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The Ethics of Genetic Engineering in Medicine

Bwanbale Geoffrey David

Faculty of Pharmacy Kampala International University Uganda

ABSTRACT

Genetic engineering in medicine offers transformative potential in preventing and treating human diseases through gene therapy, somatic modification, and germ-line editing. This paper critically explores the ethical dimensions of genetic engineering by analyzing historical development, current medical applications, ethical theories, informed consent, and regulatory frameworks. It further examines public perception and highlights real-world case studies to underscore both the promise and perils of genetic manipulation. While technologies like CRISPR/Cas9 drive rapid innovation, they also challenge existing legal, moral, and societal norms. The ethical debate is intensified by the blurred lines between therapy and enhancement, the risks of unintended consequences, and concerns about equity, consent, and long-term impact on human identity. This paper advocates for robust ethical oversight and global dialogue to ensure that genetic engineering advances are guided by principles of justice, transparency, and respect for human dignity.

Keywords: Genetic engineering, Gene therapy, Germ-line editing, CRISPR, Medical ethics, Informed consent, Bioethics, Human enhancement.

INTRODUCTION

Genetic engineering (or genetic manipulation) refers to the direct manipulation of an organism's genes in order to alter that organism. Reasons for wanting to manipulate genes include, but are not limited to, correcting genetic problems and creating organisms with desirable characteristics. Genetic engineering is often considered a more efficient and precise alternative to the previously employed method of cross-breeding and selective breeding, which would be carried out over many generations in hopes of achieving beneficial results. Genetic engineering takes several forms, two of which are the treatment of existing organisms, somatic gene therapy and germ-line gene therapy. Somatic gene therapy can be aimed at somatic cells (any cells except the gametes) in order to treat or prevent genetically-based diseases in already existing persons. This type of genetic engineering has displayed dramatic success in certain cases but has not yet realized its full potential. Germ-line gene therapy is the other form of genetic manipulation, which can be aimed at either somatic cells or germ-line cells (such as egg or sperm cells) in order to treat or prevent genetically-based diseases for not-yet-existing persons. Germ-line genetic engineering is the more controversial of the two types of genetic engineering proposals and is the one that is considered more appropriate for this paper. Currently, both somatic and germ-line genetic engineering for therapeutic purposes are in their infancy without regulatory oversight [1, 2].

Historical Context of Genetic Engineering

The combination of biology and engineering can be called genetic engineering. Changes can be introduced into the chromosomes of humans, animals, and plants through gene technology. Genetic engineering is a process by which genetic material is altered to make a desired product. In humans, the genetic material, or DNA, is altered by the process of recombinant DNA technology or gene cloning. These technologies explore the new possibilities of drug development for curing diseases like Alzheimer's, Parkinson's, heart diseases, AIDS, mutation, genetic disorder, etc. Applications can include the use of modified bacteria to produce human insulin or the sequencing of the human genome. Molecular techniques such as the placement of transgenes, polymerase chain reaction, preparation of recombinant DNA, and restriction enzymes are tools involved in genetic engineering. We do genetic engineering to obtain human insulin, microbial insulin, human growth hormone, and herbicide-resistant crops. Natural

variations led, through hereditary mechanisms, to designs with specific properties. Meanwhile, directed modifications of designs are rare, and the further development of the design principles themselves seems unwarranted. Genetic engineering is easy to understand, but the moral implications can be confusing. Pioneering studies on genetic engineering have pointed toward the potential of biotechnologies both to enhance and to remedy. Reassurances about remedying diseases, such as insulin for diabetes, should not blind us to the potential impacts of enhancement. There are important differences between these two kinds of attempts at genetic engineering [3, 4].

Current Applications in Medicine

Genetic engineering has two key medical applications: treating genetic disorders and improving health by altering somatic cells. Gene therapy, which replaces defective genes in somatic cells, can address disorders like cystic fibrosis, muscular dystrophy, and sickle cell anemia. The first successful gene therapy was reported in 1990, and since then, multiple gene therapy drugs have been approved globally. The second application involves enhancing health through somatic genetic modifications, which improve the immune system's ability to combat cancer or prevent it by altering somatic cells. This may also extend to indirect health improvements, such as converting adipose stem cells into chondrocytes for knee osteoarthritis treatment. Future research in cloning, aging, and epigenetics may yield significant health benefits, though such processes may not always be considered genetic engineering. The distinction between gene therapy and enhancement raises questions, particularly concerning somatic genetic engineering's classification. Enhancements to somatic cells differ from germline alterations that could affect future generations, such as through mitochondrial replacement, which also invites discussion on the heritability of such changes [5, 6].

Ethical Theories and Frameworks

As social creatures, people share common biological and environmental needs, and the attendant community of interest in fulfilling these needs leads to the formation of social institutions and so to the emergence of social groups and associations. Individuals in social groups make decisions and choices that affect both the groups and themselves. The ethical problems that arise from social decision-making can be approached from two different yet interrelated starting points. One is from the instinct of altruism and concern for the well-being of others. The second is from an attempt to think through decision problems so as not to succumb to the dangers of fraud, coercion, or short-sightedness while achieving fairness in the distribution of benefits and burdens. Social institutions in order to survive, are required to exercise restraint. However, self-restraint can be implemented in the wake of fear. Fear is an elementary and brute emotion that plays a central role in basic social institutions, whether a system of supernatural sanctions, i.e. religion, or a system of social pressures and restraints, i.e. government, are exogenous to the social group, the need to exercise self-restraint can lead to a decision to create some social machine, be it a priesthood or a government, that would monitor and supervise their actions. A kind of social institution will inevitably exist, but whether it will be effective in exercising restraint, and the specific nature of the institution, will depend on the moral consciousness of the members of the social group, on their culture, and on their shared aims or values. The moral need that gives rise to social institutions will, in the case of basic social institutions, where the requirement of self-restraint is elemental, be coeval with man's emergence as a social animal. The appropriate institutions will be broad and relatively unstructured, yet their precise features will depend on the historical contingency of the actual group. The emergence of more refined institutions will again depend on the perception of a moral need of a more sophisticated kind; specifically, the moral need of not being unduly exploited in social interactions and to make fair decisions in the abiding and ubiquitous uncertainties of life choices [7, 8].

Informed Consent in Genetic Engineering

Informed consent is crucial for ethical genetic engineering in medicine, serving as the initial step for participant inclusion. It allows researchers to educate potential participants on the science, purpose, risks, benefits, and accountability in a comprehensible way, fostering a respectful and ethical relationship. However, informed consent poses significant challenges. Adults are often pressured to agree to complex policies they may not fully understand, leading to uninformed consent. In clinical settings, consent forms can feel standardized, which might downplay risks, creating a false sense of trust in the clinician. Due to this lack of context, patients and researchers might assume all processes are legitimate, leading to therapeutic misconceptions where participants wrongly believe research care parallels regular clinical care or is assured to yield benefits. Despite these hurdles, achieving meaningful informed consent in genetic engineering is possible, exemplified by somatic-cell gene therapy trials. The text discusses challenges in germline genome editing consent and offers solutions, emphasizing that while informed consent is necessary, it is not enough to prevent harms. There is a pressing need for global oversight in

scientific practices and regulation to navigate the rise of synthetic biology and commercialization pressures [9, 10].

Risks and Benefits of Genetic Engineering

Over the past quarter-century, the prospects of genetic makeovers, perhaps for curing disease-causing defects or enhancements of a variety of favorable characteristics, have moved from the chronicles of science fiction to the parades of bold announcements by enthusiastic researchers in national and international nature concerning the results of newly initiated clinical trials or spectacularly successful animal tests. The complexities involved are such that a basic understanding of both the capabilities and potential negative effects of genetic engineering is essential not only to scientists and medical professionals but also to businesspersons and politicians. It is also essential for the general populace, who may be unwittingly inundated and besieged by the necessary attention to soon regulate the use of genetic engineering on them and those they care for most. Genetic engineering is one of those rare scientific advances with the potential to do vast and sweeping good while at the same time permitting tremendous destruction, not of the physical structure of the universe, but of life itself. Somatic gene therapy is likely to be used for the benefit of mankind long before germ-line gene therapy falls into medically safe and acceptable use. Moreover, at least some somatic gene therapy will almost certainly lead to germ-line genetic alteration, with obvious risks and benefits therefrom. In this scheme, current knowledge of gene therapy and experience with doling it out on humans as subjects are reviewed, and some potential human health advantages and disasters ranging from the possible to the probable are discussed. Serious dangers of somatic gene therapy in human beings are anticipated, while cautioning that such knowledge of dangers does not imply that the gene-altering techniques should not be pursued. Perhaps the various factors leading to the possible eventual benefits of germ-line gene therapy may be sufficiently cosseted from malfunction that these eventualities may some day become realities. Scientists have accomplished the successful insertion of new genes into target cells in animals and plants for some time. However, they cannot control exactly where the new genes are inserted into the target cell's DNA. Safer insertion techniques are either too new or non-existent. This lack of control raises the danger that an inserted gene may be inserted into a new location where it examplary activates an endogenous gene critical for maintaining the normal function of the cell, such as a tumor suppressor gene, thus resulting in uncontrolled cell division and output of abnormal proteins that compromise normal metabolism and function [11, 12].

Regulatory and Legal Perspectives

The rapid development of CRISPR/Cas9 gene-editing technology raises profound questions regarding its possible regulation and governance at national and international levels. Some scientists and policymakers attempt to trace a road map for national and international governance as an answer to these challenges. But how to approach these possible avenues for regulating CRISPR/Cas9, on which ethical principles should they be built? One possibility would be to try to establish oversight mechanisms, such as prohibitions on special types of research, review boards, and regulations on how to carry out research. Prohibitions could pertain to germline modification of human embryos, which could end the possibility of later treatment or even palliative care. Another approach would be to install mechanisms for education and public reasoning, such as "multistakeholder dialogues" and "deliberative forecasts". These initiatives could increase awareness of the knowledge and particular position of stakeholders, facilitate tailored risk and impact assessments, and identify common societal issues that could affect the direct or indirect future of gene-editing applications. Despite the extraordinary potential of CRISPR/Cas9 and future gene-editing technology to produce enormous benefits for global health, the uncertainty about possible harms of the technology is huge compared to the decades-long experimental and legal history of reliable biomedical technologies. A debate on the legal history of human gene enhancement and germline modification was facilitated by the convergence of scientific, health, and societal advancements. In this debate approach, the drastic possible differences between Japan, the UK, and the US, as countries of origin and active experimentation in the field, are explored rather than approaches to couple regulation to experimentation. Instead, a debate on regulations follows the dissemination of technology. However, the idea of pre-emptively banning GM in Europe seems attractive, but it is also flawed. The dual-use nature of gene editing technologies calls for regulatory mechanisms on both ends, which wise scholars have identified [13, 14].

Public Perception and Ethical Discourse

Public perception of biotechnology has largely focused on agricultural applications, often viewed exclusively through the lens of GMOs. However, awareness of biotechnology's medical applications is growing, especially following revelations about gene editing's potential to alter human embryos. This new dimension in genetics has sparked diverse reactions, from caution to outright rejection, particularly

in agriculture. As the focus shifts from food and animal health to human health, public sentiment is expected to evolve, reflecting deeper emotional concerns. Unlike conventional GMO discussions, these dialogues will emphasize genetic engineering and its role as an enabling technology. The societal expectations surrounding gene editing in food and its potential medical uses create a complex landscape of opinions. Increased awareness of human embryo editing has prompted calls for conversations regarding its ethical implications. While acceptance of gene editing technology may rise, understanding the nuances of public discourse is crucial for fostering effective communication. Ongoing research encompasses psychological assessments of attitudes toward human gene editing and broader discourse on its implications. Exploring public perceptions related to agricultural, medical, and dual-use applications will provide valuable insights into changing views on gene editing. Given the diverse demographics within agricultural contexts, research should address how biotechnology and perceptions intersect across academia, advocacy groups, government, and industry. Approaches to societal acceptance and public discourse must consider audience framing and participation dynamics [15, 16].

Case Studies in Genetic Engineering Ethics

Environmental Considerations of Genetic Engineering: GMOs may harm organisms beyond those intended for modification, raising concerns for laboratory-tested organisms and agricultural applications. Protective barriers help manage genetic engineering's environmental impacts, but the characteristics of GM organisms remain uncertain. Predicting unseen consequences is challenging, even with existing knowledge. Genetic engineering's effects on human traits, including aggression and temperament, spark ethical debates about its moral implications. While individuals can currently select traits through traditional means, the effectiveness of genetic engineering prompts questions about its permissibility. The ethical stance on human genetic modification contrasts with natural selection, which enhances survival. Most organisms, including humans, are shielded from artificial life forms, and nonexperimental GMOs could escape regulation, presenting a key ethical distinction. Artificial enhancements might threaten human identity, potentially reducing humans to just another variety amidst Earth's biodiversity. This long-term perspective necessitates cautious genetic modification, especially as the coexistence of machine intelligence and humanity remains uncertain [17, 18].

Future Directions in Genetic Engineering Ethics

Bioethicists, in particular, have noted the overstated quality of GGE in medicine. Really ought to push scholars not to succumb to futility. GGE is fundamentally different from other great leaps in medicine. So far, this feels like ways and means have been thoroughly explored. So we need to discuss whether it is permissible for certain kinds of GGE to exist in the world in the first place. We would then need to discuss restrictions on that permissibility, and contingency planning regarding whether one side might come to have a larger or more powerful role in regulating it. Thus, it makes sense for involvement to focus on whether GGE techniques themselves are potentially permissible, desirable, or categorically out of bounds in some fashion. This, of course, does not mean having no initial interest in GGE applications. Advances in CRISPR-Cas9 specifically, and GGE generally, provide a blank slate on which to raise questions, explore concerns, or posit potential applications and issues. But if much of what bioethicists hypothesize is the best case scenario, widespread access to safe and effective therapeutics for genetic diseases, is, in fact, the likely initial use of these techniques, these would not be the initial questions bioethicists would wish to raise. It is too early to consider how GGE might be ethically used or regulated as a point of departure. Rather, it is imperative to first ask: Is it permissible at all? Or even desirable? In ethics, it can be a sign of maturity to recognize a settled question or concern and shift to a secondary line of inquiry where philosophically serious uncertainty still exists. And the time, and pressing need, for doing this in respect of GGE is now. There is a particularly relevant role for neuroethics in this discussion. At least some of the most important issues in the ethics of gene editing generally, and BGE specifically, are made more pressing by the delivery question, and reflectively easier to address, through considerations focused on NGE as it pertains to altering cognitive traits through medical intervention. Given encouraging headway in designing safe and efficacious techniques for genetic engineering in animals, the question of whether it would be permissible, and the prudential question of whether it ought to be, to seek similar alterations in human beings through genetic engineering is positioned towards the forefront of neuroethics [19, 20].

Interdisciplinary Approaches to Ethics

In keeping with the journal's interdisciplinary theme, I wish to illustrate the connection between methods of generating ethical knowledge and the understanding of a particular kind of knowledge. If environmental ethics has not become interdisciplinary for similar reasons, these comments might have directed a more in-depth exploration of the epistemological claims of environmental ethics in service of the empirical claims of the environmental sciences. Since I am epistemologically wary of needing to justify

the inclusion of any one discipline into bioethics at the expense of another, the exploration of what can be learned about interdisciplinary activity from the disciplinary claims of epistemology is a way of abstracting from any one discipline to make it applicable to all. A cross-disciplinary collaboration investigating whether it is ever justifiable to disclose confidential information will illustrate these points. In this case, at least one practitioner from both the health law and the social work disciplines, as well as one social-scientific researcher, would need to be involved. The researchers would want to determine what a legislative code might look like and the standards of inquiry. The health law practitioner could investigate the constitutional claims to divulging information in a monitoring process to which a defense attorney had ready access. The social work practitioner could assess and present the practical implications of various findings in the protection of patients' rights and needs, including the establishment of mandatory reporting systems on which health sector practice could rely. It would also be imperative to enlist a bioethicist to comment on the realities of patients needing treatment and abuse remaining undetected. Each researcher would not only need to understand the knowledge claims from other disciplines but also risk the tradeoffs attendant on analysis, synthesis, and critique that breach disciplinary conventions. Fatigue is guaranteed before ethical judgments might be made. This is not to deny the worth of work done in collaboration with social scientists, which, it is hoped, will only spur the further development of greater cross-fertilization of disciplines. Rather, the fervent hope is that in making the disciplinary boundaries between ethics and the disciplines less rigid, more attention can be given to the nature of ethical knowledge as a function of such boundaries [21, 22].

The Role of Professional Organizations

Professional organizations are increasingly tasked with developing ethical frameworks for using benchtop CRISPR and gene-editing technologies in various fields, including biomedicine and agriculture. These organizations employ diverse methods to promote and endorse ethical guidelines. Some conduct thorough reviews of potential conflicts of interest among board members before engaging in controversial discussions; others vet membership and consult potential members before admitting experts from emerging fields. In contrast, many global societies adopt a more open approach, allowing debate and feedback from interested parties before finalizing their positions. A survey examined three categories: organizations that have released ethics statements, those invited to submit statements by September 2018 but had not yet done so, and those less likely to receive an invitation but should nonetheless be included. Many statements describe potential societal and health consequences of gene editing, often contradicting the CRISPR research community's guiding principles. A few, primarily from US or European organizations, emphasized actionable steps to ensure responsible research in human germline editing. There is a growing consensus that if germline gene editing is pursued, it should focus on preventing severe, monogenic diseases, and a concerted global effort is necessary to ensure equitable access to these technologies beyond just their availability in costly health systems [23, 24].

Cultural Perspectives on Genetic Engineering

Some of the major international collaborative projects of the last few decades have made a significant, positive impact on health, agriculture, and the environment. Examples of such projects that have involved genetic engineering include the International Human Genome Project, the International Rice Genome Sequencing Project, and the International Wheat Genome Sequencing Consortium. These efforts have necessitated close collaboration among many governmental and academic agencies in nations at different stages of social, cultural, and scientific development. Each of these projects has required the personal commitment of scientists on a worldwide scale who were prepared to share their intellectual property in the early stages of investigation, and then to share data promptly. Those projects were assisted by international agreements regarding access to genetic material, ethical concerns, and respect for indigenous peoples. Every one of these projects was designed to produce far-reaching benefits. However, in contrast, when scientists try to collaborate on the international development of methods of germ-line genetic engineering, the literature has effectively been silenced. This is an unusual response to a new technology, and a highly political one. Of course, a measure of caution is warranted, especially where there is a scientifically reasonable fear that the technology may be misapplied. Although it is already clear that there are social dangers associated with bioweapons and gene drives, germ-line genetic engineering poses a unique fear that there will be unexpected, dangerous consequences for human health or ecology. In contrast to these fears, it must be said that there is no warranted fear that germ-line genetic engineering might offer great benefits for several diseases and undesirable conditions. A resolution paradoxically prompted by writing this paper is to note that lessening the impact of Down syndrome (trisomy 21) is as great a health challenge as combating unintended pregnancies, fetal alcohol syndrome, or hunger pangs [25, 26].

CONCLUSION

The ethical landscape of genetic engineering in medicine is as complex as the science itself. While breakthroughs in gene editing hold the promise of curing genetic diseases and improving human health, they also pose profound ethical questions regarding consent, justice, safety, and human identity. Distinctions between therapeutic use and enhancement, particularly between somatic and germ-line interventions, must be clearly understood and carefully regulated. Informed consent, particularly in germ-line applications, remains a contentious yet crucial element for ethical legitimacy. Furthermore, the dual-use nature of genetic engineering necessitates international collaboration to create governance frameworks that are adaptable, transparent, and inclusive. As science advances, so too must our ethical frameworks. Ultimately, the future of genetic engineering in medicine depends not only on what can be done but on what should be done, requiring a careful balance of innovation, precaution, and moral responsibility.

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