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Deutsch-Baltisches Jugendwerk

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"EUROPE SHALL HEAR YOU"

European Answers on how to shape our Future

– POLICY PAPER –

Cure or Design: What kind of Human Genetic Engineering do we want?

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The Conference is organized by:

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The German-Baltic Academic Foundation promotes exchange and cross-cultural understanding between young adults from Germany, the Baltic States and Russia on the basis of democracy and human rights. For this purpose, we award scholarships, organize seminars and congresses, arrange internships and facilitate networking of participants and scholarship recipients through alumni work. In the context of the shared history, the Foundation aims to continuously develop towards becoming a German-Baltic Youth Office (Deutsch-Baltisches Zukunftsforum /„DBJW").

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Content

Introduction

In November 2018 there was a huge outcry all around the world when Chinese scientist He Jiankui reported the birth of twin girls whose DNA had been modified with the help of the gene editing tool CRISPR-Cas9 in order to make them resistant to HIV. Even though the experiment was later declared illegal by the Chinese government and led to a three year long prison stay for He Jiankui, it also showed how far the research in the field of genetic engineering had evolved. This case intensified the discussion of ethical questions and moral standards in relation to the modification of human DNA. We, a group of young Europeans have spent the last few months diving into this discussion which typically takes on different shapes depending on whether genes are modified for purposes of prevention, therapy or enhancement.
The following policy paper summarizes our discussions and findings we have gained from a small survey among young Europeans. It ends by listing a set of recommendations we would like to pass on to European policy- and decision-makers as part of the EU's Conference on the Future or Europe.

#EuropeShallHearYou #TheFutureIsYours

Definition of terms – what do we mean by human genetic engineering?

When talking about human genetic engineering there is oftentimes confusion about the meaning of the term and the type of cells the engineering refers to. In our discussion we made use of a **definition of genome editing** put forward by the EU Commission's Group on Ethics in Science and New Technologies:

> *"[Genome editing] involves the modification of the genome through targeted adding of, replacing of, or removing one or more DNA base pairs in the genome, regardless of whether the modifications occur in a particular gene or a non- coding region of the genome."*[1]

It is then also important to distinguish between the two **different types of genetic engineering**: 1) engineering of somatic (non-productive) cells and 2) engineering of the germline (reproductive cells) or the human embryo. Scientists have repeatedly flagged up the importance of distinguishing between these two types of engineering as this holds repercussions for research policy.[2]

[1] European Group on Ethics in Science and New Technologies (2021), p. 12

[2] Lanphier, E., Urnov, F., Haecker, S. et al. (2015), p. 411: "Key to all discussion and future research is making a clear distinction between genome editing in somatic cells and in germ cells. A voluntary moratorium in the scientific community could be an effective way to

Current legal situation in the EU

In the European Union there are different sets of rules in place to regulate the different types of genome editing. Regulations with regard to **editing of the germline** have been set by the EU Commission and the European Medicines Agency (EMA). The 2014 Clinical Trials Regulation banned clinical trials for gene therapies that cause modifications to the germline. Additionally, many EU member states have their own national legislation banning germline engineering.
In all legislations relating to human genetic engineering the EU and its member states are guided by the 2000 EU Charter of Fundamental Rights and the 1997 Convention on Human Rights and Biomedicine (Oviedo Convention) of the Council of Europe (CoE).
The Oviedo Convention, which has been ratified by 29 of the 47 CoE member states, stipulates that "[a]n intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any

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discourage human germline modification and raise public awareness of the difference between these two techniques. Legitimate concerns regarding the safety and ethical impacts of germline editing must not impede the significant progress being made in the clinical development of approaches to potentially cure serious debilitating diseases."

descendants".[3] It is interesting to note that the text of the convention clearly calls for "appropriate public discussion" (Ch. X, Art. 28) on the ethical and scientific implications of gene editing.
Interestingly, Germany has to date not ratified the Oviedo convention, whereas Lithuania, Latvia and Estonia have.
In this year's April meeting of the Committee on Bioethics of the Council of Europe, the importance of the Oviedo Convention was underlined. However, it was also argued that there is still a need to provide certain clarifications, "in particular on the terms "preventive, diagnostic and therapeutic" and to avoid misinterpretation of the applicability of this provision to "research""[4].

On the legal situation it is finally interesting to note that many regulations outside Europe are much more liberal, both towards germline as well as somatic engineering (see overview in Annex 1).

[3] Council of Europe (1997): Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine Ch. IV, Art. 13
[4] Council of Europe (2021): Genome editing technologies: some clarifications but no revision of the Oviedo Convention, accessed 24 Oct, 2021

Preventing/Curing/Enhancing - where to draw the line?

In most literature on ethics of human genetic engineering, authors do not only differentiate between the different types of cells that are modified but also between the different aims or purposes of a genetic modification. One typically speaks of prevention/protection, therapy/cure and enhancement.

Prevention is aiming at modifying DNA strings in order to prevent the outbreak of a disease in the human body in the first place. This is also possible for an embryo or fetus to e.g. prevent or reduce the likelihood of passing on a hereditary disease. The idea here is similar to the reasoning behind being vaccinated. Some authors have stressed the importance of differentiating between genetic modification for protection purposes and for enhancement purposes (both treatments are interventions in normally functioning individuals) because of the consequences this entails for regulations.[5]

[5] Mikkelsen, Rasmus Bjerregaard, Henriette Reventlow S. Frederiksen, Mickey Gjerris, Bjørn Holst, Poul Hyttel, Yonglun Luo, Kristine Freude, and Peter Sandøe. "Genetic protection modifications: moving beyond the binary distinction between therapy and enhancement for human genome editing." *The CRISPR journal* 2, no. 6 (2019): 362-369.

In our discussions, we stressed the argument that in relation to preventative purposes of genetic engineering, intrusive modifications should always be weighed against other preventative measures that might be taken with the same goal in mind (e.g. diet, alcohol consumption, weight).

Therapy means modifying a part of the DNA with the goal of treating or curing a disease that is inherent in the patient's body. The correction of the gene defect takes place either in the body (in vivo) or outside (ex vivo) with subsequent return of the corrected cells. Because of the therapeutic effect of this kind of genetic engineering, it could be compared to taking medication. Gene therapy holds promise for treating a wide range of diseases and has been successfully applied in treating congenital diseases such as epidermolysis bullosa[6].

While there is a broad consensus supporting the use of non-heritable (somatic) genetic modifications to treat patients with serious illness, there is nearly universal discomfort about using genetic modifications for human enhancement. Human enhancements are biomedical interventions that are used to improve human form or

[6] Epidermolysis bullosa is a group of rare diseases that cause fragile, blistering skin.

functioning beyond what is necessary to restore or sustain health.[7]

Tackling this topic, the question arises how **health, normality and sanity**, as well as "natural" per se, are defined, as the meaning of these concepts shift over time to accommodate social norms and cultural values of modern societies.

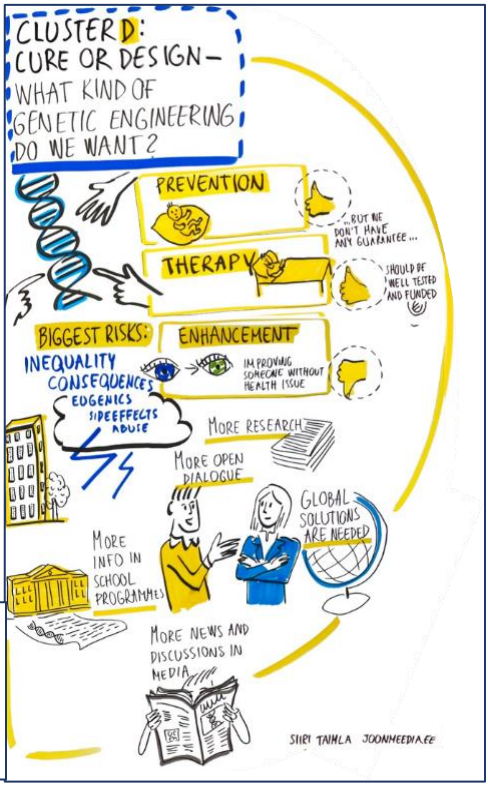


Figure 1 Visualization of Discussion on Human Genetic Engineering at DBK Tallinn, October 2021

[7] Juengst, Eric and Daniel Moseley (2019). Human Enhancement, The Stanford Encyclopedia of Philosophy

Small-scale survey

In order to gain a wider understanding of how this topic is perceived among young people in Europe, we conducted a small-scale online survey.

The survey consisted of 20 questions, was distributed in five languages via social media and ran for two weeks in October 2021. Our aim was to gain the participants' opinions on a range of topics related to genome editing, covering genetic engineering for purposes of prevention, therapy and enhancement. We also inquired about participants' views on policy-making in that area. Altogether, 56 people completed the survey. Although respondents' age ranged from 13 to 67, more than 75% of respondents were under the age of 35. Respondents were predominantly female, living mostly in Germany or Estonia, were mostly in university or working.

A visual summary of our survey can be found in Annex 2. Overall, most respondents said it should be allowed to apply genetic engineering for purposes of preventing or treating a disease (graphics 1 and 2). Interestingly, participants seemed to be a little more open towards preventative as opposed to therapeutic modifications. However, generally speaking many of the respondent opted for non-definite answers, most prominently on the question on genetic engineering in unborn and on the

question related to genetic engineering in a family with a history of short stature[8].
With regard to genetic engineering for enhancement purposes, respondents positioned themselves overwhelmingly adversely.
It was argued that enhancement could potentially have a negative impact on society, benefiting the rich and thus widening the social divide. Enhancement therapies could also lead to a raise of the norm (e.g. with regard to human skills) and therefore lead to social pressure for those unwilling or unable to undergo genetic treatment.
Although some respondents seemed to be a little hesitant regarding the merits of genetic engineering at large, it was argued that outlawing genetic engineering altogether would bear many negative consequences, such as genetic engineering tourism. Therefore, some respondents argued for the establishment of clear, internationally binding regulations.

[8] Q: Should human genetic engineering be allowed in unborn - that means without having the possibility to ask for the child's consent but with the aim of improving the child's living conditions? 21 % of respondents not sure
Q: Should parents with a family history of short stature (dwarfism) be morally obligated to have genetic surgery (through genetic engineering) performed on their offspring? 29 % not sure

Recommendations

We want human genetic engineering to be a topic that sees **open public debate**, as the potential remedies of the practice affect everyone. Right now the public is not well enough informed about the consequences that the application of such technologies could have. We want the European institutions to take initiative in bringing this topic to the public discourse as well as defining **clear legal regulations**. We encourage national governments to include education and discussions about the topic in schools' curricula.

Human genetic engineering should only be allowed for specific, proven therapeutic medical purposes and only be used to improve or restore the human health to a necessary level of sustainability, not for human enhancement.

If genetic technologies get approved for usage in humans, they should be **freely available and affordable for everyone**. Patents on sequences of the human genome should be forbidden. Other uses should not be for private financial gain, considering how public institutions contribute to the development of these technologies.

The European legal systems should have a **common position** on the boundaries of human genetic engineering and enforce these regulations irrespective of where in

the world European citizens are engaging in illegal genetic practices.

Europe should continue to participate in the search for truly **global solutions** to the ethical challenges of gene modification. This includes building on works of international organizations such as WHO, UNESCO and the Council of Europe, as well as addressing possible weaknesses of these documents which are in part due to their oftentimes eurocentric nature.

Under no circumstance should anyone be discriminated against based on their genes and/or gene modifications. No one should be forced to have their genes modified against their will. **Personal autonomy, bodily integrity, fairness, justice and dignity** are important values of a democratic world. We would like to live in a Europe that fosters these values and promotes **diversity and inclusiveness**.

References

Council of Europe (1997): Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine

Council of Europe (2021): Genome editing technologies: some clarifications but no revision of the Oviedo Convention, accessed 24 Oct, 2021

European Group on Ethics in Science and New Technologies (2021): Ethics of Genome Editing, https://doi.org/10.2777/659034

Lanphier, E., Urnov, F., Haecker, S. *et al.* (2015): Don't edit the human germ line. *Nature* 519, pp. 410–411. https://doi.org/10.1038/519410a

Mikkelsen, Rasmus Bjerregaard, Henriette Reventlow S. Frederiksen, Mickey Gjerris, Bjørn Holst, Poul Hyttel, Yonglun Luo, Kristine Freude, and Peter Sandøe (2019): Genetic protection modifications: moving beyond the binary distinction between therapy and enhancement for human genome editing. *The CRISPR journal* 2, no. 6, pp. 362-369.

Juengst, Eric and Daniel Moseley (2019): Human Enhancement, The Stanford Encyclopedia of Philosophy (Summer 2019 Edition), Edward N. Zalta (ed.)

Annex 1

Human / Health Gene Editing Index

Compare Regulatory Restrictions Country-to-Country

Gene editing regulations worldwide are evolving. The Gene Editing Index ratings below represent the current status of gene editing regulations and will be updated as new regulations are passed.

COLORS AND RATINGS GUIDE

Regulation Status	Rating
Determined: No Unique Regulations*	10
Lightly Regulated	8
Proposed: No Unique Regulations†	6
Ongoing Research, Regulations In Development	5
Highly Regulated	4
Mostly Prohibited	2
Limited Research, No Clear Regulations	1
Prohibited	0

Lightly Regulated: Gene and stem cell therapies regulated with minimal restrictions and requirements.

***Determined: No Unique Regulations:** Gene and stem cell therapies regulated as phamaceuticals with no additional restrictions.

†Proposed: No Unique Regulations: Decrees under consideration for gene and stem cell therapies that would not require unique regulations beyond current restrictions on pharmaceuticals.

Therapeutic:
Gene editing of adult human cells, including gene therapy and stem cell therapy, that is used to treat and cure disease. Recent breakthroughs include CAR T-cell therapy, which uses patients' own immune cells to treat their cancer.

Germline:
Gene editing of the human embryo or germline that results in genetic changes that are passed down to the next generation. This type of gene editing is the most controversial because changes are inherited and because it could theoretically be used to create "designer babies". A Chinese scientist announced in 2018 that he had successfully edited twins that were brought to term. International backlash from the announcement has resulted in China and other countries working to clarify regulations on germline gene editing.

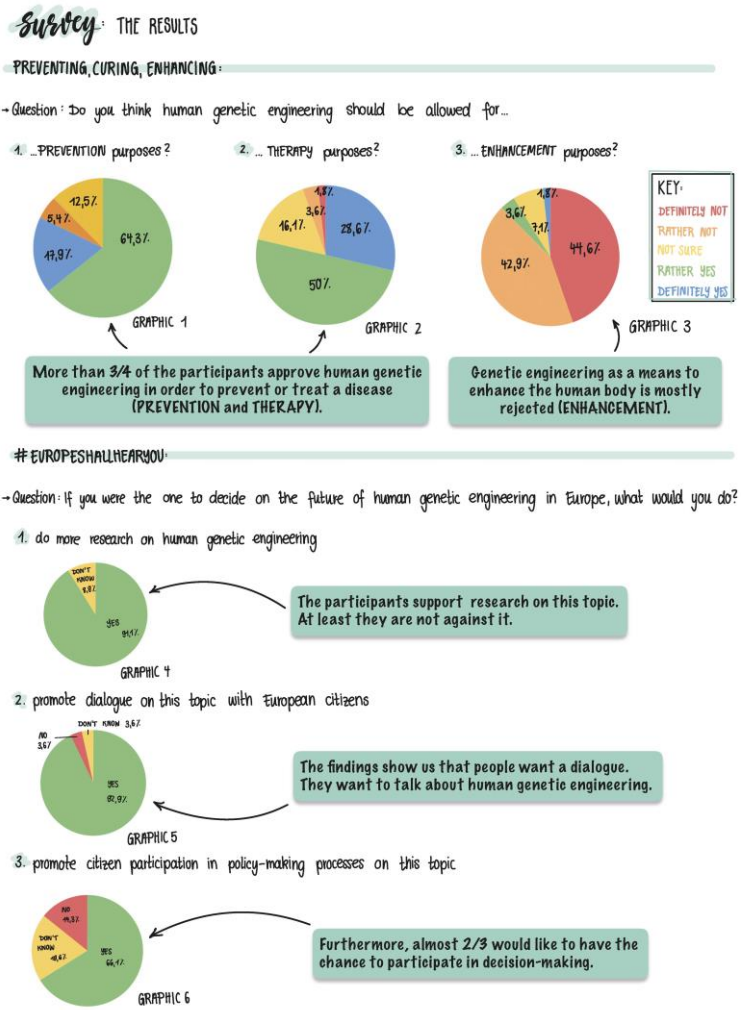
RATING BY COUNTRY / REGION

Click each column header and arrow to sort the countries / regions

Country / Region	Therapeutic	Germline	Human Rating
Japan	8	8	8
Russia	10	5	7.5
Ukraine	10	5	7.5
China	8	4	6
Israel	8	2	5
UK	4	4	4
Mexico	8	0	4
Argentina	5	1	3
Chile	4	1	2.5
Brazil	4	0	2
Canada	4	0	2
Australia	4	0	2
US	4	0	2
New Zealand	4	0	2
India	4	0	2
EU	4	0	2
Central America	1	1	1
Paraguay	1	1	1
Uruguay	1	1	1

Source: https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/eu-therapeutic-stem-cell/, accessed 24 Oct, 2021

Annex 2


survey: THE RESULTS
PREVENTING, CURING, ENHANCING:
→ Question: Do you think human genetic engineering should be allowed for...
1. ...PREVENTION purposes?
2. ... THERAPY purposes?
3. ... ENHANCEMENT purposes?
12,5%
5,4%
64,3%
17,9%
4,8%
3,6%
16,1%
28,6%
50%
1,8%
3,6%
7,1%
44,6%
42,9%
KEY:
DEFINITELY NOT
RATHER NOT
NOT SURE
RATHER YES
DEFINITELY YES
GRAPHIC 1
GRAPHIC 2
GRAPHIC 3
More than 3/4 of the participants approve human genetic engineering in order to prevent or treat a disease (PREVENTION and THERAPY).
Genetic engineering as a means to enhance the human body is mostly rejected (ENHANCEMENT).
#EUROPESHALLHEARYOU
→ Question: If you were the one to decide on the future of human genetic engineering in Europe, what would you do?
1. do more research on human genetic engineering
DON'T KNOW
YES
GRAPHIC 4
The participants support research on this topic. At least they are not against it.
2. promote dialogue on this topic with European citizens
DON'T KNOW 3,6%
NO 3,6%
YES
GRAPHIC 5
The findings show us that people want a dialogue. They want to talk about human genetic engineering.
3. promote citizen participation in policy-making processes on this topic
NO
DON'T KNOW
YES
GRAPHIC 6
Furthermore, almost 2/3 would like to have the chance to participate in decision-making.