

Gene Editing and Minorities - Preventing Regulation from Becoming Discrimination

Gene editing has always been an ethically ambiguous idea in the world of reproductive technologies. Limited understanding around the practice has so far prevented gene editing techniques from becoming part of the reproductive norm in New Zealand. Recently, developments in technology have allowed gene editing techniques to be tested and implemented in trials that indicate use in humans may be on the horizon.¹ Presently, gene editing is a prohibited practice in New Zealand under the Human Assisted Reproductive Technology Act 2004. The rise in demand for greater fertility treatments mean that questions regarding the prohibited status of the practice are likely to increase, putting pressure on the government and regulatory agencies to broach the idea of regulating gene editing. Savulescu's Principle of Procreative Beneficence has been applied in previous reproductive technology regulation, and promotes the idea that couples should select the child (or embryo) that is expected to have the best life based on the relevant available information.² This principle poses a strong ethical argument for the introduction of gene editing into New Zealand's reproductive technology sphere. By editing embryos we can create a child who is predisposed to the so called 'best life' before they are implanted. This paper will attempt to address the challenge of creating adequate gene editing regulation while upholding the dignity of minority groups. It will also argue against following Savulescu's principle as guidance for creating regulation.

Germline gene editing in embryos involves adding, removing, and altering sections of DNA in order to produce viable offspring with desired genetic traits. This procedure is of particular concern to disabled and ethnic minorities. Key genetic codes prevalent in these populations could be edited out, and potentially eradicated from society using germline gene editing. Prior to enacting any regulation consideration must be given to minorities in light of the legal, ethical, and political challenges presented by gene editing regulation. This paper will focus on the regulatory challenges facing the process of editing genes present in an in-vitro fertilised embryo prior to implantation into utero. The Advisory Committee on Assisted Reproductive Technology (ACART) is tasked with issuing guidelines and advice on assisted reproductive technologies in New Zealand.³ They are under a duty to consult appropriate members of the public, government departments and agencies, and with the Minister of Health.⁴ Any submissions must be taken into account prior to guidelines being issued, thus ensuring that affected parties are considered by the

¹ Primc N. "Germline Modifications as a Severe Intervention into Human Nature" In: Braun M., Schickl H., Dabrock P. (eds) *Between Moral Hazard and Legal Uncertainty* (Futures of Technology, Science and Society, Springer VS, Wiesbaden, 2018) 99 at 103

² Saunders, B. "First, do no harm: Generalized procreative non-maleficence." (2017) 31 *Bioethics* 2017 552 at 552

³ Human Assisted Reproductive Technology Act 2004, s 35

⁴ Human Assisted Reproductive Technology Act 2004, s 41

Committee before the guidelines become law. These guidelines are then used by the Ethics Committee on Assisted Reproductive Technology (ECART) to approve or decline applications for use of reproductive technologies in non-established procedures. At this stage the Committee has not issued guidelines regarding gene editing in any form. CRISPR-based methods are currently at the forefront of technological developments, and testing of the method has already begun on early stage human gametes.⁵ The initial driver behind germline gene editing research has been to prevent serious disease or disability. Genes that code for conditions such as Huntington's Disease or Down Syndrome could be edited out of the embryo prior to implantation, increasing the chances of healthy, life compatible offspring. Any resulting child would pass this DNA sequence onto further descendants were they to reproduce later in life, effectively creating a new, 'healthy' germline. Such a treatment would seem on the surface to be revolutionary. Infertility treatments are costly, distressing, and give no guarantee of a successful live birth.⁶ The risks are even greater where genetic abnormalities are present in parent or embryo. Research has shown "an estimated 48.5 million couples worldwide were unable to have a child after five years" due to infertility.⁷ The introduction of germline gene editing could mean life-threatening genetic diseases are eliminated from children prior to implantation and birth. This could save the child from potentially traumatic medical treatments and early death, and also prevent the implantation of genetically abnormal embryos at all. Parents with undesirable genetic mutations, for example beta-thalassemia,⁸ could produce offspring free of the mutation, and parents who produce embryos with random genetic mutations could edit these mutations out.

Savulescu argues with his Principle of Procreative Beneficence that it would be irrational to choose a lesser able embryo when the best option is available.⁹ Current guidelines in New Zealand, namely those regarding pre-implantation genetic diagnosis, appears to follow Savulescu's principle. Prospective parents who utilise pre-implantation genetic diagnosis by are able to choose the embryo they wish to implant based off of genetic diagnosis results.¹⁰ In each

⁵ Primc N. "Germline Modifications as a Severe Intervention into Human Nature" In: Braun M., Schickl H., Dabrock P. (eds) *Between Moral Hazard and Legal Uncertainty* (Futures of Technology, Science and Society, Springer VS, Wiesbaden, 2018) 99 at 103

⁶ Fertility New Zealand "Fertility Treatment Options" (2019) Fertility New Zealand, <<https://www.fertilitynz.org.nz/information/fertility-treatment-options/>>

⁷ Maya N. Mascarenhas, Seth R. Flaxman, Ties Boerma, Sheryl Vanderpoel, Gretchen A. Stevens "National, Regional, and Global Trends in Infertility Prevalence Since 1990: A Systematic Analysis of 277 Health Surveys" (December 18 2012) World Health Organisation <<https://www.who.int/reproductivehealth/publications/infertility/277surveys/en/>>

⁸ National Institutes of Health "Beta Thalassemia" (August 20 2019) United States National Library of Medicine, <<https://ghr.nlm.nih.gov/condition/beta-thalassemia>>

⁹ Saunders, B. "First, do no harm: Generalized procreative non-maleficence." (2017) 31 *Bioethics* 2017 552 at 553

¹⁰ Human Assisted Reproductive Technology Order, Schedule 2, s 6

case they must choose the embryo that is genetically normal in order to prevent genetic disease.¹¹ This is used to avoid implantation of embryos with genetic abnormalities, ensuring that any resulting children are life-compatible. Gene editing could ensure the best life for each new child, whether altering genes for cosmetic issues, deadly illnesses, or lifelong disabilities. In this way the potential capabilities of the child are paramount, and gene editing would ensure that any offspring born into society were set up with the ideal genetic background for certain types of success. However, the translation of this position into the regulatory space is not smooth. Savulescu's principle fails to provide a definition of the term 'best life', and the ambiguity of this language may give rise to concerns around the interpretation of the regulation. Without clear drafting, new regulations may be left open to costly and time consuming litigation. The United Kingdom courts have grappled with interpretive issues regarding varying interpretations of regulatory language.¹² While the court ruled in favour of the government and the original applicant in the referenced case, the women referred to had aged past her reproductive window, and the judgement came too late for her to access the approved technology.¹³ For New Zealand women who may rely on the technology in order to have children, litigation could have irreversible consequences. It is essential that any regulation is specific in its purposes, aims, and uses.

Both disabled and ethnic minorities are now widely accepted in New Zealand and legislation provides protection for minority groups from discrimination. The Human Rights Act prohibits discrimination on the grounds of disability and race.¹⁴ The Act was enacted to promote racial equality and cultural diversity, and to promote and protect full and equal enjoyment of human rights for the disabled.¹⁵ The use of gene editing techniques could lead to discriminatory consequences for current minority individuals. The challenge facing bodies such as ACART is to draft gene editing regulation that does not contravene these enactments. The potential for wide-ranging editing means seemingly unimportant aspects of a person's being, for example height or hair colour, could be changed in pursuit of offering the 'best life'. More concerningly is the possibility of editing aspects such as disability. Disability rights activists have long argued that the disabled are capable of living meaningful lives despite their disability. Abnormal has at times been taken to mean undesirable within society, and the idea still exists that disabilities are to be avoided. This idea exists within the current regulatory approach to pre-implantation diagnosis.

¹¹ Human Assisted Reproductive Technology Order, Schedule 2, s 6

¹² *R (on the application of Quintavalle) v Human Fertilisation and Embryology Authority, [2003] EWCA Civ 667

¹³ Olga Craig "Why we gave birth to a saviour sibling" (December 6 2010) The Telegraph, <<https://www.telegraph.co.uk/news/health/children/8224541/Why-we-gave-birth-to-a-saviour-sibling.html>>

¹⁴ Human Rights Act 1993, s 21

¹⁵ Human Rights Act 1993, s 5

Gene editing poses the distinct risk that disabled traits will be edited out in order to avoid ‘undesirable’ offspring. As a result, minorities may be further ostracised from society and moves towards acceptance for minority groups could cease. Savulescu’s principle assumes that we all share the understanding of a set of parameters that define the ‘best life’. In this way he fails to account for the idea that different circumstances don’t necessarily mean anything less than the best. Many disabled individuals, and indeed those around them, would argue they are living the ‘best life’. Disabled individuals are often well integrated into society and with advancements in medicine are able to live full lives. They are employed, have families and children, and travel, among other things. While their choices may be inhibited by their disability, this does not necessarily affect their ability to live the ‘best life’. The principle also ignores the idea that environmental influences can have an effect on the quality of one’s life, and that genetics alone cannot code for particular outcomes. The disabled community has clear concerns regarding the introduction of gene editing techniques. The practice has strong eugenic connotations and risks the emergence of a dominant ‘normal’ for newborn children. As a result naturally conceived disabled children may be born into a hostile, exclusionary society. For those who already exist, with we risk creating discriminatory spaces for them grow up in. Research has shown that disabled individuals often wish only to change the societal idea that they are second-class individuals because of their abnormalities, rather than to seek out a cure for their disability.¹⁶ Without adequate consideration gene editing regulation risks furthering the idea that disabled individuals should be marginalised and excluded from societal norms.

The dangers for ethnic minorities are less visible, particularly in New Zealand. *Te Tiriti o Waitangi* (The Treaty of Waitangi) principles provide guidelines for considering and interacting with Māori interests in New Zealand. The Human Assisted Reproductive Technology Act references the need to consider and give respect to “the needs, values, and beliefs of Māori”.¹⁷ Adult Māori are almost twice as likely to experience racial discrimination compared to non-Māori, and almost three times as likely to experience unfair treatment on the basis of their ethnicity by a health professional.¹⁸ In order to respect the needs of Māori regulators would need to address the reality of this discrimination. A child who is not perceived as Māori may be treated as though they are not, and therefore experience less negative treatment and outcomes. Potential parents looking to select the embryo with the chance for the ‘best life’ may be encouraged to edit out darker features such

¹⁶ Kaelin L. “Debating Genome Editing Technologies.” In: Braun M., Schickl H., Dabrock P. (eds) *Between Moral Hazard and Legal Uncertainty* (Futures of Technology, Science and Society, Springer VS, Wiesbaden, 2018) 187 at 192

¹⁷ Human Assisted Reproductive Technology Act 2004, s 4

¹⁸ “Racial Discrimination” (August 2 2018) Ministry of Health New Zealand <<https://www.health.govt.nz/our-work/populations/maori-health/tatau-kahukura-maori-health-statistics/nga-awe-o-te-hauora-socioeconomic-determinants-health/racial-discrimination>>

as skin pigment, eye, or hair colour in order to protect their children. Strict prohibitions would need to be placed on these types of editing in order to prevent the fear of discrimination from influencing gene editing uses. Of further issue is the idea of genetic research being used in a gene editing context. This practice risks characterising minority ethnicities by their genetic codes alone as opposed to accounting for environmental effects on the child after birth. In 2006 a group of researchers claimed Māori exhibited a genetic sequence that coded for “criminality, gambling, aggressive and violent behaviour, and alcoholism.”¹⁹ These claims were unsupported by their results, but the resulting controversy saw an outpouring of racism and discrimination towards Māori. The risk exists that potential parents of embryo with Māori origin will be pressured to edit out aspects from their embryos to avoid a genetic stigma applying to their child. Many Māori have also expressed opposition to gene editing from a cultural perspective.²⁰ Māori people honour the notion of *whakapapa* (genealogy) as a key cultural concept. *Whakapapa* links them to their ancestors and provides the cultural connections between past, present, and future. This connection extends past person to person relationship and exists also between people, the land, the sea, and the inhabitants of New Zealand. Each person can link themselves to their significant spaces and assumes a role of protection, or *kaitiaki* over those areas. Gene editing of Māori embryo would alter the genetic line between parent and child, effectively editing the line of *whakapapa* within the family. Without a clear genealogical line Māori children risk losing connection with their *whakapapa* and in the worst case, with their cultural background. Any regulatory decisions would need to honour the importance of *whakapapa* for Māori people and ensure that the available treatments are culturally sensitive. It is essential that any parent who endeavours to edit an embryo with Māori origins is aware of how *whakapapa* interacts with Māori culture, and it’s importance in relation to cultural identity. This is of particular importance where embryos are created with anonymous donor gametes and the prospective parents are unaware of the relevant cultural concerns.

Savulescu’s approach to assisted reproductive technology regulation does not provide adequate protection for minority groups. In order to address the risk of further marginalising minority groups of our society regulation must provide protection from discriminatory uses of the technology. In order to select embryos with the potential for the ‘best life’ based off of Savulescu’s principle,

¹⁹ Dr Dana Wensley, Dr Mike King. “Scientific Responsibility for the Dissemination and Interpretation of Genetic Research - Lessons from the ‘Warrior Gene’ Controversy” (2006) Bioethics Centre, Dunedin School of Medicine, University of Otago <<https://ourarchive.otago.ac.nz/bitstream/handle/10523/361/2006FinalDraftKing.pdf?sequence=6&isAllowed=y>>

²⁰ Royal Society Te Apārangi Gene Editing Panel “Gene Editing in Healthcare Context” (December 2017) Royal Society <<https://royalsociety.org.nz/major-issues-and-projects/gene-editing-in-aotearoa/>>

gene editing would need to allow alteration of disabled or Māori specific genes even if those genes were compatible with life. As regulation will be upstream, a restrictive tilt will provide an appropriate approach to counter Savulescu's approach. Strict constraints must be placed on the types of genetic disabilities subject to gene editing, with a specific focus on conditions incompatible with life. In cases where embryos will be unable to survive without gene editing there is a distinct therapeutic need for the treatment and importantly, no alternative option. Restriction over this topic will help address the danger of disabled individuals feeling as though they are an unwanted 'other' in society by ensuring their disability cannot be 'edited out'. It will also prevent the editing of manageable disabilities where children are able to live meaningful lives. In this way it is possible to maintain safe spaces for disabled individuals to exist in, and allow those who are subject to disabilities to receive adequate care and consideration in both legal and social situations. A restrictive tilt also will prevent unexpected or unintended uses of gene editing from occurring without sufficient regulatory oversight, and provide space for ACART or the government to relax legislation over time as needed. ACART is legislatively bound to consult on new or altered proposed guidelines with relevant parties.²¹ While this duty only exists prior to guidelines being issued, it would be better practice to ensure regular periodic consultation is undertaken by both ACART and ECART on gene editing practices. Advances in medical care could mean diseases or disabilities subject to gene editing would no longer require germline gene editing as a therapeutic treatment. In this case individuals could retain autonomy over their medical choices and seek genetic treatment after birth, under circumstances where they are able to consent. Regular consultation would also be in line with the government's partnership requirements with Māori under *Te Tiriti o Waitangi*. It is also essential that consultation is conducted with a wide range of individuals, and that the process is open and accessible. Regulatory consultation processes are often difficult to navigate and result in a lack of representation from minority viewpoints. Regulators must make a conscious effort to ensure each individual feels represented and considered before guidelines are developed, otherwise risk inadvertently marginalising minority communities.

Alternatively, ACART could utilise a freedom-type approach to regulation by issuing guidelines that place no restriction over the types of genetic codes available to be edited in regards to disability or ethnicity specific genes. The regulatory approach to pre-implantation diagnosis has followed Savulescu's principle and prevents the use of the technology for "purposes other than the prevention or treatment of a genetic disorder."²² In this way regulators are determining the type of children society will allow by preventing parents from seeking a genetically 'abnormal'

²¹ Human Assisted Reproductive Technology Act 2004, s 41

²² Human Assisted Reproductive Technology Act, Schedule, Part 2, s 6

child. The 'Freedom Approach' would allow Savulescu's principle to apply within the parameters of those who are choosing the embryo rather than the parameters of the regulatory body. With no generic 'best life' definition this approach would allow space for gene editing to effect change in all directions, rather than towards a pre-determined norm. Each parent would have total freedom to edit their embryos into their ideal child, with both 'positive' and 'negative' traits open to alteration. The idea of editing in 'negative' traits is likely a concerning concept to a genetically 'normal' adult who idealises their 'normality'. However, open editing could give disabled individuals the ability to pass on a random genetic mutations and maintain diversity within the population. In some cases, disabled individuals have begun seeking ways to pass on their disability using current reproductive technologies, but found themselves blocked by one-sided legislation.²³ The 'Freedom Approach' would send the regulatory message that each embryo has worth irrelevant of it's genetic structure, and that parents are the primary decision makers when it comes to embryo selection. The approach would also allow Māori parents the freedom to continue disabled genetic lines if they so wish, in line with *whakapapa* values. In the case disabled or Māori parents do not wish to pass on mutations they would still have the ability to edit these out. Regulators would still be able to provide oversight around unethical gene-editing uses, but individuals actors would retain the right to make personal reproductive decisions without government intervention.

The potential uses of germline gene editing means careful consideration ought to be given to any use of the technology. Regulation must provide protections for the disabled and Māori communities by maintaining diversity and acceptance of minority traits. In doing so, it must reject the Savulescu Principle of Procreative Beneficence from a regulatory standpoint. Initial and continued consultation regarding any guidelines would be required in order to achieve this, particularly in reference to medical developments. Initial regulation would also need a strong restrictive tilt to prevent disabled actors from losing their place of value in society. Alternatively, unrestricted accessibility to the technology could help to create fair regulation. In this case both 'positive' and 'negative' traits must be open for editing in order to ensure diversity of choice and outcomes. The 'Freedom Approach' would allow open access to editing and give individuals the ability to make decisions regarding their offspring, rather than allowing regulators to exercise this right on their behalf. In either case minority circumstances must be at the forefront of consideration in order to ensure they maintain a valued and predominant part of New Zealand society.

²³ Gaby Hinsliff, Robin McKie. "This couple want a deaf child. Should we try to stop them?" (March 9 2008) The Guardian
<<https://www.theguardian.com/science/2008/mar/09/genetics.medicalresearch>>

