GENE EDITING: OPERATING WITHIN THE PRECINCTS OF THE LAW AND ETHICS

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ABSTRACT
Gene editing is the alteration of the genetic material of a living organism by inserting, replacing, or deleting a DNA sequence, typically to improve some characteristic of crop or farm animals or correct a genetic disorder. CRISPR, a biological system for altering DNA was discovered in 2012 by Jennifer Doudna and Emmanuella Charpentier. This groundbreaking discovery of CRISPR-CAS9 in 2012 earned these two researchers the Nobel Prize in Chemistry in 2020.CRISPR-CAS9 is preferred to other gene editing tools like Zinc finger nucleases, and TALENS because it has precise and site–specific gene editing capabilities. It is also relatively cheap and easy to use\. CRISPR/CAS9 is so efficient in cutting and adding genes that many researchers across the globe have adopted it. A program organized by the faculty of Law University of Ibadan and the WELLCOME TRUST UK ''An International Workshop on Genome Editing" on the 17th and 18th of April,2023 further crystalised the serious legal implication of gene editing. The announcement of gene-edited babies by a Chinese Scientist, He Jiankui sparked widespread controversy and condemnation from the global scientific community and bioethicists. Many raised concerns about the ethical implications of such an experiment, as well as the potential unknown risks and long-term consequences for the children involved. Bioethicists, Lawyers, Doctors, Geneticists, Animal Scientists, Botanists, Crop Scientists, Veterinarians, policymakers and many other stakeholders have to bring their little bits to the table to ensure that humanity maximally harnesses the great benefits accruable from Gene editing,
Keywords: Gene editing., CRISPR-CAS9., TALENS., Zinc Finger Nucleases

INTRODUCTION

In Traditional Animal Breeding (TAB), animals were selected for breeding purposes based on phenotypic observations. Traits that manifest later in life, traits that have a low heritability (h^2), and traits that are limited to a sex (sex limited traits) are most difficult to improve. A method called the BEST LINEAR UNBIASED PREDICTION (BLUP) combined individual records and those of relatives to obtain the ESTIMATED BREEDING VALUE (EBV) to improve the prediction of Performance. But TAB was slow and expensive. Molecular Genetics therefore provides a marked advancement over TAB.

Different definitions of gene editing and relevant synonyms

Gene editing is the alteration of the genetic material of a living organism by inserting, replacing, or deleting a DNA sequence, typically to improve some characteristic of a crop or farm animal or correct a genetic disorder **(**Smith and Walters,. 2020., National Academies of Sciences, Engineering, and Medicine. 2016.,).

Genome editing is a method that lets scientists change the DNA of many organisms, including plants, bacteria, and animals. Editing DNA can lead to changes in physical traits, like eye colour, disease susceptibility and their likes. **(**Doudna and Charpentier, 2014; Gaudelli, *et al.* 2017).

Synonyms for Gene editing

Several terms are used to describe genetically engineered animals: genetically modified, genetically altered, genetically manipulated, transgenic, and biotechnology-derived, amongst others. In the early stages of genetic engineering, the primary technology used was transgenesis, literally meaning the transfer of genetic material from one organism to another. However, with advances in the field, new

technology emerged that did not necessarily require transgenesis: recent applications allow for the creation of genetically engineered animals via the deletion of genes, or the manipulation of genes already present. To reflect this progress and to include those animals that are not strictly transgenic, the umbrella term "genetically engineered" has been adopted into the guidelines developed by the Canadian Council on Animal Care (CCAC). The CCAC defines a genetically engineered animal as "an animal that has had a change in its nuclear or mitochondrial DNA (addition, deletion, or substitution of some part of the animal's genetic material or insertion of foreign DNA) achieved through a deliberate human technological intervention." Those animals that have undergone induced mutations (for example, by chemicals or radiation — as distinct from spontaneous mutations that naturally occur in populations) and cloned animals are also considered to be genetically engineered due to the direct intervention and planning involved in creation of these animals.

Gene editing is the alteration of the genetic material of a living organism to improve disease résistance and up some production traits. Clustered Randomly Interspersed Short Palindromic Repeats (CRISPR) is a biological system for altering DNA.It was discovered in 2012 by Jennifer Duodena and Emmanuella talensCharpentier. This groundbreaking discovery of CRISPR-CAS9 in 2012 earned these two researchers the Nobel Prize in Chemistry in 2020.CRISPR-CAS9 is preferred to other gene editing tools like such as Zinc-finger nucleases, TALENs because it has precise and site–specific gene editing capabilities. It is also relatively cheap and easy to use. CRISPR/CAS9 is so efficient in cutting and adding genes that many researchers across the globe have adopted it.Gene editing has to be approached with caution as there is THE REAL FEAR OF UNINTENDED EFFEECTS. Researchers in China edited genes in a non-viable human embryo to try to treat an inherited blood disease. They ended up with a lot of unintended potentially dangerous changes.

The Spectacular CRISPR Gene-Editing Tool

The CRISPR gene-editing tool has been making headlines for the last 10 years, since scientists showed it could be used to easily alter the genome of a living organism. Gene editing is the alteration of the genetic material of a living organism to improve disease résistance. Clustered Randomly Interspersed Short Palindromic Repeats (CRISPR). CRISPR, a biological system for altering DNA was discovered in 2012 by Jennifer Doudna and Emmanuella Charpentier. This groundbreaking discovery of CRISPR-CAS9 in 2012 earned these two researchers the Nobel Prize in Chemistry in 2020.CRISPR-CAS9 is preferred to other gene editing tools like Zinc finger nucleases, and TALENS because it has precise and site–specific gene editing capabilities. It is also relatively cheap and easy to use\. CRISPR/CAS9 is so efficient in cutting and adding genes that many researchers across the globe have adopted it.

Gene editing and the law: On the second week of March,2023, the lead author got a WhatsApp message from a friend. It read: 'FACULTY OF LAW, UNIVERSITY OF IBADAN AND WELLCOME TRUST, UK presents AN INTERNATIONALWORKSHOP ON GENOME EDITING IN NIGERIA.17th and 18th April, 2023'. I was so excited… then I began to wonder,' why the Faculty of Law? Why not the College of Medicine? or Zoology? or Microbiology? or Veterinary medicine? or Animal Science? Why Law? 'Then my attention was drawn to the fact that Gene Editing has serious ethical and legal implications. A Chinese scientist named He Jiankui, who claimed to have edited the genes of embryos resulting in the birth of twin girls in November 2018, made headlines worldwide for his experiment which involved using CRISPR-Cas9 gene-editing technology to modify the embryos' DNA in an attempt to make them resistant to HIV.

Gene editing and ethical concerns: The announcement of the gene-edited babies sparked widespread controversy and condemnation from the global scientific community and bioethicists. Many raised concerns about the ethical implications of such an experiment, as well as the potential unknown risks and long-term consequences for the children involved. The consensus among the scientific community was that the experiment was premature, ethically problematic, and potentially dangerous. In the aftermath of the announcement, He Jiankui faced significant backlash and was widely criticized for conducting the experiment without proper ethical oversight and transparency. He was subsequently investigated by Chinese authorities, and in December 2019, he was sentenced to three years in prison and fined for "illegal medical practice". He Jiankui has served out his term and has since been released. Beyond the advantages-better health, more meat, eggs and better flavour, we need to look at the legal and ethical implications of Gene/Genome editing.

Gene editing, particularly using techniques such as CRISPR-Cas9, has the potential to revolutionize medicine and agriculture. However, it also raises important ethical considerations that need to be carefully addressed. Here are some of the key ethical aspects of gene editing:

1. Safety: Gene editing techniques are still relatively new, and there is a need to ensure the safety and long-term effects of altering the genetic makeup of organisms. Thorough research and rigorous testing are essential to minimize potential risks and unintended consequences.
2. Informed Consent: In the context of human gene editing, obtaining informed consent is crucial. It involves ensuring that individuals or their legal guardians fully understand the purpose, risks, benefits, and potential limitations of the gene editing procedure before giving consent. Special attention should be given to vulnerable populations, such as children or those with limited decision-making capacity.
3. Germline Editing: Germline editing involves modifying the genetic material of embryos or reproductive cells, potentially resulting in heritable changes that can be passed on to future generations. This raises significant ethical concerns, as it raises questions about the limits of human intervention in the gene pool and the potential for unintended consequences or the creation of "designer babies." There is ongoing debate about whether germline editing should be allowed, and if so, under what circumstances and with what limitations.
4. Equity and Access: Gene editing technologies could exacerbate existing inequalities in healthcare and access to resources. Ensuring equitable distribution of gene therapies and addressing concerns of accessibility, affordability, and availability is crucial to prevent further disparities in healthcare outcomes.
5. Off-Target Effects and Unintended Consequences: Gene editing techniques may not always be precise and can result in unintended changes in the genome. The potential risks associated with off-target effects need to be carefully assessed to minimize any adverse impacts on the individual or the environment.
6. Enhancement vs. Therapy: Gene editing can be used for therapeutic purposes to treat genetic disorders or diseases, but it also opens the possibility of enhancing certain traits beyond what is considered medically necessary. This raises ethical questions about the boundaries of gene editing and the potential for creating an "enhancement divide" in society.
7. Environmental Impact: Gene editing techniques can be used in agriculture to modify crops and livestock. While this has the potential to increase yields, improve nutrition, and reduce the use of pesticides, it also raises concerns about the impact on biodiversity, ecosystem stability, and the unintended spread of genetically modified organisms in the environment.
8. Long-term Consequences and Unknown Risks: Gene editing is a rapidly advancing field, and there may be long-term consequences or unknown risks associated with manipulating the genetic code. A cautious approach and ongoing monitoring and evaluation of the technology's effects are necessary to address any potential adverse outcomes.
9. International Cooperation and Regulation: Gene editing technologies transcend national boundaries, making it essential to establish international guidelines, standards, and regulations to ensure responsible and ethical use. Collaboration among scientists, policymakers, and stakeholders from different countries is crucial to navigate the ethical complexities and ensure that gene editing is used for the benefit of all.

Gene editing and its application in medicine and livestock production

Although gene editing and more specifically the CRISPR technology was met with great expectations for genetic improvements in animals, a few challenges are still unresolved and are under constant research and development. For instance, many of the economically relevant traits for animal production are controlled by many genes with small effects (polygenic traits). For these traits, editing many loci would be required to make significant improvements, which adds a lot of complexity for the current technologies. Another challenge for further development, and deployment of this technology has been on the regulatory side, in which legislation for the use of gene edited animals for food production is still under development, and many regulatory aspects are not clear. These have been largely addressed on case-by-case basis, with recent approvals for Atlantic Salmon (fast growing), swine (hypoallergenic) and beef cattle (slick coat) being granted for specific use cases.

Other examples of applications of gene editing are the coat color change, and creation of polled animals in cattle, which target improvements on environmental adaptability and animal welfare. In swine, researchers have been working on developing pigs that are resistant to the Porcine Reproductive and Respiratory Syndrome (PRRS) which could lead to a great health and economic benefits for the swine industry. Researchers have tinkered with the thought of the potential use of genetically modified pigs as organ donors for transplantation into humans (Logan, and Sharma 1996., Rudmann and Durham,1999)**.** These are a few examples of how gene editing could help improve disease resistance, well-being and climate adaptation traits for many livestock and aquaculture species in the future. (Downloaded from https://academic.oup.com/jas/article/101/Supplement_1/43/7151488 by guest on 10 February 2024)

Conclusion

Bioethicists, Lawyers, Doctors, Geneticists, Animal Scientists, Botanists, Crop Scientists, Veterinarians, policymakers and many other stakeholders have to bring their little bits to the table to ensure that humanity maximally harnesses the great benefits accruable from Gene editing, bearing in mind the limitations imposed by law and ethics in different climes and regions. Further refinements of the technology, the development of policies and legislation, and strategies for deployment in commercial applications will continue to be key aspects to guide a safe and responsible use of gene editing in livestock production.

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