Policy As Discourse: Analysis of Problem Representations in Policies on Human Genome Editing

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Author's Declaration

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Abstract

Recent developments in human genome editing (HGE) have precipitated a boom in scientific interest and policy recommendations for national and international governance frameworks for HGE. Due to the significant moral and ethical implications of HGE policies, there is benefit in assessing the extent to which the representations of problems in HGE policies are able to create appropriate solutions, and how this can inform future policymaking. This thesis uses Bacchi's (2009) "What's the Problem Represented to be?" approach to analyze national and international HGE policies as discourse. It argues that problem representations in existing HGE policies are able to capture the most pressing issues and propose solutions to them within the constraints of relevant institutional factors. However, HGE policies would benefit from expanding upon the ways in which institutions and assumed knowledges and assumptions shape policymaking and whether these influences should be reexamined.

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List of Abbreviations

CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
DNA	Deoxyribonucleic acid
GMO	Genetically modified organism
HGE	Human genome editing
HIV	Human immunodeficiency virus
IGO	Intergovernmental organization
IP	Intellectual property
IVF	In vitro fertilization
IVG	In vitro gametogenesis
PGT	Preimplantation genetic testing
UNESCO	United Nations Educational, Scientific and Cultural Organization
WHO	World Health Organization
WPR	What's the Problem Represented to Be?

Introduction

Genome editing refers to the modification of the genome through the targeted addition, replacement, or removal of deoxyribonucleic acid (DNA) sequences in living cells (Ormond et al. 2017). Human genome editing (HGE) technology has supplied crucial insights in genetic research and offers promising potential for the prevention and treatment of, *inter alia*, communicable viral diseases, cancers, and numerous other hereditary diseases which were previously considered incurable (Li et al. 2020). Developments in HGE have opened up the possibilities of its use for more ethically controversial purposes, including reproduction and enhancement, topics which have been explored in bioethical debates for over half a century.

Recent scientific developments of HGE, including the reveal of the birth of the first genetically-edited babies, have recently brought the discussion of its applications to the forefront of national and international policy debates. The results of these discussions have been a number of policy documents addressing the topic of HGE. Because policies on HGE will have significant moral and ethical implications, there is much to gain from an analysis that works backwards to understand how problems are represented in HGE policies. Such an analysis has not yet been explored.

This thesis uses Bacchi's (2009) "What's the Problem Represented to be?" (WPR) approach to analyze policies on HGE in order to determine how their problem representations have shaped the policy and whether alternative policies should be explored instead. In doing so, it answers the question: To what extent are the problem representations in HGE policies able to create appropriate solutions, and how can this inform future national and international policymaking?

Analysis of HGE policies suggest that their problem representations are sufficient in their ability to describe the most pressing issues and propose solutions to them within the constraints of relevant institutional factors. However, HGE policy recommendations can go

further in exploring and reexamining the ways in which institutions and assumed knowledges and assumptions influence policymaking.

I begin this thesis with a review of the literature on the topic of HGE policies, including the historical and scientific contexts in which policies are situated. I then describe institutional factors that affect HGE policies, such as the medical industry and national/international governance, before outlining the methodology used for the analysis. Next, I present the results of my analysis of HGE policy discourse, along with a discussion of their implications. Finally, I conclude by addressing the research question in light of the results of my analysis.

Chapter 1: Literature Review

This chapter begins with a review on the literature concerning the contexts that affect the creation of policies on HGE. These include legal, cultural, and bioethical contexts. The next section explains recent events in the field of HGE and their importance in precipitating renewed national and international interest and concern in regulating HGE.

1.1 Human Genome Editing in Context

The creation of policy and legal frameworks for HGE has developed within historical, technological, and scientific contexts. Governance of HGE falls under the wider framework of international conventions and legal norms protecting human rights and research on human subjects (National Academies of Sciences, Engineering, and Medicine 2017).[1]

Public policy on HGE is further formed in the broader context of the opinions of the general public and opinion leaders (Walters 1991). Science fiction in popular culture has been an avenue for the public to be exposed to and to form opinions on HGE. Narratives in popular culture are important for their ability to influence public opinion and debate on a topic (Iltis, Hoover, and Matthews 2021).

In 1970, scientist Bernard Davis declared that discussions of HGE up to that point had been too exuberant, and misled the public into expecting that genetic engineering would lead to the blueprinting of humans (Davis 1970). Davis further warned that the continued exaggeration of HGE would distort public opinion of the technology (Davis 1970). Public outcry and scientists' wishes to quell fears surrounding human blueprinting led the scientific

[1] The Universal Declaration of Human Rights is a foundational document for subsequent human rights conventions and treaties (United Nations 1948). It is followed by the Convention on the Rights of the Child and the Convention on the Rights of Persons with Disabilities, which call for the provision of health care and respect for and acceptance of persons with disabilities, respectively (UN General Assembly 1989; 2006). These conventions are followed by more topic-specific guidelines on biomedical research (National Academies of Sciences, Engineering, and Medicine 2017).

community to accept the use of therapeutic HGE, which is intended for the treatment or prevention of disease. Therapeutic uses of HGE were contrasted with uses for enhancement, which refers to genetic alterations for non-medical purposes, such as talent, physical attributes, or emotional characteristics (National Academies of Sciences, Engineering, and Medicine 2017).

Skeptics of HGE for enhancement warn that it has the potential to lead to injustice, since it would – at least initially – only be available to those who could afford it (Sandel 2007; Smith, Chan, and Harris 2012). Furthermore, skeptics warn that a cleavage between a class of genetic elite and a lower, unenhanced class could come into existence (Smith, Chan, and Harris 2012). Sandel (2007) suggests that beyond such a societal divide, genetic enhancement could shift societal values from individual achievements to genetic makeup.

Though HGE for the purpose of enhancement is generally not accepted by scientists, institutions, or the public, some bioethicists are in favor of HGE for enhancement. These voices argue that HGE is a continuation of human improvement and that the benefits of these therapies outweigh potential risks (Harris 2007). Savulescu (2001) coins the term "Procreative Beneficence," which promotes the idea that parents should use any available information to choose the best child possible, even if the result is the maintenance or worsening of social inequalities. Following this line of thinking, HGE would be an important method of improving future people's genetic makeup (Nuffield Council on Bioethics 2018).

One of the more radical opinions is that of Nozick (1974), who proposes an unregulated "genetic supermarket" where parents could design their children. Other opinions accept that the "supermarket" could be a realistic option in the future, and propose a framework for regulating such a market (Gyngell and Douglas 2015; Glover 2006; Buchanan et al. 2000). Glover (2006) argues that attempts to ban or regulate a genetic market in the interest of ethical values would be unsuccessful, and would instead result in a genetic tourism market. Despite

this, he maintains that the issue's vital importance should still push policymakers and scientists to consider a framework for regulation.

At a similar point in time as the creation of the distinction between therapeutic and enhancement HGE, the somatic/germline editing distinction came about (Evans 2021). Editing of somatic tissues, which can be executed both in vivo and ex vivo, affects existing, consenting patients (Saha et al. 2021). In contrast, HGE of germline cells can transmit genetic changes to offspring. (Saha et al. 2021). The delineation between somatic and germline therapies is attributed to theologian Paul Ramsey, who suggested that genetic therapies should only be applied to existing humans (via somatic interventions), and that any modification of future generations is a form of eugenic design (Evans 2021). Ramsey's delineation was widely accepted, cementing somatic editing as an acceptable use of HGE (Evans 2021).[2]

Germline editing has indeed been the cause of most controversy in the literature on HGE. Ethical skeptics of germline HGE argue that altering the genetic make-up of future generations for a non-lifesaving purpose is a form of commodification of humans (Sandor 2023). Habermas (2003) suggests that generations of genetically manipulated humans would feel constrained by irreversible changes made to them by third parties, and would ultimately lose their sense of authority and self-determination in their own lives.

While somatic HGE is generally accepted by the scientific community and governments around the world, it still raises concerns around ethical issues such as social justice and discrimination (Nordberg and Antunes 2022). Furthermore, questions arise as to which diseases (or enhancements) should be eligible for somatic HGE. What diseases are considered

[2] Surveys show that public opinion echoes differing views towards somatic and germline editing (Walters 1991; Vajen et al. 2021). A survey of 96 policy documents from around the world found that 75 countries with policies on HGE prohibit heritable HGE (Baylis et al. 2020). Of these, nearly all of them contain blanket prohibitions; only five allow specified exceptions, and none permitted heritable HGE (Baylis et al. 2020). The difference in acceptance of germline and somatic editing is thus mirrored in public opinion and national policy documents.

worth treating, and who should be in charge of such decisions? There is no uniform answer to such questions, and creating criteria for the classification of diseases even within the context of a single society will prove difficult.

1.2 He Jiankui and the Future of HGE

Until 2018, editing the genes of embryos had been purely hypothetical (Sandor 2019). Towards the end of 2018, Chinese researcher He Jiankui revealed at the Second International Summit on Human Genome Editing that the first babies with edited genes, a set of twins, had been born (Begley and Joseph 2018; Regalado 2018). Subsequently, it was discovered that a third gene-edited baby had also been born around the same time (Iltis, Hoover, and Matthews 2021; Sandor 2023). The babies' genes had been edited using Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) in order to make the babies resistant to human immunodeficiency virus (HIV) (Sandor 2023). The response to He's announcement was international outrage from both the public and the scientific community (Begley and Joseph 2018; Regalado 2018; Iltis, Hoover, and Matthews 2021). He was found to have skipped ethical procedures during his research (Sandor 2023; Royal Society et al. 2020), which resulted in legal consequences and stricter HGE regulations in China (Sandor 2023).

Following the announcement of the first gene-edited babies by He Jiankui, leading scientists and ethicists called for a global moratorium on clinical applications of germline editing (Baylis et al. 2020). They contend that germline editing poses too many unknown risks to those affected and that the risks outweigh the potential benefits of an intervention (Adelman et al. 2019; Deutscher Ethikrat 2019).

CRISPR-Cas is a technology that has recently raised the ethical and legal debate surrounding germline editing once more (Schleidgen et al. 2020). The ability for CRISPR-Cas to mediate a germline intervention without affecting an embryo's offspring raises questions

around the current legal, ethical, and policy responses to germline editing (Schleidgen et al. 2020). Furthermore, it has made the editing process more efficient and affordable (Nordberg and Antunes 2022). With new developments in technology, including CRISPR-Cas, the meaning and permissible uses of germline editing are being revisited.

The announcement of the birth of the first gene-edited babies means that the use of HGE for reproductive purposes is no longer a hypothetical. Technological advancements often outpace policy responses. Other technologies also continue to advance rapidly, including the potential use of in vitro gametogenesis (IVG) in humans in the near future (Stein 2023). IVG allows for the laboratory production of eggs and sperm from any cell of the human body, meaning that infertile people, same-sex couples, and people past reproductive age could have children (Stein 2023). The possibility of this technology raises previously unforeseen ethical questions.

With these technological developments in mind, and considering the recent developments in HGE including the He Jiankui case, and a growing number of reports on and guidelines for HGE, this thesis aims to offer a novel analysis of the problematizations of policies on HGE. Because many policy documents were published in the last three years, there is a current lack of analyses of these policies in the literature, especially with regard to discourse analysis.

Chapter 2: Institutional Considerations

Policies cannot be considered in isolation from the institutions that shape their development. This chapter describes institutional considerations of science and the medical industry, followed by an exploration into how these industries intersect with global governance and national borders. These explanations are crucial for the analysis of the problematizations of HGE policies that follow.

2.1 Science and the Medical Industry

The perception of scientific research among institutions and the public has significant effects ranging from regulatory frameworks permitting some forms of research over others to allocation of research funds. The scientific community and its goals are generally understood in terms of liberalism and meritocracy (Nuffield Council on Bioethics 2016). For example, the United Nations Educational, Scientific and Cultural Organization (UNESCO) Universal Declaration on Bioethics and Human Rights states, "scientific and technological developments . . . should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the dignity of the human person and universal respect for, and observance of, human rights" (UNESCO 2005, 74). This statement mirrors much of the wider discourse on science and knowledge production, which promotes the idea that it should be done with people's best interests in mind and grounded in liberal ideas of human rights and dignity.

In economic terms, scientific information and technological know-how can be understood as public goods because they are non-exclusive and non-rival (Nuffield Council on Bioethics 2016).[3] To avoid a free rider problem, intellectual property (IP) frameworks have the

[3] In economics, non-excludable refers to goods that are available to all for little to no cost. Non-rival goods refer to goods which can be possessed by more than one person. See Liberto (2021).

intention of incentivizing innovation and scientific research by rewarding patent-holders with monopolies on their products in exchange for their knowledge. This framework is in many ways at odds with the idea of science as a public good; capitalist systems instead tend to categorize knowledge and technology as forms of private property (Nuffield Council on Bioethics 2016).

How knowledge, research, and technology are perceived by institutions and the public is important because their perception influences the material outcomes of science, such as technological developments, research funding, and the health and welfare of individuals and societies. Of course, these material outcomes in turn inform public and institutional perceptions of the scientific community, forming a two-way transmission of feedback.

2.2 National Borders, Global Governance, and Human Genome Editing

The history of the medical industry, and especially the human reproductive industry, suggest that services and actors cross national borders in pursuit of options that are otherwise unavailable (Saldaña-Tejeda et al. 2022; Nuffield Council on Bioethics 2018). For example, in 2016, a baby was born in Mexico to Jordanian parents after US-based researchers performed mitochondrial replacement (or "three-parent") techniques, which helps avoid certain mitochondrial genetic diseases (Hamzelou 2016). The technique had not been approved in the US (Hamzelou 2016).

The heterogeneity of different groups and regions within nations must be considered when creating national policies. Where there are varying regulations within one country, as in a federalist state (Zettler 2022), or in cases of colonization or internal conflict, national

regulations can pose challenges to ensuring that human rights are resepected (Saldaña-Tejeda et al. 2022).[4]

Though regulatory frameworks for the governance of research and innovation are usually developed and implemented in national jurisdictions (Nuffield Council on Bioethics 2018), these jurisdictions must operate within a global context, where other nations likely have differing laws and regulations. As Saldaña-Tejeda et al. (2022) point out, the He Jiankui case illustrates how HGE is not limited by legal constraints or national borders. The most salient stakeholders in cases of HGE will likely be located in various countries. On the one hand, this could allow nations and actors an escape from responsibility (Saldaña-Tejeda et al. 2022). On the other hand, it underlines the importance of a global framework for HGE that takes into account the diversity of resources and contexts around the world. Challenges for a global framework for HGE mirror those that exist for any application of global governance. They include knowledge, compliance, or normative gaps (Weiss 2013). This refers to gaps in technical knowledge and know-how, an inability to ensure complete stakeholder compliance with the framework, and agreements on what ethical, legal, and cultural norms should be, respectively.

Understanding the institutions that shape policies on HGE is necessary in order to fully grasp how they influence the representation of problems within policies. The next chapter discusses the methodology used to analyze these problem representations in HGE policies.

[4] For example, although – and indeed *because* – the US and Puerto Rico were under the same national jurisdiction, the US used Puerto Rican women as test subjects for trials of harmful – and sometimes lethal – birth control in the 1950s (Womack 2020). They did so under the justification that the women were of less value than women on continental US soil (Womack 2020).

Chapter 3: Methodology

This thesis uses a discursive approach to analyze policy documents on HGE. It does not attempt to evaluate the ability of the policies to address a problem, but rather the knowledges underpinning the policy themselves. This thesis thus distances itself from most policy approaches, which use a rationalist method that focuses on evidence-based solutions to perceived problems (Goodwin 2011). These approaches tend to focus on solving problems, rather than questioning the problematization of such "problems" (Bacchi 2009; Goodwin 2011).[5] This thesis thus offers a novel perspective on the issue of HGE by assessing current policies as discourse. Such an analysis is important in the field of policy because it allows researchers to question the problematization of issues and better situate policies in the context of changing societal needs and norms.

Analyzing policy as discourse allows uncontested 'truths' to be questioned and evaluated for their role in influencing policy solutions (Goodwin 2011). Discourse analysis of policies, then, can lead to a better understanding of how policies create meaning and problematize issues in their design, which allows for alternatives to policies to be considered (Goodwin 2011; Marston 2004; Colebatch 2006; Bacchi 2009).

Choosing the documents for analysis is an interpretive exercise in itself (Bacchi 2009; Goodwin 2011). Recognizing this, the international policy documents analyzed in this thesis were chosen for their normative importance in the field of biology and medicine. In the case of documents from national jurisdictions, texts were chosen which were in the English language and from jurisdictions with high levels of genome editing research and/or health biotechnology (Millett et al. 2023). Selected texts aim to represent at least one country from each continent.

[5] For more on rationalist approaches to policy, as well as critical, interpretive and discourse approaches, see Goodwin (2011).

The texts include binding instruments (such as the Oviedo Convention) and non-binding instruments and guidelines. A complete list of analyzed sources can be found in the Appendix.

Based on the literature review, I first created coding categories based on key themes to analyze in the texts. Using a process of evolutionary coding (Mayring 2002), I then explored the texts to understand which how the coding categories needed to be amended to better mirrored issues of importance. After the initial reading of the texts, I created the final coding categories of Actors (focusing separately on researchers and the public) and Social Justice and Equality. The discourses on these coding categories are varied and bring up multiple policy recommendations. I chose the most dominant policy discourse for each coding category based on its frequency and overall importance in the texts.

After coding each of these categories in each document, I analyzed the dominant discourse by drawing from Bacchi's (2009) WPR approach. This entails asking the following questions for each policy:

1. What is the problem represented to be?
2. What assumptions underlie the representation of the problem?
3. How has representation of this problem developed?
4. What does the problem representation leave unproblematized?
5. What effects are produced by the problem representation?
6. How is the representation of the problem reproduced and how could this be disrupted?

Through the WPR approach, I created problematization narratives for each coding category, which offered opportunities for rich analysis of the assumptions in and implications of the problem representations. These results are explored in the following section.

Chapter 4: Analysis and Discussion

4.1 Actors

The ways in which the actors and stakeholders are framed within a policy matter for the success of its implementation as well as future policy directions. The following section aims to analyze how researchers and the public appear in polices on HGE and how this impacts the problem representation.

4.1.1 Researchers and the Medical Industry

Researchers within the scientific community operate within a certain societal and cultural context that shapes their actions. The German Ethics Council recognizes this interplay between researcher and society:

> Research on germline interventions touches on a broad spectrum of responsibilities. However, it is not easy to draw the line between the responsibility of individual researchers and collective responsibility. For this reason, it is essential that science and society engage in an appropriate discourse process on these issues, also when it comes to specifying the respective responsibilities. (Deutscher Ethikrat 2019, 24-5)

However, in many policy documents on HGE, the discourse on medical science and researchers is less sympathetic to researchers, nearly framing these actors as predators from which individuals must be protected. The Preamble of the Oviedo Convention, which is the only legally binding instrument on HGE, considers the potential for medicine to be harmful:

> Conscious that the misuse of biology and medicine may lead to acts endangering human dignity . . . (1997, 1)

The most obvious interpretation of this excerpt is that the "misuse" is most likely to be at the hands of researchers, who are at the frontlines of applications of biology and medicine.

The discourse in policy documents suggests that the He Jiankui case affirmed the potential for researchers to act in ways which endanger the rights of individuals. In response to the announcement of He's gene-edited babies, the African Ethics, Community Engagement and

Patient Advocacy Working Group of the Global Emerging Pathogens Consortium condemned He's actions:

> This trial sets a dangerous precedent and sends the message that a scientist can bypass established regulatory and ethical systems and conduct relatively high-risk research on the sidelines, in pursuit for new knowledge and fame, without due consideration of the welfare and respect for the research subjects and the society at large. (2018, 2)

Their subsequent recommendation is that other researchers follow ethics regulations and laws on HGE and that future studies condemn He's actions.

Other documents echo the cautious tone found in the Oviedo Convention and the African document and widen its scope to commercial companies, as found in the document from India:

> When research is conducted by commercial companies, steps should be taken to protect researchers and participants from possible coercion or inducement. (Mathur 2017, 117)

This language puts commercial companies involved in biotechnology on the offensive when it comes to protecting individuals, and in this discourse fragment, also researchers.

Table 1 outlines the problem representation of such discourse using the WPR approach. This discourse problematizes (WPR Q1) scientists' ethics and suggests that they are liable for unethical practices which may put individuals at risk. The assumption underlying this problematization (WPR Q2) is that the scientific community operates within the context of liberalism, under which the rights of individuals shall be respected. The origins of this problem representation (WPR Q3) include the trial of He Jiankui, but may go back further to the issue of eugenics,[6] particularly in light of the crimes against humanity committed during the Second World War and which resulted in the Universal Declaration of Human Rights (Facing History & Ourselves 2020).

[6] For more on the issue of eugenics and its relation to HGE, see Nordberg and Antunes (2022).

Table 1. Analysis of HGE Policy Discourse on Researchers Using the WPR Approach.

WPR Approach Question	**Analysis**
1. What is the problem represented to be?	Scientists are liable to act unethically with regard to HGE research.
2. What assumptions underlie the representation of the problem?	Scientists should operate within a liberalist perspective.
3. How has the representation of the problem come about?	History of eugenics and the case of He Jiankui.
4. What is left unproblematic in the problem representation?	The culture of the scientific community, including meritocracy, and the incentives for research and innovation, including IP rights.
5. What effects are produced by the representation of the problem?	Decreased trust in scientific research and scientists among individuals.
6. How is the problem representation reproduced and how can it be disrupted?	Reproduction of the problem should remain in future policy documents, but while empowering individuals to have more autonomy with regard to medical decisions and participation in research.

Left unproblematic in this problem representation (WPR Q4) is the role of the culture within the scientific community and the motivations of scientists who act unethically. Scientists largely believe that their field operates as a meritocracy, whereby those with the most publications or breakthroughs in research are the most accomplished and highest funded (Blair-Loy and Cech 2022).[7] Furthermore, IP rights on technological products may incentivize researchers to bypass ethical guidelines in order to patent new technologies.[8] In order to ensure that scientists act ethically, it may not be enough to encourage ethical procedures from scientists or even from ethics boards. A review of the institutional background in which researchers operate as well as the culture of the scientific community may lead to improved outcomes in regards to HGE research ethics.

[7] I do not promote the idea that the scientific community is a meritocracy and recognize that such a view devalues those who have historically not been allowed a space within the community.
[8] The Nuffield Council on Bioethics (2016) makes a similar recommendation with regard to a rethinking of IP and innovation, albeit from a global social justice perspective.

The effects of the problem representation of researchers and the medical industry (WPR Q5) could be the creation of opposition between researcher and participant. Furthermore, there may be a lowered level of trust towards the medical and scientific community among individuals if they perceive researchers as actors from whom they must be protected.

Finally, this problem representation may be reproduced (WPR Q6) in policies which regard biology and medicine warily and emphasize the need to protect the rights of individuals. However, this does not mean that future policy documents should not replicate these ideas. Instead, in addition to a review of the cultural and institutional frameworks governing the medical industry, individuals must have greater agency when it comes to making their own decisions with regard to their health. This can be done through empowerment measures that include, *inter alia*, scientific literacy and the availability of multiple sources of information about potential research and clinical applications, such as genetic counsellors. These recommendations are included in many of the policy documents, such as the one by Nuffield Council on Bioethics (2018).

4.1.2 The Public

The role of the public with regard to HGE policies is also salient throughout the analyzed sources. The main discourse topic concerning the public is the need for policies which engage the public in discourse and decision-making. All but one policy document, that of Brazil's (National Health Council of Brazil 2004), mention the need to engage the public in debates, dialogue, or discussions on the uses of HGE. The most robust description of a policy calling for the need for public debate is from The Nuffield Council:

> [W]e recommend that consideration should be given to the establishment of a separate body or commission in the UK, independent of Government and independent of existing regulatory agencies, which would have the function of helping to identify and produce an understanding of public interest(s) through promotion of public debate, engagement with publics and monitoring the effects of relevant technological

developments on the interests of potentially marginalised subjects and on social norms. (2018, 143)

The need for public debate as it is envisioned by the Nuffield Council is clear. Public policy decisions must be based on the needs and opinions of the general public. However, when approaching this policy recommendation from the WPR framework, deeper concerns behind such a recommendation start to surface. Table 2 explains the WPR analysis of this policy, which represents the problem (WPR Q1) as not having enough public engagement on the issue of HGE because of a lack of an independent body to foster such debates.

Table 2. Analysis of HGE Policy Discourse on Public Engagement Using the WPR Approach

WPR Approach Question	**Analysis**
1. What is the problem represented to be?	There is not enough public engagement with biotechnology developments because of a lack of a separate body presiding over the matter.
2. What assumptions underlie the representation of the problem?	The concept of democracy and the importance of the will of the public.
3. How has the representation of the problem come about?	Previous debates on other biotechnological issues (e.g. IVF, GMO, PGT).
4. What is left unproblematic in the problem representation?	What are reasons the public may not engage? Would the public, and especially vulnerable populations, want or be able to participate in such debates? What concerns may be more pressing to them than HGE?
5. What effects are produced by the representation of the problem?	Governance and policies may not address concerns and needs of the public that are hindering their engagement with HGE topics.
6. How is the problem representation reproduced and how can it be disrupted?	The problem is reproduced in stakeholders and policymakers calling for more public engagement. It can be disrupted by understanding what communities need most to be able to engage with such topics and promoting educational initiatives on the subject.

The assumptions underlying this problem representation (WPR Q2) are found in the concept of democracy and that all should have a say in public policymaking and broad ethical, societal issues. The representation of this policy (WPR Q3) recommendation can be traced back to previous public debates on other biotechnologies, such as in vitro fertilization (IVF), genetically modified organisms (GMO), and preimplantation genetic testing (PGT) (Nuffield Council on Bioethics 2018). The Nuffield Council (2018) contends that public debates on these issues have previously informed societal norms and explains that the debate over GMOs in particular exemplified the fact that a clear explanation of the science behind a new technology is not enough to ensure the public's understanding of the many implications of certain science-related policies. This example led the authors to create a recommendation which aims to tie in the interests of those already interested in HGE and those who have yet to become interested.

The main issue with this problem representation is that it leaves unproblematic (WPR Q4) the other factors that explain why previous attempts at engagement have failed or why future public engagement may be low. Aside from low levels of scientific or medical literacy, the public may have reasons for low political engagement in general, which must also be explored within the context of HGE policy. Furthermore, this recommendation is not transferable to under-resourced countries and communities, where priorities for policymaking are likely different. It is difficult to imagine, for example, that someone would want or be able to engage in HGE debates if they do not have access to basic medical care or are in the midst of a civil war. The Nuffield Council (2018) report, which is widely cited by literature outside of the UK, must be expanded on to better include locations which have other priorities in terms of policymaking.

The effect of this policy (WPR Q5) is that policymakers may not go further in questioning what the needs are of individuals before they can engage with discourse on HGE and may therefore miss out on opportunities for fostering more widespread discussion on the topic. To that end, policies and institutions that reproduce this problematization (WPR Q6) can be disrupted by understanding what various communities and populations need beyond the context of HGE in order to better be able to engage with HGE debates and discussion.

4.2 Social Justice and Equality

The topic of social justice and inequality is discussed in some form in every analyzed source. Some of the national documents explore how existing issues of social justice should influence policy decisions within their own jurisdictions. For example, the document from New Zealand (Royal Society Te Apārangi 2019) repeatedly cites the need to take into account Māori perspectives when creating HGE policies. The document from South Africa recognizes that

> a large part of the South African population, consists of vulnerable groups and poor populations with low levels of education, who accept authority without question and who are easily influenced. This poses new ethical dilemmas which have to be addressed. The vulnerability and inequity, coupled with the unique research environment in South Africa, emphasizes the need for an ethical guideline governing biotechnology research which ensures that research is conducted ethically and that vulnerable persons and communities are not exploited. (Dhai, Msomi, and McQuoid-Mason 2008, 5)

On the other hand, many of the regional and international documents address how policies impact outcomes in social justice and equality. In some cases, concerns over these outcomes differ according to type of HGE. When discourse focuses on somatic editing, concerns mainly address inequality in terms of access to medical care. Nordberg and Antunes (2022) directly connect the dangers somatic editing pose to inequality and discrimination, especially with regard to expensive procedures that are unavailable to most of the world's population. Even if the same connection is not made explicitly, it is implicit in national documents which prohibit

germline editing, since social justice concerns remain a topic for consideration with regard to permitted (somatic) HGE.

National Academies of Sciences, Engineering, and Medicine (2017) make a similar point when discussing germline editing. They note that if heritable HGE is only available for the world's wealthiest or best-insured, it could divide populations into those with less money and higher prevalence of avoidable diseases and those with more money and less prevalence, similar to the concerns raised by Smith, Chan, and Harris (2012). Such a division between people would shift inequalities from being culturally to biologically constructed (National Academies of Sciences, Engineering, and Medicine 2017). The authors sum up this discussion by remarking that these concerns of inequality are not unique to HGE and apply to many facets of health.

Similar concerns are evident in the documents' discussions of therapeutic and enhancement HGE, especially regarding issues of unequal access to HGE. However, discussions of the potential implications of therapeutic and enhancement HGE bring in the issue of medical tourism and travel and how the international character of medicine plays a role in policies on HGE. The document from Japan predicts that countries with less stringent HGE regulations will lead to the cross-border use of HGE for enhancement purposes:

> [I]n countries where reproductive medicine is not strictly regulated, some people fear that it might be abused by prospective parents to attain a desired trait, such as appearance, for their child. (Science Council of Japan 2017, 2)

This discourse fragment is representative of the fear that lax HGE regulations in some countries and stricter regulations in others may entice researchers and patients to travel to countries which lack regulations or the ability to enforce them in order to engage in ethically questionable

research (Nordberg and Antunes 2022).[9] This fear, combined with the issue of financial inequality raised by the discussion of somatic/germline editing, prompted the World Health Organization (WHO) to declare

> a commitment to share the benefits and burdens of research and clinical care among all people, to minimize the risk of exploitation and to promote the common good. (WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing 2021, 14)

Bearing in mind the potential for medical travel and tourism and the need to ensure all benefit from and are burdened by HGE equally, WHO recommends

> that somatic or germline human genome editing research should only take place in jurisdictions with domestic policy and oversight mechanisms. WHO, with guidance from the Science Council, should integrate into all of its relevant activities a focus on fostering responsible international research and medical travel. (WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing 2021b, 4)

Notably, this policy does not differentiate between somatic or germline editing. The problem representation of this policy (WPR Q1) is one that suggests that social justice and inequality issues with regard to HGE are exacerbated by a lack of global governance and the use of HGE in countries which lack domestic policy and oversight mechanisms. As seen in Table 3, applying the WPR approach to this policy reveals that this problem representation is based on assumptions (WPR Q2) of universalism and the idea that some concepts, such as ethically responsible research, can be applied to all contexts. Furthermore, in these policies is an underlying assumption of international power relations. This is illustrated by a related recommendation by Nordberg and Antunes, which suggests

> the extraterritorial application of EU and Member State law to procedures performed abroad (provided that fundamental rights and freedoms are respected). (2022, II)

[9] Lax national regulations may also be purposeful, with the goal of encouraging a medical tourism industry (Nordberg and Antunes 2022).

A policy such as this one is based on the assumed (and proven) power of the EU to influence global societal norms in a particular area (Gstrein and Zwitter 2021), a concept which Bradford (2012) termed the "Brussels Effect." Policies which call for global governance to influence national policies thus have the underlying assumption of international power relations.

Table 3. Analysis of HGE Policy Discourse on Social Justice Using the WPR Approach

WPR Approach Question	**Analysis**
1. What is the problem represented to be?	Social justice and inequality issues with regard to HGE are exacerbated by a lack of global governance and the use of HGE in countries which lack domestic policy and oversight mechanisms.
2. What assumptions underlie the representation of the problem?	Universalism (that some concepts can be applied to all people and contexts), international power relations.
3. How has the representation of the problem come about?	Case studies of other biotechnologies.
4. What is left unproblematic in the problem representation?	What are other reasons for inequalities among nations? How has global governance failed before and what challenges might arise in the future? Is a global framework able to accommodate all societies and communities?
5. What effects are produced by representation of the problem?	Resources and efforts, especially on the part of international organizations, may go towards the creation of an international framework while giving less attention to local forms of governance.
6. How is the problem representation reproduced and how can it be disrupted?	This problem representation is reproduced by those who have access to this discourse, such as policymakers, IGOs, and academics. Disruption can happen through media attention to local policy solutions and capacity-building between low and high-income countries on topics that go beyond HGE.

As for tracing the roots of this problem representation (WPR Q3), previous case studies of the global use of biotechnologies, especially regarding reproductive and cosmetic procedures, likely informed this and other policies on social justice and equality.[10]

The problem representation in these policies are not in themselves problematic. Social justice and inequalities would indeed likely be exacerbated by a lack of a global framework for HGE regulations and operations of HGE in domestic jurisdictions with insufficient regulations. However, this problem representation is silent on three important points (WPR Q4).

Firstly, it leaves unproblematic the factors that may lead some jurisdictions, especially low-income countries, to be unable to regulate HGE properly. Examples of external factors that could influence a country's ability to regulate HGE are war, internal conflict, or corruption. When creating policies that consider a country's ability to govern specialized technologies like HGE, these external factors must also be considered, as well as ways to responsibly respond to them.

Secondly, this problematization is silent on the challenges that accompany a global governance framework. Apart from simple logistics and the resources needed to manage an international framework for HGE governance, challenges may also include gaps in knowledge, compliance, or norms. Not acknowledging these challenges in policies addressing global governance may not allow for self-reflection of international actors, such as WHO.

As mentioned in Chapter 2, normative gaps can pose a challenge to the effectiveness of global governance. This is especially relevant in the discussion of HGE, where scientific decisions are heavily influenced – and in turn, influence – moral and ethical opinions and

[10] For example, the case of Jordanian parents who were treated by a US-based team using mitochondrial replacement techniques in Mexico that was referenced earlier in this thesis.

standards of a society. The problematization of the social justice and equality issues surrounding HGE in the analyzed policy documents does not account for the difficulties of creating a global framework that can accommodate the vast societal, legal, and cultural differences in regions, nations, and communities around the world.

The effects of this problem representation (WPR Q5) are that it may lead to more resources and investment being put into a global framework, which could be difficult to create considering the variety of laws, needs, and cultures around the world, at the expense of finding solutions that allow better local governance of HGE. This problem representation is reproduced (WPR Q6) by those who have access to this discourse, including intergovernmental organizations (IGOs), global institutions, policymakers, and academics. It can be disrupted via a global focus on enabling local governance solutions to HGE, including engagement with local communities through dialogue and capacity-building projects that go beyond HGE, recommendations which are also promoted by WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing (2021a). While this analysis has arrived at similar conclusions to these documents, it uses an alternative framework to do so, suggesting that the policy recommendations are appropriate for the problem representations of the issues.

Conclusion

This thesis analyzes the policies which exist on HGE in order to understand what role these policies play in creating certain problematizations of HGE. Important to the WPR approach used in this analysis is the exploration of the underlying assumptions that are implicit in policy discourses and how these assumptions can be challenged. This analysis concludes that the policy documents analyzed in this thesis generally create problem representations that are able to provide useful recommendations and solutions that fit within existing institutional and societal structures. Many of the recommendations made in analyzed documents are the same conclusions I draw by analyzing the problem representation of the policies. However, my analysis goes a step further by probing for the assumptions that lay behind the HGE policies.

In sum, this analysis should encourage policymakers and stakeholders to reassess the wider institutional structures underpinning the policies at hand, including the medical industry, IP rights, international power dynamics, and external factors that impact individuals' abilities to be active political participants. Analyzing documents focused on one relatively narrow area of research, HGE, illustrates how the policies interact with and are embedded in other institutional structures and elicit reflection on said structures for future policymaking.

Appendix

List of Sources for Discourse Analysis

Country or Organization	Source	Date	Type of Instrument
Council of Europe	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 (Oviedo Convention)	1997	Binding legal document
UNESCO	Universal Declaration on the Human Genome and Human Rights	1997	Non-binding legal document
Brazil	National Health Council Resolution 340 on Human Genetic Research	2004	Non-binding policy document
South Africa	General Ethical Guidelines for Biotechnology Research in South Africa	2008	Non-binding policy document
Nuffield Council on Bioethics (UK)	Genome editing: an ethical review	2016	Non-binding policy document
India	National Ethical Guidelines for Biomedical and Health Research Involving Human Participants	2017	Non-binding policy document
United States	National Academies of Sciences, Engineering, and Medicine; National Academy of Medicine; National Academy of Sciences; Committee on Human Gene Editing: Scientific, Medical, and Ethical Considerations.	2017	Non-binding policy document
Japan	Genome Editing Technology in Medical Sciences and Clinical Applications in Japan	2017	Non-binding policy document

Nuffield Council on Bioethics (UK)	Genome editing and human reproduction	2018	Non-binding policy document
Deutscher Ethikrat (Germany)	Intervening in the Human Germline: Executive Summary & Recommendations	2019	Non-binding policy document
International Commission on the Clinical Use of Human Germline Genome Editing	Heritable Human Genome Editing	2020	Non-binding policy document
Royal Society Te Apārangi (New Zealand)	Gene Editing: Legal and Regulatory Implications	2021	Non-binding policy document
World Health Organization	Human Genome Editing: A Framework for Governance	2021	Non-binding policy document
World Health Organization	Human genome editing: position paper	2021	Non-binding policy document
European Parliament	Genome editing in humans: A survey of law, regulation and governance principles	2022	Non-binding policy document

Glossary

Clustered regularly interspaced short palindromic repeats (CRISPR): a technology used to selectively modify the DNA of living organisms.

Deoxyribonucleic acid (DNA): the material in the cells of living organisms that carries genetic information.

Enhancement: the use of HGE for non-medical (therapeutic) purposes.

Ex vivo: outside of the living body.

Genetically modified organism (GMO): an organism whose genetic material has been altered via genetic engineering.

Genome: the complete set of genetic material (in the form of DNA) in an organism.

Germline genome editing: the editing of germ cells, which are those responsible for the sexual reproduction of offspring. This type of editing affects offspring.

Human genome editing (HGE): a method of making changes to the genome of a human being via the insertion, deletion, modification, or replacement of DNA.

Hereditary disease: genetically transmitted or transmittable disorder that is passed on from parent to offspring.

In vitro fertilization (IVF): the laboratory fertilization of an egg.

In vitro gametogenesis: a technique that enables embryos to be grown in a laboratory by reprogramming adult cells to become sperm and egg cells. This technique would allow for reproduction to occur from any cell in a human body, such as hair.

In vivo: in the body.

Mitochondrial replacement techniques: procedures which enable the prevention of maternal transmission of mitochondrial DNA diseases.

Preimplantation genetic testing (PGT): a screening test performed on embryos that are created via in vitro fertilization (IVF) in order to evaluate the embryos for genetic diseases or chromosomal disorders.

Somatic genome editing: the editing of somatic cells, which are any germ (non-reproductive) cells. This type of editing does not affect offspring.

Therapy (HGE): the use of HGE for medical purposes, such as the prevention or treatment of a disease.

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