively and strongly opposes biowarfare and has publicly wished other major countries would do the same, as seen through their launching of the

⁵⁴https://www.fda.gov/news-events/press-announcements/fda-continues-strong-support-innovation-development-gen e-therapy-products

https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/18/fact-sheet-biden-harris-administration-releases-strategy-to-strengthen-health-security-and-prepare-for-biothreats/

⁵⁶ https://www.ojp.gov/ncjrs/virtual-library/abstracts/biological-weapons-national-security-threat-and-public-health

⁵⁷ https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/eu-germline-embryonic/

⁵⁸ https://brooklynworks.brooklaw.edu/bjil/vol45/iss1/9/

⁵⁹ <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5449436/</u>

⁶⁰ <u>https://www.armscontrol.org/act/2022-07/news/germany-prioritizes-biosecurity-global-partnership</u>

https://fourninesecurity.de/en/2023/02/15/pandemic-pathogens-as-biological-weapons-revisiting-german-biodefense

⁶³ https://www.reuters.com/article/us-france-agriculture-gmo-idINKBN29N1T9/

⁶⁴ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5449436/

"International Partnership against Impunity for the Use of Chemical Weapons" in 2018, dedicated to fighting against any country involved in producing or using chemical or bioweapons.

<u>CHINA</u>

China is currently the global pioneer of human genome editing technology and research. Being the site of He Jiankui's designer babies and extensive research into the extent and possibilities of human genome editing, the country is paving the way for CRISPR technology and has done work that many other countries have shied away from.⁶⁵ The methods used in Dr. Jiankui's experiments and the success of his genetically modified children have effectively made him a martyr for the advancement of the field, and have opened a door for continued technological advancement in the field.⁶⁶ The key to China's success as the global hub for human genome editing relies on their ability to preserve the ethics of their experiments while pushing back against restrictive laws which limit their revolutionary work. China has many centers for viral research, most notably the Wuhan Institute of Virology which was the center of the COVID lab leak conspiracy.⁶⁷ While this conspiracy was debunked, there are still many fears of Chinese lab leaks from countries around the globe. Not only could another viral outbreak be devastating to the Chinese population, it could also be devastating to the world's view of China as a global power. For China, it is of the utmost importance to push back against misinformation in the genetic engineering field and make sure its research labs are protected against scrutiny and outside interference.

<u>UKRAINE</u>

A few companies in Ukraine have been experimenting with the human genome. For example, at the Medeus Medical Center, CRISPR technology could be used to edit the human genome.⁶⁸ However, due to Ukraine's current military status, the topic of the human genome is not a high priority. This status also clears the way for the potential of the use of bioweaponry, which could become an extremely advantageous military tactic in the fight against Russia. The country has also been the subject of a conspiracy by Russia that bioweaponry work was happening in Kyiv and a network of bioweaponry labs existed across the country.⁶⁹

SINGAPORE

⁶⁵ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6724388/

https://www.technologyreview.com/2018/11/26/138957/the-chinese-scientist-who-claims-he-made-crispr-babies-has -been-suspended-without-pay/

⁶⁷ https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology/

⁶⁸ https://www.geneticsandsociety.org/biopolitical-times/gene-edited-enhancements-sale-ukraine

⁶⁹ https://lieber.westpoint.edu/russias-allegations-us-biological-warfare-ukraine-part-i/

Singapore supports embryonic genome editing and genome research with certain restrictions. Human embryos can be created for germline research, however, they cannot be allowed to grow past fourteen days, preventing the creation of designer babies. These regulations, however, are unclear in the case of clinical trials.⁷⁰ Singapore, being a densely populated island, is extremely prone to viral outbreaks. This is exacerbated by the fact that the country has large ports for both air and sea traffic.⁷¹ The country, however, has been seen to handle such outbreaks well, as evidenced by its effective response to the COVID pandemic.⁷²

INDONESIA

The status of genome editing in Indonesia is currently highly ambiguous, as there is a general lack of education on the technology in the country. In a survey of Indonesian medical students, only roughly 35% percent knew about the technology.⁷³ Furthermore, since the country is mostly Muslim, there are some religious convictions against the process.⁷⁴ Currently, Indonesia seems to have no interest in viral genome editing. The country is already heavily affected by diseases, especially malaria, which kills approximately 2,000 people each year.⁷⁵ Indonesian cities are also densely populated, so genome-edited viruses would be able to easily and quickly spread throughout the population.⁷⁶

BELGIUM

Gene editing on embryos is currently allowed in Belgium as long as it is for research purposes only. This means that, under current Belgian law, the creation of designer babies is heavily forbidden. Furthermore, all research on embryos must be approved by an ethics committee.⁷⁷ In the case of viral genome editing, the creation of bioweapons is also forbidden, and the country was one of the nations to ratify the Biological Weapons Convention in 1979. The country has pushed for increased safety around all genome editing sites and has pushed for stronger punishments for creating and using bioweapons.⁷⁸

JAPAN

⁷⁰

https://www.cambridge.org/core/books/abs/human-germline-genome-modification-and-the-right-to-science/regulation-no-fhuman-germline-genome-modification-in-singapore/57BBB7B16B8850341503D03E5E2A24AB

⁷¹ <u>https://pubmed.ncbi.nlm.nih.gov/2825585/</u>

⁷² https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7214001/

⁷³ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9327639/

⁷⁴ <u>https://www.state.gov/reports/2022-report-on-international-religious-freedom/indonesia/</u>

⁷⁵ https://www.cdc.gov/globalhealth/countries/indonesia/default.htm

⁷⁶ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7442427/

https://www.nationalacademies.org/documents/embed/link/LF2255DA3DD1C41C0A42D3BEF0989ACAECE3053 A6A9B/file/D17ECFF26C74AA2C9CA9FEB18C853D28C86F1FC7ED8A?noSaveAs=1

⁷⁸ https://diplomatie.belgium.be/en/policy/policy-areas/peace-and-security/weapons-mass-destruction

In recent years, Japan has been shot into the spotlight for some of its advancements in genome editing. Scientists at Osaka University have been developing new technology for IVG (in vitro gametogenesis), a process that may allow researchers to create and fertilize human eggs. It also may allow for people to develop designer babies.⁷⁹ While the topic of such designer babies is a touchy subject, Japan could quickly become one of the largest and most powerful centers for genome editing. Japan also has a touchy history with bioweapons and viral editing, as in World War II the country was the site of Unit 731, a site which tested the effects of various biological weapons on prisoners of war.⁸⁰ It is an extremely dark part of the country's history, and one they wish to never see implemented anywhere around the world again.

<u>GREECE</u>

While Greece does not have any laws specifically forbidding the creation of designer babies and genetically advanced humans, the country does still follow the established UN conventions.⁸¹ In spite of this, the country was still the site of a controversial "three-parent baby" experiment, where a child was born with the DNA of three separate people. The technologies used in this experiment can also be used to treat and prevent mitochondrial disease, making babies much healthier.⁸² Greece, being a country with a large network of global trade, interacts with people from all over the world daily.⁸³ This means that bioweapon threats can spread very quickly, and it must be of the utmost importance for the country to preserve its biological safety and protect its economy.

FINLAND

Finland is not generally involved in the rampant editing of the human genome and the creation of designer babies. Currently, it follows the UN's established guidelines. However, to many Finnish people, these UN guidelines on genome editing prevent the country from producing stable, resistant crops. This greatly hinders its agricultural production and affects many parts of Finnish life.⁸⁴ In the case of viral genome editing, however, Finland is a hub for virus production, with some companies offering virus-synthesizing services.⁸⁵ These may become extremely profitable in the future, so it is in the country's best interest to keep these services safe and contained.

COSTA RICA

⁷⁹ https://news.wgcu.org/2023-09-28/japanese-scientists-race-to-create-human-eggs-and-sperm-in-the-lab

⁸⁰ https://ahf.nuclearmuseum.org/ahf/history/unit-731/

⁸¹ https://www.sienna-project.eu/news/news-item/?tarContentId=824542

⁸² <u>https://www.bbc.com/news/health-47889387</u>

⁸³ https://www.trade.gov/country-commercial-guides/greece-market-overview

⁸⁴ https://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/163143/VNTEAS_2021_39.pdf

⁸⁵ https://bioscience.fi/services/genome-editing/services/viral-vector-production/

Currently, Costa Rica does not have significant clear-cut restrictions and regulations on human genome editing. Most Costa Ricans support the process for crops but do not approve of the creation of designer babies.⁸⁶ The country is also a hub of tourism, and many people travel in and out of the country daily.⁸⁷ If a bioweapon attack were to reach the country, its effects on tourism and the economy would be devastating. Costa Rica is also a "megadiverse" nation, with high numbers of unique species, some of which may carry genes useful for crop or human genome editing.

UNITED ARAB EMIRATES

Since there are currently no clear-cut restrictions on human gene editing in the UAE, companies have been experimenting with IVF technologies that may allow parents to create designer babies.⁸⁸ One company, Fakih IVF, offers various screening services that may be able to be used to create such designer babies.⁸⁹ Due to these advancements, the country may become a center for genome editing in the future. Being an international hub for business and travel, a bioweapon threat would be devastating. However, gene sequencing and editing technology can be very useful in analyzing diseases, so it is important that the safety of bio labs in the UAE have adequate safety procedures but are still allowed to carry out their work.⁹⁰

SOUTH KOREA

Historically, South Korea has followed the established EU and UN guidelines on genome editing. However, in recent years, their views on the restrictions imposed by Europe have changed a bit. There has been a recent push to remove some of these restrictions and regulate CRISPR use less than other forms of genome editing.⁹¹ Furthermore, South Korean scientists recently used CRISPR to correct a gene mutation in a human embryo.⁹² In recent years, the country has also been experimenting with Virus-induced genome editing (VIGE) which involves infecting plants with viruses to cause genome mutation in a process said to be much quicker than CRISPR.⁹³ This process is new, and poses lots of risks, but may be the key to rapid genome editing in the future. It is important for South Korea to balance the safety of the process but also allow for rapid advancement in the field.

THE NETHERLANDS

⁸⁶ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10468379/

⁸⁷ <u>http://www.costarica-embassy.org/index.php?q=node/19</u>

⁸⁸ https://www.liebertpub.com/doi/full/10.1089/crispr.2020.0082

⁸⁹ https://fakihivf.com

⁹⁰ https://www.nature.com/articles/s41598-021-92851-3

⁹¹ https://www.science.org/content/article/european-commission-proposes-loosening-rules-gene-edited-plants

⁹² <u>https://www.nature.com/articles/nature23305</u>

⁹³ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10782499/

The Netherlands allows for embryonic genome editing and research with some restrictions. The biggest of these restrictions is that there must be a clear risk of passing down some disease for a human embryo to be edited in order to protect against such a disease.⁹⁴ Furthermore, many Dutch citizens support embryonic gene editing to prevent serious muscle diseases, but few support genome editing for the improved intelligence of humans.⁹⁵ In the Netherlands, there are a majority of companies studying viruses.⁹⁶ Some of these research sites use genome editing tools to make vaccines and other treatment options, so it is important for there to be a clear standard of lab safety around the use of such viruses that both prevent risk and promote research.

PANAMA

In Panama, human genome editing is allowed when it is "for the purpose of curing or preventing a serious hereditary disease."⁹⁷ This language, however, is somewhat ambiguous and it is unclear exactly what a "serious hereditary disease" is. Panama is also a big exporter of bananas and coffee.⁹⁸ If a genetically engineered virus happened to escape a lab or be released into Panama, its effects on the country's farming, exports, and economy could be devastating. Bananas, in particular, show the devastating effect biological weapons could have on crop supplies. The Gros Michel banana, once the dominant variety of banana grown globally, was nearly eliminated by Panama disease in the 1950s and had to be replaced by the now dominant Cavendish banana.

COLOMBIA

Colombia currently prohibits human genome editing with the exception of when the procedures are "aimed at relieving suffering or improving the health of the person and humanity."⁹⁹ Similarly to that of Panama, this language is very ambiguous and leaves lots of room for interpretation. Due to cartel activities in Colombia and its already numerous diseases, it is of utmost importance for the leaders of Colombia to prevent a new, genetically edited viral outbreak, and make sure other countries around the world are practicing safe research and holding themselves accountable.¹⁰⁰ In the hands of the cartel or another dangerous non-national organization, such as a terrorist group, the threat of bioweapons may be even greater.

DEMOCRATIC REPUBLIC OF THE CONGO

⁹⁴ https://www.secjure.nl/2015/09/14/designed-babies-within-the-current-legal-framework/

⁹⁵ https://www.nature.com/articles/s41431-022-01114-w

⁹⁶ https://www.knvm.org/virology/dutch-virology

⁹⁷ https://www.liebertpub.com/doi/epdf/10.1089/crispr.2020.0082

⁹⁸ https://oec.world/en/profile/country/pan

⁹⁹ https://www.liebertpub.com/doi/epdf/10.1089/crispr.2020.0082

¹⁰⁰ <u>https://wwwnc.cdc.gov/travel/destinations/traveler/none/colombia</u>

Congo does not currently possess significant resources to engage in human or viral gene editing. However, the country is affected by a number of diseases which could be prevented through viral gene editing. Sickle cell anemia, for example, is a genetic disorder with a high prevalence in the country. Genome therapies are currently being developed to cure sickle cell anemia, but their exorbitantly high costs may keep them out of the hands of most Congolese. For the DRC, it is essential to ensure that genome therapies are accessible to less developed countries.

TURKEY

Geopolitically, Turkey straddles between East and West. While it holds many trade and military ties to Europe, it also maintains connections to Asia. Turkey's position on gene editing is similarly a mix of EU-type restrictions with more freedom. Turkey controls parts of northern Cyprus, but this control is not internationally recognized. This has created a legal gray-area, which several companies are exploiting. Using clinics in Northern Cyprus, they are marketing "designer babies" to parents from foreign countries. In order to stop these programs, Turkey will need to join in international collaboration with other nations to create international regulations.

FURTHER READING

- The Basic Science of Genome Editing, National Library of Medicine: https://www.ncbi.nlm.nih.gov/books/NBK447276/
- Global Gene Editing Regulation Tracker, Genetic Literacy Project: <u>https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/</u>
- 1975 Biowarfare Convention: https://front.un-arm.org/wp-content/uploads/2020/12/BWC-text-English-1.pdf
- 2015 International Summit on Human Gene Editing: https://nap.nationalacademies.org/read/21913/chapter/1#4
- Future Bioterror and Biowarfare Threats for NATO's Armed Forces until 2023, MCU: <u>https://www.usmcu.edu/Outreach/Marine-Corps-University-Press/MCU-Journal/JAMS-vol-14-no-1/Future-Bioterror-and-Biowarfare-Threats/</u>
- The History of Biological Warfare, National Library of Medicine: <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1326439/</u>
- Chemical Weapon Convention (CWC), OPCW: https://www.opcw.org/chemical-weapons-convention
- International Partnership against Impunity for the Use of Chemical Weapons, NICW: <u>https://www.noimpunitychemicalweapons.org/-en-.html</u>