The Significance of Bioethics Committees in Enhancing the Regulation of Human Germline Enhancement Technologies in South Africa

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Abstract: The advancement of technology that allows human genome modification has received significant attention lately. This is due to the ethical concerns that arise from such advancements, which call for establishing bioethics committees to implement recommendations for regulating human germline enhancement technologies. Bioethics committees are most suitable for this task due to their ability to foster public debates and encourage discussions on relevant issues. Although South Africa has seen increased research committees established over the years, the country has yet to establish bioethics committees to promote ethical regulation of germline enhancement technologies nationally. Through a comprehensive review of existing literature, the paper explores how bioethics committees could contribute to regulating human germline enhancement technologies in South Africa.

Using the normative ethical theory of consequentialism, the paper suggests that including independent experts like religious and community leaders in the current national bioethics committees defined by UNESCO would be advantageous in the South African context as this would ensure that the recommendations generated would be a true reflection of the salient values of the rainbow nation.

Keywords: Bioethics Committees, Enhancement Technology, Genetic Modification, Human Genome, Human Germline

Introduction

The technological age has revolutionized our world in various facets of life, ranging from our form of communication and transportation with smartphones that support virtual reality and autonomous cars to the use of artificial intelligence in almost every sphere of our lives, chatGPT being one of the most controversial tools, particularly in the field of education. Additionally, there have been numerous advancements in healthcare, including gene therapy, which has yielded positive results over the years in the attempt to cure heritable diseases such as cancer and diabetes. Today, several technologies that were initially created for medical purposes are currently being utilized to improve certain physical traits of our bodies, such as brain-stimulating devices that can improve cognitive ability, control our mood, and hormones for muscle growth, which are also used for therapy, especially for children of short stature (Almeida & Diogo, 2019: 183). This highlights humankind's desire to transcend normal human capacities and transform into a nearly "perfect," which has long been a part of civilization's history, extending across arts, religion, and philosophy. This idea of perfectionism is said to have deep roots in Western and religious thinking. The same idea has been inherited in both modern science and medicine, leading to the development of human germline enhancement technologies (Comfort, 2012: 10).

Although technologies that could remove or replace genes have been around for years, they were only applied to bacteria, plants, and even animals. The prospects for using human germline enhancement technologies have recently gained tremendous traction. In 2012, the most developed system, Clustered, Regularly Interspaced, Short Palindromic Repeat (CRISPR) was discovered and due to its precision, efficiency, cost, and ease of use, the technology is already widely being used by scientists to research human germline enhancement. Today, we also

have what is called Do-It-Yourself Biology also known as bio-hacking which Samuel Sigal (2019: 1) defines as "the attempt to manipulate your brain and body to optimize performance, outside the realm of traditional medicine" and the technology to do so is readily available for purchase online.

It is against this backdrop that the authors of this article argue for the establishment of bioethics committees on a national level in South Africa to ensure a national consensus on the fundamental ethical grounds concerning the regulation of genetic technologies. Through the use of the ethical theory of consequentialism, the paper argues that the opinions formed through public engagement, which is the primary role of national bioethics committees, can improve the regulation of human germline enhancement technologies in South Africa. The paper is divided into five sections: Firstly, it provides a brief background on human germline enhancement technologies. Secondly, it examines South Africa's current regulatory framework for germline enhancement technologies in South Africa. Thirdly, it explores the significance of bioethics committees. Fourthly, the paper discusses the ethical implications of establishing a national bioethics committee in South Africa. This is followed by a conclusion.

Human Germline Enhancement Technologies

Human germline enhancement technologies promise us the possibility of increasing life expectancy as well as enhancing physical and cognitive capabilities. According to the World Health Organization (2021), the current average life expectancy of a human being is 79 years, and as biotechnologies continue to advance, there is a great possibility that this number could be doubled in the near future. The technology enables the possibility to genetically modify specific characteristics of unborn children including gender selection, prevention of genetic diseases, and enhancement of inherited physical traits such as eye color and height (Masci, 2016: 3). This brings us closer to the possibility of designer babies where human embryos are altered for aesthetic purposes. The simplicity and accuracy of gene technologies have enabled scientists to identify certain genes that are essential in controlling particular cognitive processes. Moreover, as stated by Andrea Lavazza (2018: 497), neuroscientists are currently researching how this in-depth knowledge and understanding of how the brain functions may be applied to develop applications that would enable the genetic enhancement of human cognitive abilities.

The advent of human germline enhancement technologies has also brought about several bioethical concerns ranging from its safety and efficacy to sociocultural and regulatory challenges (Greely, 2019: 119). Scholars such as Rui Gaspar et al. (2019: 1) have argued that many successful cases of advances in human germline enhancement have been documented in the literature, however, the safety of these technologies remains substantially undetermined due to the inability to predict all of the long-term effects of the altered genes which could have harmful social implications on the sanctity of future generations. Thus, raising questions about accurate modification and patient safety. This is because these issues are key factors in how well the technologies are received as well as how procedures are carried out with utmost care to prevent off-targets and mosaicism when the technology reaches clinical applications.

Dolli Player and Alicia Matsuura (2020: 3) argue that even if the technology could be proven safe to use, there are still a few ethical, sociocultural, and religious issues concerning human germline enhancement. These include the essence of humanity and the ambiguity surrounding the moral status of the human embryo since germline enhancement rests on scientists conducting experiments in the very early stages of human development. There is also the fear of eugenics where developed nations could potentially misuse these technologies to create the "master race" - humans that are genetically superior to others, more intelligent, beautiful, and athletic (Friedmann, 2019: 352; Evans, 2021: 1). Further, there is the major religious concern that stems from the Christian perception of "playing God". This is a concern raised by many scholars depicting the immorality of "producing a genetically enhanced human" which would involve altering God's creation (Shozi, 2020: 62). Lastly, germline enhancement technologies present the challenge of merging tradition with science, especially within an African context as there is a concern that the various applications presented by germline enhancement technologies have the potential to infringe on the ethical values, cultural beliefs, and practices that are embedded in authentic African traditions (Nabyonga-Orem et al., 2021: 3). An example illustrated by Augustine Nwoye (2017: 46), explained that humankind, in African traditional cosmovision is seen as a product of divine creation, be it from a spiritual and/or a religious viewpoint, whereas scientists see humanity as a component of the animal species. Thus, cultural and religious relevance, including the specific setting in which they are applied or envisioned needs to be critically examined.

According to the Nuffield Council on Bioethics (2019: 114), there is no international treaty on how the modification of the human genome should be regulated, and with the absence of appropriate ethical principles and effective regulation, there is no sufficient framework to prevent violations and unethical applications of genetic technologies. In an attempt to address this issue, the Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing, established by The World Health Organization (WHO) issued its Draft Governance Framework on Human Genome Editing in 2020. The draft consists of global recommendations on the governance, regulation, and oversight of human genome editing, placing a focus on safety, efficacy, and ethics. The recommendations focus on systemic changes required to increase the capacity for safe, effective, and ethical use of human genetic technologies. Bonginkosi Shozi et al. (2021: 3) further echo that the draft is "a positive step in the direction of establishing a global framework on the regulation of human genome editing". A closer look at this global framework suggests that since countries differ from one another, economically, socially, linguistically, and even culturally, nations always encounter challenges when technological improvements confront or collide with the variety of values held by its citizens (UNESCO, 2023). Thus, there remains the need for a regulatory framework that enables the inclusion of various societal, religious, and cultural viewpoints on controversial bioethical issues concerning emerging technologies.

A Brief Overview of the Current Regulatory Framework for Germline Enhancement Technologies in South Africa

South Africa's current regulatory framework is not structured in a way that provides clear guidance as to how human germline enhancement may be regulated. One may argue that this is due to the complexity associated with this type of genetic modification. On one hand, South Africa's legal and regulatory framework, theoretically, allows for a method that simplifies research on human germline editing. On the other hand, its legal framework for human germline editing in clinical settings is not yet apparent. As a result, South Africa is seen as ambiguous and inexplicit in terms of the legality of enhancing the human germline. Thus, as stated by Donrich Thaldar et al. (2020: 1), the country's current ethical and legal framework needs reform. The following section discusses the inconsistencies found in South Africa's current regulatory standing on human germline enhancement in light of the three main ethics guidelines, namely; the South African Department of Health, the Health Professions Council of South Africa (HPCSA), and the South African Medical Research Council (MRC).

The Department of Health's ethics guidelines include sections on genetic and genomic research that emphasize overarching ethical issues with these fields of study. However, as has been pointed out by several scholars including Thaldar et al. (2020: 2), Beverly Townsend and Bonginkosi Shozi (2021: 5), among others, the department is somewhat silent on its ethics guidelines concerning the enhancement of the human germline which is a more specialized subject of genome editing. Furthermore, HPCSA's code of ethics for biotechnology research in South Africa, also known as 'Booklet 14', has a section under 'Gene Therapy Research' which states that "all research in relation to gene therapy must be directed to alleviating diseases in the individual patients and no attempts should be made through the use of gene modification, to change human traits not associated with disease" (Health Professions Council of South Africa, 2008: 42). It later states under 'Germline gene therapy research' that "…Research relating to germline gene therapy is therefore not acceptable". This is problematic as the assumption seems to be that gene modification for non-therapeutic purposes will never be a point of discussion. Whereas, once the technology is proven safe to be used for enhancement purposes, South Africa will have to have guidelines and regulations in place to guide how the clinical application of germline technology may be used ethically or have a sound reason why the country decides to prohibit these technologies. Thus, deeming the HPCSA guidelines incomplete.

Lastly, according to the MRC ethics guidelines, any attempt to alter human traits unrelated to diseases through gene editing would be deemed unacceptable. However, there are also some inconsistencies detected where the MRC states that "…Germ- line therapy should not be contemplated" (South African Medical Research Council, 2004: 17). The phrase "should not be contemplated" is not appropriate given that these ethics guidelines may become fundamental for handling germline enhancement. As asserted by Thaldar et al. (2020: 2), to understand South Africa's position on the acceptability of human germline enhancement technologies, one must certainly think about germline modification. Further, the MRC also mentions a section on 'Pre-embryo modification and research'. Here, the council appears to adopt a different stance stating that "Pre-embryo manipulation and research may yield valuable medical information. However, it can be regarded as ethical only if the embryos are not specifically produced for the purpose of research. In addition, the embryos should not be transferred to the uterus unless there is reasonable certainty that the manipulation carries no potential risks for the foetus" (South African Medical Research Council, 2004: 12). This statement, as indicated by Townsend and Shozi (2021: 15), is where the inconsistency lies as it suggests a more permissive approach to genetic modification of embryos rather than an outright ban. Overall,

there seems to be hostility towards human germline modification considering the ethical guidelines from the HPCSA and MRC. However, apart from the concern about the safety and efficacy of genetic technologies, both the HPCSA and MRC declare no apparent reason for completely banning germline enhancement, especially on a research level.

Research on human germline modification will necessitate the adoption of the regulations relating to research with human participants which is found under South Africa's National Health Act. The Act states that research involving human participants must – "(a) comply with the Department of Health's national ethical guidelines for research with human participants at a minimum…" (National Health Act, 2014: 6). Furthermore, the Act emphasizes the importance of the research participants' consent to the given research and ensures that there is no harm or threat to them. However, when considering human germline enhancement, meeting this requirement is a challenge since, as established previously, the Department of Health is silent on its ethics guidelines concerning human germline enhancement which is an aspect that requires immediate attention. A plausible concept related to human germline enhancement currently found in NHA is the 'reproductive cloning of a human being'. This concept is defined as: "the manipulation of genetic material to achieve the reproduction of a human being and includes nuclear transfer or embryo splitting for such purpose" (National Health Act, 2003: 62). Here, the NHA prohibits reproductive cloning of human beings by stating that "a person may not (a) manipulate any genetic material, including genetic material of human gametes, zygotes or embryos; or (b) engage in any activity, including the nuclear transfer or embryo splitting, for the purpose of the reproductive cloning of a human being" (National Health Act, 2003: 62). This section of the NHA is somewhat closer towards providing sound regulation for genetic enhancement. However, as asserted by Kriti Shrinet (2020: 1), the term 'cloning' is widely understood to be an identical genetic copy of a piece of DNA and thus, cannot be deemed equivalent to germline enhancement. Nonetheless, since the NHA defined 'reproductive cloning of a human being' as a type of 'modification of genetic material' it is ultimately very similar to what germline enhancement is and therefore if germline enhancement were to reach clinical applications, according to the NHA, this would be considered illegal and subject to legal penalties in South Africa, unless specific changes to the word 'cloning' is provided (Thaldar et al., 2020: 3).

As indicated above, indeed human germline enhancement is a complex type of genetic modification and that necessitates cautious navigation toward reaching an appropriate regulatory framework. Moreover, the case of South Africa is peculiar as it is a liberal country consisting of communitarian undertones inclusive of a multiplicity of religious and cultural beliefs. Therefore, deliberations on the acceptability of human germline enhancement technologies should involve public engagement due to their impact on strongly held moral, religious, and ideological convictions that cannot be resolved by science alone.

The Significance of Bioethics Committees in South Africa

According to the United Nations Educational, Scientific and Cultural Organization (UNESCO), a bioethics committee is made up of a group of individuals who meet regularly to discuss and provide guidance on ethical issues concerning the health sciences, advancements in science and technology, and public health on a national, regional, local, or institutional level (UNESCO, 2010). Hence, such a committee is recognized for its independence, multidisciplinary, and transparent composition. Bioethics committees play several different roles, depending on the needs of the country or institution. Some directly report to the government or participate in legislative procedures, while others offer advisory services without being given any specific or guaranteed authority. However, one of the main roles of bioethics committees is to "facilitate public debate on controversial bioethical issues and to produce opinions and recommendations that can help inform the public and policy-makers" (Hummel et al., 2021: 1). Bioethics committees are primarily concerned with providing practical recommendations on the use of novel biotechnologies as well as philosophical discussions on bioethics.

Monique Wasunna et al. (2016: 1) note that the International Bioethics Committee (IBC), established by UNESCO in 1993 came to being with the primary objective of promoting leadership and influencing the culture of bioethics in science and medicine. Its other function is to protect human dignity and well-being. The committee comprises 36 independent experts from various disciplines, such as philosophy, law, medicine, and genetics. Their role is to monitor the advancements in the life sciences and their applications to ensure the protection of human rights and dignity. In 2005, UNESCO released a universal declaration on bioethics and human rights which stated that "Independent, multidisciplinary and pluralist ethics committees should be established, promoted, and supported" (UNESCO, 2005: 1). The primary objectives were to assess scientific and technological advancements, formulate recommendations, and contribute to the development of guidelines on bioethical issues. In addition, these committees aid in promoting discussion, education, public awareness, and engagement in bioethics (Universal Declaration on Bioethics and Human Rights: UNESCO, 2005).

UNESCO mandated each country to develop its bioethics infrastructure to create sound public policies that represent the interests and concerns of its society and citizens. Africa is part of the International Broadcasting Convention (IBC) and plays an active role in shaping its global agenda. However, it seems most African societies are still unfamiliar with basic bioethics issues, techniques, and principles as most of the fundamental issues, practices, and principles of bioethics are currently exclusively dominated by Western perspectives (Wasunna et al., 2016: 3). Cletus Andoh (2011: 72) has argued that within the African context, the understanding of bioethics consists of two conceptions; one relates to the sets of moral principles embedded in culture, where shared beliefs, values, and assumptions are often deeply embedded in our language and practices. The other conception refers to bioethics as an academic discipline. Moreover, the overall growth of bioethics in Africa is varied as different nations within the continent embrace the concept from different perspectives and a limited number of higher education institutions incorporate bioethics in their curriculum. However, for Africa to generate adequate solutions to the moral, legal, and social issues associated with human germline enhancement technologies. Such a platform may be observed through upholding one of the primary functions of NBCs which is promoting public engagement on controversial issues brought up by human germline enhancement technologies. This will ensure that the data gathered from these discussions are credible and significant in terms of informing legislation that is reflective of specific cultural, religious, and moral diversity.

Bioethics committees are most suitable to deal with the ethical concerns associated with human germline enhancement technologies as its main function as aforementioned, is to address new issues in bioethics inclusive of the common good and public interest. Moreover, according to UNESCO (2005), part of the issues that bioethics committees discuss in their regular meetings are social responsibility, traditional medicine, biodiversity, and cultural issues concerning biotechnology which is mostly done through public engagement. According to Ana Iltis et al. (2021: 3), public engagement plays a crucial role in the work of bioethics committees. These committees engage in discussions about new biotechnologies, including which applications should be allowed and which principles should guide engagement efforts of entities developing recommendations or guidelines on regulation for such technologies. Public engagement is important because public involvement in deliberations is required as a matter of principle in a democratic society, such as South Africa. Iltis et al. (2021: 3), have recommended that those who will be impacted by a decision, whether they are stakeholders or laypeople, should have an equal opportunity to participate in decision-making as this may help to improve adherence to scientific recommendations, decrease controversy, and increase acceptance of results. In this instance, the decision in question would be, which applications of germline enhancement technologies may be acceptable and which may not be considered, providing that the technology is proven safe and efficient.

The composition of an NBC within a South African context would require the inclusivity of religious and cultural experts such as theologians and various community leaders. This is in agreement with Thaldar et al. (2022: 2), who stated that "decisions surrounding technological advancements should be made by society as a whole—rather than by just a small group of experts as traditionally is the case". This ensures that the recommendations generated by the committee are a true reflection of an authentic South African context. Furthermore, research by Keymanthri Moodley et al. (2020) revealed that bioethics committees are often confused with research ethics committees, which primarily function to protect research participants and provide advice for the Department of Health on research-related ethical issues. This is because research ethics is the most developed area of bioethics in Africa. Although the various tasks may be combined in some conditions when the main objective is the evaluation of research procedures, the role of that committee is no longer that of a NBC. Since many ethical issues, particularly those involving the enhancement of the human germline, are of great interest to both the general public and professional legislators, these tasks should not be neglected and should instead, play a major role in a bioethics committee's objective.

Ethical Implications of Establishing a National Bioethics Committee in South Africa

So far, the paper has discussed the significance of bioethics committees and how a plausible establishment of such committees may be beneficial for South Africa in terms of strengthening its regulation of human germline enhancement and other applications. A critical look at the role of NBCs calls for a consequentialist theory which determines the morality of actions by evaluating their outcomes or potential outcomes, and the best action is one that brings about the greatest happiness or benefit (Elliott & June, 2018: 159), which suggests that the right action is based on that particular action.

Looking at the NBCs' primary role of public engagement through the lens of the above theory, the cultural, religious, and moral diversity found in South Africa stands a better chance of being considered in the regulation of human germline enhancement technologies. Since consequentialism advocates for actions that bring about the greatest happiness or benefit, in this case, the process would be the true representation of the citizens' opinions in the decision-making processes regarding the implementation of genetic technology. Here, it is important to mention that public engagement towards the implementation of the NBC might be a lengthy process because of the inclusion of more voices that are typically left out in policy-making. While this space might expose moral conflict, because of the make-up of the committee members (scientific experts, policy-makers, and ordinary citizens from different religious and cultural backgrounds), this might break down the power relations that would prevent legitimate dissatisfaction individuals from being heard. Thus, enhancing the overall happiness of the citizens (UNESCO, 2023).

Conclusion

The development of human germline enhancement technologies has brought about several bioethical concerns which necessitate contrasting wide professional viewpoints and public concerns. As noted from the discussion above, currently, there is no international treaty on how the modification of the human genome should be regulated. Therefore, nations have individually decided to either partially allow or put an outright ban on human germline enhancement. It is unclear what South Africa's position is regarding human germline editing as their stance seems ambiguous and lacks clarity. On the one hand, it appears that research on human germline editing is allowed and on the other hand, its legal framework for the clinical environment on human germline editing is not apparent. South Africa's current ethical and legal framework needs to be reformed to include the religious and cultural diversity of the country. The article has argued for the need for the establishment of a well-functioning NBC made up of a group of independent experts including religious and various community leaders. Through the committee's primary function of facilitating ongoing dialogue between the aforementioned individuals, researchers, policymakers, and the public, it is hoped that South Africa can produce recommendations that are reflective of its salient values. Thus, bringing the country a step closer to strengthening its current regulatory standing on human germline enhancement technologies.

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