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Page | 14

# **Ethical Considerations in AI-Driven Genome Editing**

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#### ABSTRACT

The intersection of artificial intelligence (AI) and genome editing represents a rapidly advancing frontier with the potential to revolutionize biology and medicine. This convergence, however, raises significant ethical concerns. This paper explores the ethical implications of AI-driven genome editing, focusing on issues such as unintended consequences, autonomy and informed consent, regulatory frameworks, and social equity. The analysis underscores the necessity for robust ethical guidelines, transparent regulatory practices, and equitable access to emerging technologies. These measures are crucial to ensure that the advancements in genome editing are conducted responsibly, safeguarding public trust and promoting beneficial outcomes for society.

Keywords: AI-driven genome editing, ethics, autonomy, informed consent, regulatory frameworks.

# INTRODUCTION

In recent years, a rapid cross-disciplinary learning and assimilation of artificial intelligence (AI) methods to many areas of science and technology has occurred. Machine learning and methods to apply these in data-rich areas such as natural language processing and computer vision have become powerful and general tools. Within the life sciences, advances in DNA sequencing and gene editing, underpinned directly through AI methods and also through infrastructure engineering for large-scale sequencing and gene editing, have enabled profound exploration of biology and potential new therapies for long-standing diseases [1, 2]. In a rapid co-evolution of these two powerful technology areas, some methods originally developed for application in domains where direct assessment of the intended and unintended consequences of using the method were the key control have been transferred with less concern for this single point into other application areas. Remarkably, existing methods, which while validated for a single desired outcome, have been applied directly and at large scale in ethical domains with minimal specific validation that the applied method achieves any essay in a meaningful way. The science has launched into a full commit and ask questions later trajectory favored by lower value research, without explicit understanding of the potential exponential downside risk. Here we focus on the implications of the AI methods within genome editing, with an emphasis on the unintended consequences of these methods in the design of the DNA postcode that trade-off completely in favor of a specific point solution  $\lceil 3 \rceil$ .

#### **OVERVIEW OF AI-DRIVEN GENOME EDITING**

A typical cell contains about 2 billion base pairs and hundreds of genes. An error in the sequence of base pairs can result in genetic diseases such as hemophilia and cancer. Previous research in genetics has yielded gene therapy such as Retroviral vectors and Adeno-associated virus (AAV) whose effectiveness depends on the accuracy of the initial sequence detected from gene fragment's p-map to the victim's genotype (base modifications). Base modifications are slow as it is subjected to a high-gain/lowbandwidth system where we are using external agents in the form of reverse transcriptase (RT) and CRISPR-Cas as players for our gene editing tools. We need to rethink the diabetes forecast as to how we can approach this earlier by dealing with real nucleotides in the form of Adeno and inverse transcriptase

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(RT). The type of forecast will determine whether the base edit is performed using external agents as currently done or in vitro synthesis of the correct small interfering RNA (SiRNA). Once diagnosed, a potential numerical value would predict mathematically how to approach the treatment of gene expression performed by COX-Prostaglandin Synthase  $\frac{2}{2}$  (PGS2). The body's willingness to turn on interferons could encourage other agents such as specific adaptors to enable performance of base editing on ourselves [4]. Genomics is a branch of genetics that studies genome sequences to make predictions about phenotypes phenomena of genome function, phenotypes and population structure given genetics data of an individual. We want wider assurance given earth's diverse phenotypes and population allele frequencies. Can we trust the source of genetic information given Privacy, Bias, Increasing Cost of Genetic Testing and Sharing with Flawed Data are in place? Assuming they are met, we rely on the interpretation of genetics to solve the right genetic problem in the form of Base editing therapy, gene expression; and polymorphism. Base editing therapies involve in-vivo genome editing using CRISPRassociated System Protein M1 (CasM1) and RNA-guided reverse transcriptase. Editing takes place in the single-nucleotide and oligonucleotide gaps to restore protein function in Prostaglandin synthesis. Other researchers are exploring genome editing targeting carriers like Adeno-associated vectors (AAVs). Expression problems could arise if the genetic problem of protein function was only activated. Individual studies requiring meta-analyses for accurate expressions have generated statistical and computational problems. However, suppose we take the predicted validity of gene expression for granted, we can ask the AI motif problem of "how support and inference to further improved therapies models are induced (supported)?  $\lceil 1, 5 \rceil$ .

# ETHICAL PRINCIPLES IN GENOME EDITING

Ethical principles for considering when and how to implement genome editing largely center on how to responsibly balance the incentive for scientific inquiry (which could potentially lead to important health interventions) with established norms, values, and ethical considerations for respectful engagement where groups and individuals may be affected by the research, its applications, and their results. These considerations outline how and when genome editing and other connected and convergent technologies should ethically enhance, rather than harm, the well-being of populations, cultures, and environments. Although there are multiple guiding documents and valuable frameworks that are intended to apply similarly to many ethical and normative issues relevant to genome editing, four are specific to genetic research due to their deep institutional support, public credibility, and ability to provide actual norms and values [6]. First, the US National Academies of Sciences, Engineering, and Medicine guidelines have established principles to shape the design and development of research to better serve the central goals of genome editing. These guidelines were expanded to a second and separate set of ethical principles specific to human genome editing, which warns against germline editing attempted without broad societal consensus. Both sets of guidelines hold forward-looking principles in "establishing a robust and apparent governance framework in order to address a number of moral, ethical, and societal issues regarding human germline editing, research involving human germline and somatic cell gene editing, and clinical applications" and to create "smart and useful public and professional audience education to promote understanding and engagement" regarding the research. Although they offer strong governance and communication foundational principles for nearly all genome editing and other gene-specific research, the goals exclusively focus on achieving the benefits of altering the genetics of organisms, regardless of larger consequences that could arise from the research  $\lceil 5 \rceil$ .

# AUTONOMY AND INFORMED CONSENT

In the context of AI-driven genome editing, it is important to reflect on the meaning of the concept of "autonomy". Information regarding gene variant carriers may need to be treated with particular consideration. Gene variant carriers may need privacy safeguards that are more stringent than those offered under existing frameworks. In particular, when it comes to preventative measures, gene variant carriers will need to be better informed about how they can make use of these measures. Realizing the right to privacy, the right to equal protection under the law, and other relevant rights of gene variant carriers living in conflict or post-conflict situations places additional burdens on database developers. It is crucial to consider and engage with the roles of both victims and perpetrators of atrocities in these post-conflict justice processes. Responsible data sharing is a key aspect of such engagement [6]. Currently, informed consent is widely recognized as a key foundation of research on humans and is a major tool in bioethics for the protection of human rights and human dignity. The detailed methodologies for achieving informed consent are still under consideration and debate in the context of research with human subjects.

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Cases in which obtaining informed consent is projected to be unfeasible often involve large numbers of participants. The core issue is whether an AI method could understand the concept of "consent". Is it possible for an AI-driven database to extract only the required information, with all other content being erased? Researchers should consider the answers to such questions, bearing in mind current models of informed consent. The development of AI could conceivably embolden large research projects into the clinical testing of data-driven preventative measures based on non-disclosed data obtained through techniques such as federated learning or secure multiparty computation techniques [4].

#### **REGULATORY FRAMEWORKS**

The international regulatory frameworks related to human genome editing are multilayered and complex. A recent review discusses regulation and policy guidance of germline genome editing globally. The present review does not describe each country's unique national architectural framework in detail because such an exercise is more suited to a parallel paper. However, below, we summarize existing international regulatory frameworks or guidance that is particularly relevant to potential human germline genome editing applications. This framework includes the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (Biological and Medicine Convention; Oviedo Convention), Universal (UNESCO) Declaration on the Human Genome and Human Rights, Cartagena Protocol on Biosafety, International Declaration on Human Genetic Data, Food and Agriculture Organization (FAO; Code for the Use of Antibiotics in Agriculture), World Health Organization (WHO), International Convention for the Protection of New Varieties of Plants (UPOV), International Treaty on Plant Genetic Resources for Food and Agriculture, Convention on Biological Diversity (CBD), Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters [1, 5]. It is important to note that these international frameworks or guidance may provide a starting point, but they do not specifically address ethical and institutional mechanisms to genuinely and effectively address AI-driven genome editing. AI-driven genome editing may have specific ethical, regulatory, and transparency challenges that members of these multilateral governance organizations and biomedical researchers need to consider to minimize the risks as they identify feasible pathways to translate AI-driven genome-editing advances into therapies that improve public health  $\lceil 5 \rceil$ .

# CURRENT REGULATIONS IN GENOME EDITING

As a result of scientific breakthroughs and the potential for misuse, genome editing activities are currently highly regulated. Scientific research and therapeutic applications are the primary areas of focus in the regulation of genome editing. Although regulation/law in the area of science corresponds to public attitudes, it is clear that ensuring the uncontrollability of the individual who will reflect on society or have leadership roles that represent the masses is equally important in this area. Therefore, no matter how advanced it is, positive science is not sufficient to decide to proceed in such sensitive subjects [7, 8]. Within the scope of curative genome editing, the discussion is focused on Heritable Germline Genome Editing. The moratorium calling for the restriction of genome editing on human embryos was initiated by Edwards et al. in 2015 in the first place and in 2018 too by Lander et al. and Reinberg et al., and their proposal has been adopted by the scientific community, and more than 180 countries have proposed a ban on the research [4]. New laws and regulations particular to this technology (CRISPR) have not yet been elaborated, and existing ones are focused on genome editing on somatic cells. Therefore, it is of utmost importance in the field of considerations to determine the laws not only to prevent its misuse as a destructive warfare tool but also to make ethical use of potential benefits widely available to the public considering future employment [7]. In response to the recent CRISPR rapprochement into the sanctuary of the human gene pool through a subtle amendment to the regulations established by the Chinese Ministry of Health in 2003 (Statement on Gene Editing in Human Embryos), it is asserted that new regulations and ethical underpinnings are required, which means that there is an urgent need to evolve into a comprehensive, clearly defined standard to distinguish the roads between regulatory and legal shades [9]. At the time of the meeting of the Alliance for MacBook Zo in December 2015, the coordination of the efforts was offered, but no progress has yet been achieved. A committee including numerous organizations and individuals believes that research on the reduction of the technical and social inabilities of the Heritable Germline Genome Editing plasmid must be led open and transparent, ensuring that it is used for beneficial purposes  $\lceil 7 \rceil$ .

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#### SOCIAL IMPLICATIONS

The societal impacts of creating heritable changes to the genome raise a number of different challenges. Not only is the possible need for direct, global regulation problematic, but the role of states, international agencies, and private corporations in such regulation is also a source of contention. It is not simply conditions of scarcity and the political-economic structure of society that determine the 'delivery' of genome editing, but also the contested constitution of social processes, 'value', and human identity that is being proposed with the deployment of this technology [1, 7]. If the risk of creating social, health, and environmental damage was slight, then the whole question of who has the power and legitimacy to make authoritative decisions about genome editing is to avoid creating irremediable damage through the creation of 'evidence'. The intentions behind actions as to what is best for all humanity are always uncertain and under debate, but are these intentions informed by both democratic consent and national and international law? With the prospect of AI-driven, heritable judicial decisions in the offing, we need to take heed of the disquiet and societal resistance to the creation of socially disembedded and directionless forces [8].

# EQUITY AND ACCESS TO GENOME EDITING TECHNOLOGIES

Genome editing technologies have rapidly developed, accelerating the pace of research in many scientific fields. Moreover, at a global level, the practical applications of genome editing technologies in biotechnology, especially in humans, animals, plants, and microorganisms, are also expanding. In realizing practical applications, AI has recently made remarkable progress in genome editing technologies. However, in fact, biotechnology in recent years has led to increasingly diverse ethical, legal, and moral issues, and genome editing technologies are no exception. Therefore, it is necessary not only to pay attention to technological progress in genome editing but also to widely and deeply debate related issues. In this study, some of the ethical implications of AI-driven genome editing that pose challenges to society are considered. Especially in the analysis of ethical implications, reference to AI and genome editing is actively made [10].

EQUITY AND ACCESS то GENOME EDITING **TECHNOLOGIES** One possible negative consequence of genome editing is that it may exacerbate social or income disparities, leading to inequities. If genome editing technologies are used to eliminate genetic disease, then there will be a difference in the distribution of people, leading to a society that is different from the previous society. That is, parents with genetic abnormalities who must bear a child who might be expected to suffer and/or cause hardship and expense to their society have used genetic embryo modification of gene-edited child birth to solve this serious problem. There is an unfair expectation of inequality in promoting AI gene-editing technology for income disparities, even when it comes to perfect, desired, and overall superior genes. The one approach uses a voluntary incentive that makes gene-edited people reluctant to conceive a child when their children have a better gene. From an economic standpoint, the government provides direct incentives to the gene-edited individuals and their future descendants and provides both artificial and affordable future technology. It can also compensate those who do not intend to survive genetic illness  $\lceil 11 \rceil$ .

# FUTURE DIRECTIONS AND RECOMMENDATIONS

Addressing the above complexities and ambiguities of AI-driven tools for genome editing requires multidirectional efforts that can support the alignment of AI-driven tool research with ethical and professional needs. AI-driven tools, in most cases, operate as a sequence of problem analysis to guide rational rules for problem-solving. As such, conversations focusedly targeted at major and medium ethical and legal considerations that together construct a solid genome-planning goal and choice space can indicate to which peculiar setup parameters to tune up a parser for genome planning. These conversations, which have many options for topic organization—for instance, consider genome planning process models and best professional practices by genomic healthcare professionals—aim at charting an agenda that brings precision into our expectations, desired goals, preferred genome results, and genome-level questions that setups for genome planning aim to respond in actual expert practice [12]. Considering professional, public and social interests, current global experiments for regulation of AI in healthcare services, and advances in the practice of genome editing, AI-driven tools may not be seen simply and cold-bloodedly as design solutions that aim towards efficient business performance. We advise that developers must consider AI-driven tools for genome-based preliminary diagnostics in the broader context of genome editing and enhancement advance so that in the short term, these tools contribute

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towards developing concrete arguments in support and grounding of state and state-like current efforts in regulating agents. Proper conversations and integration of these current efforts are necessary to exhibit how product design responds to and supports the advancement of scientific and cognitive inquiry more broadly [12, 13, 11].

#### CONCLUSION

AI-driven genome editing holds tremendous promise for advancing medical science and addressing genetic diseases. However, the ethical considerations surrounding its use are complex and multifaceted. Ensuring responsible application requires a careful balance between scientific innovation and ethical standards. Robust regulatory frameworks, informed consent protocols, and equitable access to these technologies are essential to prevent misuse and to promote trust and inclusivity. As we move forward, continuous dialogue among scientists, ethicists, policymakers, and the public will be vital in shaping the future of AI-driven genome editing in a manner that benefits all of humanity.

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