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Genome Editing Technologies: Ethical and Regulation Challenges for Africa

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Abstract: Human germline modification, using Crisp Cas-9 technology, increases the chances for scientists to seize control of our genes and redirect our evolutionary futures, which can lead to production of a morally bifurcated world of humans. Confronted with the reality of tailor-designing humans to ultimately tailor-make a human person and of remaking humanity, many scientists advocate for a ban or moratorium to evaluate the benefits and risks. While others counter that we need to embrace the uncertainties and let science move on. This work, critically examines the ethically contentious issues of editing DNA of healthy human embryos and maps out the regulatory challenges accompanying the futuristic development of genome editing technologies in Africa. It explores the range of mechanisms that have been adopted for regulation, oversight and mediation of public concerns. The absence of robust oversight and ethical control mechanisms to prevent technologies from being misused is a serious challenge for Africans to develop regulatory safeguards. There is still a huge lack of study to establish evidence if gene editing technologies would be used to foster the eugenic agenda of the gene rich of the West over the gene poor of Africa, or promote the common good. Work further identifies the need for African governments to formulate new guidelines for genome editing technologies and build appropriate regulatory structures to identify, anticipate and respond to public concerns on embryo gene editing for reproduction.

Keywords: Germline Modification, Genetic Engineering, CRISPR-Cas9, Gene Editing, Designer Babies, Enhancement, Ethics, Regulation

1. Background

Recent development in genome editing technologies, such as Crispr Cas-9 (clustered regularly interspaced short palindromic repeats), will change the landscape of biomedical research radically as it offers great therapeutic possibilities, including establishing disease models, correcting defective genetic mutations, and treating diseases, and potentials for scientific research. Scientists now have the tools to study the genome of humans, for re-engineering human nature and to genetically manipulate the human germline (gametes and embryos) and for engineering the genome in diverse organisms. This genome editing tool has improved our ability tremendously with respect to exploring the pathogenesis of diseases and correcting disease mutations, as well as phenotypes [31].

Regardless of where medicine is practiced, genome editing technologies are inexorably changing our understanding of the biology of nearly all medical conditions. The technology has applications in almost every field of human activity, which is important to our well-being and way of life, including medicine, industry and agriculture. There is the perceived utility of reproductive medicine for treating intractable infertility, the prevention of genetic disease in offspring and serious cases of life-threatening conditions, where no alternative medicine is available. Genome editing technology can facilitate topics of basic research involving: research to understand and improve the technique of genome editing itself on the different types of target cells which can later be used to modify the germline; genome editing used as a tool to address fundamental questions of developmental biology: altering developmental genes with CRISPR/Cas9 could help to reveal their functions [44].

CRISPR/Cas9 opens unprecedented possibilities for therapy and has enabled a new paradigm in which the sequence of the human genome can be precisely manipulated to achieve a therapeutic effect. This includes the correction of

mutations that cause disease, the addition of therapeutic genes to specific sites in the genome, and the removal of deleterious genes or genome sequences [29]. However, many technical challenges, significant ethical and bio-safety concerns still need to be overcome in order to achieve adequate efficiency and precision of the technology in human embryos. Despite the perceived utility, the new innovations are irreversibly transforming our various conceptions of life and this challenge us to revise our very definition of what it means to be human. In germline editing, the new gene would be passed to future generations. This could change the genetic makeup of humans, in possibly unpredictable ways or would change human nature fundamentally. As such, a critical challenge is to know whether the changes would better our collective well-being or create a morally distorted version of human beings.

Genome editing technologies force us to reconsider questions of identity, personhood and responsibility, and the long-term consequences of altering human nature and capabilities. The development also shapes the legal, social and ethical environment in which we act. As scientists, researchers and policy makers confront the ethical, social, and legal implications of these revolutionary tools for changing DNA, people are having mixed, and apparently not firm views on emerging gene editing techniques. There is increasing awareness that some applications are controversial like human germline modification which would alter the trajectory of human evolution. The new possibilities of irreversible transformation of the human gene pool, nature of human species and society. This raises serious questions and intense moral debates on the future of gene editing in humans, including gene editing on human embryos and germline cells. Genome editing in human embryos using current technologies could have unpredictable effects on future generations and future generations cannot give consent to have their genome altered. It is difficult to evaluate the benefits, risks and off-target effects, and the unforeseen or unintended consequences of modifying the germline.

How far will we go in our efforts to engineer humans? Would gene editing technology fix only the sick, create serious risks, or make changes that future generations could inherit? What about subsequent generations? Within the context of Africa, genome editing evokes many unanswered questions in the ethics platform, the need for harmonization, regulation, monitoring, auditing and a blue print for ethico-legal laws that governs researchers and stakeholders. What regulatory structures or mechanisms are in place to ensure that technologies are not misused? What oversight frameworks are required to ensure the effective use, safety, permissibility and acceptability of germline modification? This work is designed to enhance the regulatory process and decision-making on the cross-cutting ethical issues of genome editing technologies that would irreversibly transform the human gene pool and irrevocably reshape our humanity. It seeks to understand the possible impact of CRISR/Cas9 technology on human reproduction from the ethical point of view.

As policy-makers and judiciaries in many countries are making serious decisions, work identifies the need for a moral compass to guide African governments in decision-making on genome editing technologies. Further, it raises awareness on the need for Africans to identify and define ethical questions, and promote scientific and public discussions on human genetic modification. New ethical guidelines for monitoring development and applying the technology into clinical settings with controllable safety must be established. This becomes the forward-thinking move for establishing prospective guidelines to avoid abuses of germline genome editing. African governments need to draft appropriate regulatory structures and oversight institutions to regulate embryo gene editing for research versus reproduction (implantation of a gene edited human embryo in a womb).

2. Human Gene Editing and Regulatory Challenges

Incrementally, genome editing technologies are improving human health and well-being, and alleviating the burden of diseases around the globe and advancing research that helps to treat complicated inheritable disorders and life threatening diseases. Scientists have outlined many areas that could lead to treatment including: prevention of inheritable genetic diseases in offspring of at-risk parents, correction of infertility genes in the sperm or oocytes of parents, research for advancement in assisted reproduction technologies and pre-implantation genetic diagnosis. Despite the therapeutic possibilities, the technologies create problems which pose challenges to all of us as we all make decisions on birth and issues on beginning of life, death and the life in between. They harbor unknown risks to human health and well-being, and have implications for our individual and common humanity. We are confronted with the case for rapid use of gene editing technology, the rise of the platform economy, the issue of rethinking society's active orientation, science driven by policy and the challenges of strictly regulating germline engineering research.

Recently, international conferences are organized to examine the scientific underpinnings, clinical, ethical, legal and social implications of the use of human genome editing technologies such as Crispr-Cas9 in biomedical research and medicine. The use of Crisp-Cas9 technology for germline modification of human embryos is creating challenges for existing legal frameworks and for responsible use in the world. Regardless of what is done in the world, germline gene editing for reproductive purposes will be done somewhere. But genome editing and the technology are not easily accommodated by current laws within individual jurisdictions, nor under wide regulatory instruments and under international law. And as we gain more knowledge on the effects of genes on human health through Crispr-Cas9, the prospect of a bright future free from the sufferings of genetic disease could be contrasted starkly with darker fears

of eugenics. Despite their tremendous promise to improve our lives, they also present novel and sometimes unsettling prospects.

The technology will challenge ethical and legal conceptions of responsibility and its use in clinical settings will require new approaches of regulation. With the expectancy of making germline gene correction feasible in clinical setting, the development of ethical and regulatory frameworks to ensure safe and effective use is an increasingly important consideration. Further, with the development of CRISPR-Cas9, which can precisely make very specific, targeted changes to any living organism's genetic structure, experts proposed a worldwide moratorium on altering the genome to produce changes that could be passed on to future generations. Human germline modification has for many years been widely considered off-limits, for safety, ethical and social reasons. There seem to be general agreement that human germline gene modification should be forbidden due to the serious and unquantifiable safety concerns, unprecedented informed consent, challenges to human dignity, and the potential for permanent negative impact on future generations, including its abuse for eugenics or enhancement (the parental pursuit of specific traits for non-medical reasons) [1].

Prior to the advent of CRISP-Cas9, earlier techniques for germline genetic modification were too laborious, inefficient, imprecise, expensive and impractical to justify their use in human beings. The recent possibilities and facility with which such modifications can now be accomplished using CRISPR-Cas9 has made discussion of the issues more urgent. The Asilomar conference of 1975 instigated a moratorium on the genetic modification of humans – germline modification. The risks of recombinant DNA, which radically transformed the economic and social practices of biotechnology in the mid-1970s, seem a poor model for governing newly emerging gene-editing technologies. But with CRISPR-Cas9 and new possibilities of application and direct access to the source code of life, the international regulatory landscape for the modification of human cells is challenged. Although CRISPR-Cas9 is transforming our ability to modify, manipulate, and visualize the human genome, which greatly advances both biological research and therapeutics development.

Scientists can now investigate the function of particular genes and design new therapies, including gene therapy based on gene correction. However, the tool conjures everything anyone has ever worried they would—designer babies, invasive mutants, species-specific bio-weapons, and a dozen other apocalyptic sci-fi tropes. Without guidelines on the ethics of gene editing, scientists are now crossing a controversial legal and ethical line to tailor-make a human being. The consensus holds that genetic-engineering tools may be applied, with appropriate care and safeguards, to treat an individual's medical condition, but should not be used to modify gametes or early embryos and so manipulate the characteristics of future children [10]. Attempts to gestate a gene-edited embryo and the procedure are still illegal and banned in most of the world. Implantation of a gene-edited human embryo in a womb is prohibited. This raises the question if human germline research should be suspended and under which conditions could it proceed?

Historical debates culminating to the present ethical and regulatory control controversy, grouped critiques on two different categories. Arguments for and against genetic modification was categorized as consequentialist and non-consequentialist. Consequentialist argument focuses on the possibilities for improving the human condition, through the elimination of deleterious characteristics or mutations. It asserts that the negative consequences of genetic modification far outweigh any benefits that may occur. These may include harms to children and to future generations; loss of biological or cultural diversity; economic costs; and the degradation of social values such as acceptance of disabled people, respect for the value of human life, and equality of opportunity. Non-consequentialist arguments claim that there is something *inherently* wrong with genetic modification of human beings: genetic modification would still be wrong even if the good consequences of modification outweighed the bad [34].

Today, many countries in the Western world are addressing the ethical challenges and dilemmas in forms of regulation, guidelines, legislations and national laws. But African countries are lagging behind in addressing the issues raised by genome editing technologies and their onward development into medicine for preventing genetic diseases and the risks of genome editing. Genome editing is experiencing extensive problems ranging from poor regulation: lack of stringent regulatory laws, policies and guidelines for scientific and ethical research; the inexistence of adequate safeguards and structures to protect the dignity and rights of vulnerable populations. Absence of oversight mechanisms: institutional, procedural and professional capacities to enhance quality, safety and ethical propriety of research. Generally, African communities have limited, underdeveloped legal and regulatory structures to control genome editing research and the potential health risks. Many African countries have no relevant legislation and guidelines or enforceable rules on human germline gene modification. African states lack appropriate regulatory frameworks – ethical, legal and administrative, to confine the accomplishing of unparalleled heights of perfection, greatness and power of genome editing technologies.

Meanwhile, the technologies shall disrupt our perception of family structure, embryos and human values. Furthermore, though the recent discussions and reflection toward the international governance of gene editing are characterized as global bringing researchers, scientists and people from the public, there is a noted absence of African representation. African perception on the ethical and social issues that corrective genome editing would raise in the field of reproductive medicine are lacking. Additionally, the African continent is still highly under-developed in terms of health technologies with a critically high need for new tools to fight serious life threatening diseases. Childhood deaths due to

infectious heritable diseases have declined dramatically over the past century in most Western countries, with new developments in medical technologies and public health tools. But it is increasingly on the rise in Africa as many are not free from preventable morbidity and mortality. Africans and children are still very susceptible to deadly killer diseases.

Yet, African public opinions about germline engineering, gene editing in adults and children, what they think about changing the genetic characteristics of human embryos or germline cells, and how interested they are in taking genetic tests in the future. Their diverse opinions on the ethical, scientific and regulatory issues pertaining to germline modification are misrepresented. African views on making changes on human germline, embryo research and the act of choice where creating and altering life is concerned are lacking. There is currently no uniform, African approach to ensuring that novel clinical approaches using genome technologies are scientifically, medically and ethically sound. Additionally, with the possibility of CRISPR/Cas9 use in the context of human reproduction, to modify embryos, germline cells, and pluripotent stem cells. Little is known on the effectiveness, safety, reversibility, cost of gene editing and policy governance system, the relevant regulatory policies that is both informed by the science and guided by the concerns and values of citizens. That is, limited knowledge on regulatory apparatus that is integrated with public opinion and legislative oversight. There is paucity of knowledge on the development of ethical principles underpinning gene editing technologies and whether human germline modification for reproductive purposes can be ethically justified.

As our capacities to interfere into our genes are growing dramatically, uncertainty characterizes African capacity to assess the capabilities and consequences of genome editing technologies, their current and envisioned uses and the future regulation of germline modification. In the process of DNA replication, scientists may make errors. These errors or mutations will pass to future generations. Such errors often affect the ability of the new generations to withstand their environment. Furthermore, the mosaicism underlying human embryos as well as the off-target effect by artificial nucleases will likely hamper preimplantation genetic diagnosis prior to embryo transfer [17]. Very little knowledge exists to improve understanding on the full potential for human genetic modification or genetics of human germline and the consequences of the technology if misused. That is, the potential for editing the nuclear DNA of human gametes or embryos or germline editing. This is problematic because it deprives African societies of the freedom to decide what forms of progress are culturally and morally acceptable. Their ability to direct life, to make decisions and choices, is diminished. They lack the moral rationale for making prudent choices in critical crisis situation.

Further still, new innovations are affecting our lives in ways we are only just beginning to understand, but ethical deliberations over their implications from an African perspective are still lagging behind. There is the issue of a collapse in the communitarian moral values, policies and procedures that ought to regulate human germline modification in Africa. Additionally, scientists have constantly struggle to conquer and re-engineer the self, nature and to transform the physical and social environment. This has been accompanied by a long tendency to codify ethical positions into quasi-legal guidance and governance mechanisms. Ethical practices have been consolidated into advisory and regulatory structures. Till date, most African countries do not have appropriate regulatory oversight or a system in place for overseeing genetic engineering that potentially poses a risk to human health and environment. New technologies are always a cause for moral concern and new development creates ethical dilemmas or even tragic dilemmas that require decision-making in which someone will either benefit or lose. These decisions generally involve questions of individual life or death or situations that involve benefit or damage to the health of populations.

However, there is need to know why creating regulatory policy for germline enhancement is so important for Africa. Or is there anything inherently wrong with human germline modification? There are several critical issues for regulation of genome editing research and protection policy to ensure that adequate care is taken to avoid engendering more harm than good. There is the issue of the relationship between the interests of the subject and those of science and future generations. Another issue is to know in what manner the conduct of the researchers may be monitored or controlled by third parties. And the questions of special protection for vulnerable populations by virtue of age, medical condition, or social status. Genetic engineering is the manipulation of an organism's genome through biotechnology or modern molecular techniques.

Gene editing involves altering or disabling existing genes. "Human germline gene editing" or "human germline modification" means deliberately changing the genes passed on to children and future generations – in other words, creating genetically modified people. Changes in germ-line cells create heritable alterations and such changes would be inherited not only by the next generation but by all subsequent generations. 'Germline modification' is the creation of genetically modified children, and the introduction of genetic changes that may be inherited by future generations. Germline cells including eggs, sperm and cells of the embryo do transmit their DNA from generation to generation. Germline editing has often been described in polling questions as changing "the genes of unborn babies," "a child's genetic structure in the womb," or "a baby's genetic characteristics" [3]. Germline engineering is a very sensitive issue because it allows science to tinker with life and death, and this can affect future generations as it may alter the entire trajectory of human evolution. There is the issue of artificialisation of human life and the changing relationship between natural and artificial persons.

Scientists have long thought that genetic engineering could radically improve the human race, extending our lifespan or boosting our intelligence. While more responsible scientists

have suggested that genetic modification could be used to cure lethal genetic diseases like Huntington's, Tay-Sachs, and other deadly inherited conditions. Currently, it is directed towards changing the genetic makeup of the cells in the body of an individual and would change the genetic makeup of the next generation. Germline modification changes the genes in a sperm or egg, which impacts all future DNA of every cell in the embryo. The geneline can be subtly altered from its normal form into a novel version never seen in nature. Editing the genes of human embryos raises serious concerns including the prospect of irreversible harms to the health of future children and generations, to concerns about opening the door to new forms of social inequality, discrimination, and conflict, and new era of eugenics. Can we justify germline genome editing from the perspective of the prospective child?

Furthermore, scientists have increasingly targeted African communities for biomedical research into the etiology, especially the genetic determinants, of common diseases. As research move across national borders they pose major challenges for regulation and governance. Additionally, Africans live in a state of high exposure to certain risks and uncertainties as unregulated technologies move across borders. Combined with a reduced ability to protect or defend themselves against these risks with diminishing abilities to cope with threats and challenges of health inequality. Many African countries do not have oversight structures and explicit legislation in place permitting or forbidding genetic engineering in humans. How can we control the creation of genetically modified children, and the introduction of genetic changes that may be inherited by future generations? That is, if some researchers decide to implant viable embryos for reproduction in the womb of African women, in view to create genetically modified babies. There are no regulations which deal specifically with safety, efficacy and governance needs of gene editing and CRISPR technology in most African countries at this time. There is a critical lack of mechanisms for long-term monitoring and healthcare of children born using the procedure because it could be associated with a potential risk of health impairment.

There exist no regulations to prevent the reproductive uses of modified embryos for research or embryos implanted for reproduction. The challenging issue of regulating which embryos can be implanted (viable or non-viable), rather than which embryos can be used for research. The case of Sub-Saharan African countries is very challenging because there is a regulatory vacuum in genetic and genomic research. Even blanket bans, prohibitions or moratoria on the more menacing aspects of human genome modification, are nonexistent. There exist no normative documents (guidelines, standards, best-practices, policies, etc) or regulatory instruments (government regulations, legislation, etc.) to check the abuses or misuses of germline genome editing. A careful investigation reveals that there are limited policies that distinguish between degrees of permissiveness, that is, between legally binding legislation and regulatory and/or professional guidance or research versus clinical applications. However, a careful investigation suggests that most African countries would likely adopt ethical and regulatory guidelines on clinical trials and biomedical research that comply with universally accepted international documents including the Nuremburg Code, Helsinki Declaration and CIOMS/WHO International Ethical Guidelines. Yet, serious debates about the substantive controversial issues that they address and the relevance of these guidelines have not been discussed within the context of Africa.

Major challenges confronting research include: limited local expertise, absence or weakness of legal controls, inadequate resources due to low priority given to science and technology in Sub-Saharan Africa, and the cycle of disease and poverty. This increases the possibility for unregulated and underground or even black market use of the new technologies. Furthermore, despite the potential for abuse with gene editing and despite its historical misuse in the eugenics movements in the world, it remains unclear and uncertain how gene editing technology will be regulated in Africa, as regulatory regimes cannot anticipate the simple precision offered by CRISPR-Cas9. Though gene editing technologies raise issues that cut to the core of what it means to be human and what it means to be a just and fair society. Little attempt has been made to create an overall conceptual framework to regulate genetic technologies and unintended germline editing. African countries have not yet established the necessary legislation, institutions or infrastructures to regulate and address ethical issues in gene editing technologies such as intentional germline editing or the use of genome editing of germ cells or zygotes to correct disease-causing mutations in all cells of the person to curatively prevent these diseases from developing.

Meanwhile, technologies will influence our lives in a variety of ways, with profound effects. But no comprehensive policy framework or legal policy exists for regulating gene editing and there are no genetic services for regulating and prohibiting certain kinds of research in Africa. Due to this, it is difficult to provide systematic, comprehensive assessment of genome editing technologies and their implications for society. The challenge is for African governments to develop workable, fair and ethical guidelines that closely monitor the use of genetic technologies and regulate human genome modification. Create stronger government awareness and policies to protect against existential risk and to promote responsible research in Africa. Governments in the African region need to produce sound policies around the permissibility of conducting research on clinical applications of genome editing on early human development. They need to develop a comprehensive legal framework governing the regulation of genetic information in their various countries. Policies and approaches (restrictive to permissive) regarding human germline editing, human embryonic stem cell research, human somatic gene therapy and pre-implantation genetic diagnosis are still vaguely developed within Africa. It is still a cumbersome issue to determine whether these researches are being governed by laws (legislation) or by normative

documents and policies (regulatory).

There is need to develop guidelines and legislation that protect human subjects, the general public and environment as the inability to regulate means a lot of things go on without obstacles. This signal a need for the region to develop its own bioethics theory of intervention, protection, human rights, human development, gender studies and poverty and inequality in African populations. The need to establish institutions with frameworks that are neutral in outlook regarding assumptions about inherited genetic modification and identity issues is a necessity in Africa. The frameworks should reflect openness to the possibility of change and the welfare of the future child, reproductive autonomy and potential risks and expected benefits. Additionally, raising public awareness and promoting an open and transparent discussion of the societal, environmental and ethical implications of gene editing technologies in African societies. Develop ethical awareness within the region's scientific community by engaging the public, policymakers, and broader scientific community to actively participate in shaping the ethical discourse. There is need to develop safe and efficient mechanisms to enhance protection for potential abuses from programs that empower the wealthy and privileged to choose the genetic makeup of their children, to mishaps causing damaging mutations that could be passed from generation to generation.

In this unregulated context, there is the possibility that the technology might be used in the reproductive contexts of Africa long before there are sufficient data to support such use, and before the potential benefits and risks of harm are properly identified. Further, there are still very limited discussions on genomic research, very limited biobanking repositories, Genetic Resource Centers and infrastructures in Africa. Regional discussions and debates to assess potential benefits and harms of human genome editing for research and making decisions on the ethical acceptability or permissibility of different potential uses of human genome editing for clinical reproductive purposes are still lacking in Africa. Scientific debates to assess standards for safety, efficacy, and robust governance of the technology are nonexistent. There is still lack of an explicit African engagement in the crucial bioethics debates that evaluate the capacity of research to denature, demean, harm and poses risks to human welfare, human rights and dignity. There are currently no laws or regulations directly applicable to the use of embryos in privately funded research. Little is known about the knowledge and concerns of current and prospective export, reuse, storage, and benefit-sharing of bio-specimens. Regulatory guidance on collection, use, export, ownership and storage of bio-specimens is still non-existent.

While major segments of African societies are uninformed of this kind of research and do not know the beneficial purposes versus risks. As such, their humanity, dignity, welfare and future is at stake as they lack the knowledge, means, mechanisms and structures to restrict or control, regulate and to protect themselves from risk and harm that might emanate from technological development. Meanwhile, the ethical issues raised are as crucial for the African public to understand as the science. It is really unfortunate that innovative development creates chances and challenges for the world and the scientific community warns humanity of potential risks and possible benefits of technological breakthroughs, that our regulatory mechanisms and our society may not be prepared for. African countries are still largely unprepared for the genetic futures now in the pipeline. The fact that regulatory structures do not exist, imply that Africans cannot protect themselves from possible harm. The possibility to predict harm and regulations on risks anticipation are still underdeveloped. As such it might not be possible to know in advance what harms might arise and what measures to counter it future unknowable consequences.

The lack of regulation for genetic tests with health related problems is a critical issue for the African Union to address. Member states must now come together and balance the amazing potential against possible consequences of the powerful new tool. There is a serious need to develop a vigilance system in order to ensure that rapid advances in gene editing will not result in uncontrollable evolution or unacceptable deviation or harm. The way forward would require African governments to demonstrate political will and commitment in addressing the challenging issues in gene editing by establishing transparent and accountable bioethics expert committees to enhance ethics education and ethics expert panels, and establishing relevant legislation and guidelines. They need to develop a legal framework of principles and procedures to guide states in the formulation of their legislation, policies or other instruments to regulate the clinical application of genome editing research.

This requires developing novel approaches that promote responsible research and sustainability, and which balance innovation with safety, maintaining public trust. That is, the approach of testing public opinion, putting the issue to parliament and carefully monitoring laboratory research. Education is needed to strengthen and empower community capacity to review and monitor protocols for the collection and use of bio-specimens, guided by clear national policy on priority-setting, partnerships, review, and oversight [2]. Moreover, the prospect of irreversibly changing the human gene pool could lead to unpredictable effects which may be devastating to humanity. The value of human life and dignity of the human person is being threatened by genomic research. As CRISPR-Cas9 technology allows scientists to tailor the genetic material by adding, removing or substituting parts of the genome [33].

Further still, there is already a race to get gene edited cells into clinics around the world. A Chinese group has become the first to inject a person with cells that contain genes edited using the revolutionary CRISPR–Cas9 technique [9]. Researchers may tailor-design deadly mutations or create genetically modified "tailored" organism, which would spell an end to the human race. The nucleases used for editing genes could make mutations at locations other than those targeted, potentially causing disease. This could inadvertently target other *loci* in the genome and such unanticipated

genetic manipulations could alter biological functions in problematic ways [40]. For instance, some groups of researchers recently reported that the microinjection of CRISPR/Cas9 into tripronuclear zygotes can produce human embryos with an intentional genetic modification, but also indicated three technical problems: low efficiency of on-target gene modification, off-target mutations and the mosaicism of genetic modification in the embryos [20]; [27].

Concerns on the potential genotoxic effects of gene editing and issues of assessment of genotoxic risk of nuclease-mediated genome editing. There is no guarantee that unintended modifications created through an editing procedure would not result in a devastating long-term outcome. Currently, researchers are one step closer to tailored-made humans, but the laws in most African countries remain silent on these issues. There is little or no discussion on the ethics, avoidance of abuses of germline genome editing and the unintended consequences of these technologies. Making laws about the ethics become an absolute necessity and establishing stable, knowledge-based grounds for debating human germline modification. There is a critical need for legal regulations of genome editing technologies that promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings. Since a legal void does not help African, we need a kind of ethical institutionalization and establishment of a transparent and accessible form of ethics.

Additionally, there is the need for transformation of ethical reflections into regulations, guidelines and national laws, which enhance human flourishing. Human flourishing is a morally central aim shared by all persons by virtue of their humanity, with human dignity at its heart. It captures the idea of human capability, which includes human agency, an essential human good to be protected and promoted. The fact obtains that, health is intrinsically and instrumentally valuable; all individuals should have equal capability to be healthy [35]. As such, African communities ought to engage in discussion in order to create a set of recommendations for scientists, policymakers, and regulatory agencies on when, if ever, germline modification might be permissible. Developing appropriate regulation is a moral imperative for Africa, due to irreversibility or irreversible transformation of the human gene pool which would result to reshaping our humanity. This can also lead to devastating unpredictable outcome to our well-being. Regulatory framework should strive to address unshaped safety mechanisms, augmented risk of multigenerational side-effects, ethical hurdles regarding human embryos, as well as any equity concerns.

3. Ethical Issues of Editing the Human Genome with CRISPR-Cas9

Today, the possibility of using CRISPR-Cas9 in the context of human reproduction, to modify embryos, germline cells, and pluripotent stem cells creates serious ethical problems. Ethical concerns involve the safety of subsequent generations and the potential misuse of genome editing for human enhancement. Confronted with the challenge of trading ethics for efficiency, that is, the issue of technology cultivating moral and social progress instead of endless growth, it is imperative to investigate what makes germline modification ethically problematic? Ethical claims have the power to motivate, delineate principles, duties and responsibilities, and hold global and national actors morally responsible for achieving common goals [36]. The process of ethical analysis involves identifying relevant principles, applying them to a particular situation, and making judgments about how to weigh competing principles when it is not possible to satisfy them all [47]. Do genome editing technologies pose any risks of harm to present and future generations? Additionally, the challenge of identifying and promoting policies in Africa, and fostering practices that ensure scientific research and technological innovation are conducted in an ethically responsible manner.

The use of CRISPR-Cas9 technology to edit the genome of humans implicates a variety of ethical concerns pertaining to such values as beneficence (doing good), non-maleficence (preventing or mitigating harm), justice, equity, fidelity and trust within the fiduciary investigator/participant relationship, human dignity, and autonomy pertaining to both informed, voluntary, competent decision making and the privacy of personal information [45]. Further, there is the emergence of six new, interconnected areas of ethical consensus and emphasis for policy in genomics: governance, security, empowerment, transparency, the right not to know, and globalization [24]. These ethical concerns are issues requiring careful analysis, in order to be translated into a complex regulatory apparatus which would provide legal provisions to insulate against abuse and ethically wrongful use of such innovations. Other ethical considerations concerning germline editing include the goal of the intervention: disease curative or “genetic enhancement” and whether the change will re-create what is naturally found in human genetics or whether it will create a human genome that is not normally found in the human population, such as by using editing to add a gene into a specific genomic location [23].

Although gene editing holds the potential for correcting genetic defects associated with genetic disease, not only in patients, but theoretically in future generations as well [11]. Germline editing, raises ethical questions because the edited gene would be passed to future generations. This could change the genetic makeup of humans and could have unpredictable effects on future generations. Additionally, it raises a number of unresolved ethical concerns around germline modification, including: the risks of inaccurate editing and incomplete editing of the cells of early-stage embryos; the difficulty of predicting harmful effects that genetic changes may have under the wide range of circumstances experienced by the human population; the obligation to consider implications for both the individual and future generations who will carry the genetic alterations; the fact that, once introduced into the human population,

genetic alterations would be difficult to remove and would not remain within any single community or country; the possibility that permanent genetic 'enhancements' to subsets of the population could exacerbate social inequities or be used coercively; and, the moral and ethical considerations in purposefully altering human evolution using this technology [46].

Genetic engineering increases the potential to design, perfect, manipulate, and control human evolution. Our inner nature is penetrated to the most intimate core to facilitate it domination and with the aim of reconstructing and reinventing its reality. The most precious aspects of being human may be modified with huge unrecognized ethical implications for future generations. Research subjects would include not only embryos but also future generations. The challenge is to know, if it would irrevocably alter the nature of the human species and society. Would the creation of genetically modified children and the introduction of genetic changes be inherited by future generations? Do we have the right to make decisions about our children's genotypes? Genetic engineering assumes that we know which traits are good and which are bad. How do we know which traits to enhance or get rid of? What is good in one environment might be deleterious in another. How do we know the functions of the genes that might be changed? We are constantly finding that genes are not "for" a particular function; rather they are "used in" a particular function. If we alter a gene thinking it will only affect one function, we may find that it also disrupts another function.

Arguments on what is wrong with modifying the human germline are linked to risk of health complications; unethical use due to sanctity of the human genome: sacredness, naturalness and human dignity. The transgressions of the natural and divine laws, irremediable risks to the offspring and future generations, and the serious societal harms that eugenics and genetic enhancement (parents pursuing offspring with specific traits for social reasons) represents [16]. A crucial issue that confront Africans to make decisions on where to draw the line and what procedures to perform, policy makers shaping social practice and legislators crafting law. Researchers are increasingly taking a step closer to ultimately tailor-make a human being or to gestate a gene-edited embryo to the stage agreed as a no-go zone by the scientific community. Scientists are crossing the controversial line to engineer tailored-made humans or custom-made human beings. Many countries in the world allow gene-editing but prohibit implantation of a gene-edited human embryo into the womb. What are the oversight and controls in Africa to prevent the technology from being misused? What mechanisms are in place to oversee gene-editing proposals?

In an age where human beings increasingly gain the power to alter human nature, to determine the manner in which persons come into existence and of self-modifying freedom that knows no limit. As some persons gain the ability to efficiently manipulate evolution without the consent of future generations, to make a 'master race' or create 'designer babies' by removing undesirable traits from the gene pool. When, scientists overstep ethical boundaries in manipulating human genetics in order to improve a population, which may change the human gene pool and transform our entire being and uniqueness as both a species and as individuals. As researchers Play God, violate the sanctity of life, open a Pandora Box leading to eugenics. At this moment of great divide over whether we should ban or allow research altering the genes we pass onto our children.

There exist no major policies to oversee inheritable genetic modifications and absence of oversight of germline genetic interventions. With no major organizations to oversee research into the ethical issues of human germline engineering, it may be difficult to anticipate the foreseeable harms and undesirable outcomes of germline altering in humans. We may be undermining the genetic future of our species. Since we have virtually no ability to accurately predict or control our evolutionary changes and future. Additionally, there is the growing threat of overestimating genetic modification techniques and underestimating the repercussions of human germline enhancement. Meanwhile, inventions change the world, and the reinvented world changes us. As the developments grow faster, too complex and unpredictable for our institutions to handle, Africans need effective, accountable systems for regulating gene editing technologies that may have some beneficent uses, but could dangerously be abused. Africans are still ill-prepared and ill-equipped to make fully informed decisions as they are propelled into the new era with no plans, no control, no brakes and precautionary principle to evaluate the consequences of germline genome editing.

The responsibility for ushering in the brave new world is as undecided as the ethical and existential questions it raises. Not only are our African deliberative institutions inadequate to the task of oversight, but we fail to recognize the full ethical dimensions of technology policy. Political mechanisms for the ethical oversight of technology and research have failed to keep pace with rapid developments. How can we fulfill our great responsibility of using safely and ethically the incredible power over our heritable information? The responsibility relates to both how we modify our own genomes and the genomes of our progeny, and the genomes of the species that inhabit our planet [7]. There is an acute need for rethinking entirely the ethical discourse on germline modification in Africa, going beyond technical risk assessment to give due weight to economic, cultural, social and religious perspectives. The question arises, what should happen in Africa, where there are no laws and regulatory guidelines limiting or regulating germline editing on human beings.

Technically, for close to four decades of genetic research, much or perhaps most of what is being proposed on human germline modification may prove impossible. Modifying human zygotes and implanting them to generate humans still has insurmountable safety and ethical limitations. Consequently, genome editing cannot actually be performed with sufficient precision to permit scientists to responsibly

contemplate creating genetically modified babies, due to inaccurate editing, and off-target mutations. Many technical challenges still need to be overcome in order to achieve adequate efficiency and precision of the technology in human embryos. There is lack of evidence on the long-term safety risks associated with embryo engineering techniques and a relative scarcity of good quality human embryo research. Embryo gene editing using Crispr Cas-9 technology is still very controversial both because of inadequate evidence of safety. Additionally, the germline or heritable modifications produced raise serious social and ethical concerns. The use of the technique poses dire risks to future children and generations. But that will not stop scientists trying. Scientists are ignoring ongoing policy debates and conducting dangerous and socially fraught experiments on mothers and children.

Although evidence of safety and efficacy of the technique has not been well quantified, many scientists are using Crispr Cas-9 technology to create embryos for reproduction or implantation into womb, which is prohibited. Many scientists may escape regulation from Western countries to carry out their research in Africa without any regulatory structures. Without any control mechanism to stop, or at least *slow down, take care, beware,* it is very difficult for Africans to anticipate, prevent and protect themselves from risky research. This means greater risks, less oversight, less expertise and lesser hi-tech environment for scientists. There is also the ugly face of commercial and status incentives driving unscientific human experimentation in Africa. Even Research Ethics Committees in Africa are ill-prepared, ill-equipped and lack training in evaluation or assessment of the risks and safety of the technique. This development will soon penetrate our individual lives and direct our culture to such an extent that we can scarcely create the distance required to assess and evaluate it.

There are social concerns as society struggle to grapple with issues of protecting public health, safety and social values. The consequence is uncritical and premature acceptance of research without careful assessment of the dangers inherent. Uncritical acceptance implies Africans cannot recognize and distinguish the ethical challenges of life and death clamoring for their attention. They are simply unaware or uninformed of how huge and radically important the issues racing towards them are. And they lack adequate information to identify the risks of new research, cannot foresee potentially disastrous consequences and would remain unaware of the future dangers. Premature acceptance of risky research has harmed society and continues to pose serious threat to human health and wellbeing.

Furthermore, germline modification will transform irrevocably the overall structure of our gene pool, human nature and moral experience. They could change the self-understanding of the species in so fundamental a way that the attack on modern conceptions of law and morality might at the same time affect the inalienable normative foundations of societal integration [13]. As our human nature would be irrevocably transformed and challenged, there exist in most African countries no regulations and adequate safeguards to serve as warning from harm or prevention from exploitation. Serious considerations of the potential socio-ethical impact of gene editing technologies on the extremely vulnerable population in African communities are lacking as their views are increasingly marginalized and the public perception or expectations are left unaddressed. In this context of regulatory uncertainty Africans cannot easily identify what policies, principles, values or frameworks might provide appropriate guidance or oversight for genome editing technologies.

Meanwhile, prudence warrants that we pause and consider the long-term implications of research before it rushes headlong into changing the human condition. on formulation of ethical guidelines, regulatory laws for the development and use of gene editing technologies implies we undermine and underestimate the potential health risks and dangers research poses to lives as the lure of commercial profits continue to attract vast resources. We remain unsure of whether the beneficial uses of genome editing are adequately safe and acceptable and whether regulatory oversight appropriately balances realistic risk assessment with achievement of the anticipated benefits. Furthermore, inadequate analysis and exploration of safety issues, efficacy problems and benefit issues, and absence of legislative or regulatory bans on germline modification in many African nations. This implies that African societies would lack the knowledge to assess the biological, medical, social, and economic consequences of genetic modification. And if the medical benefits exceed the potential health risks associated with the genetic intervention and capacity to evaluate the benefits or risks of new development. This cannot allow morality or the public interest to affect the trajectory of germline engineering.

Further still, the potential clinical use of germline editing and the evaluation of efficacy and risks of gene editing in humans based on appropriate understanding and balancing of risks, potential benefits, and alternatives are serious challenge for future direction. The precautionary principle warrants a strong justification before permitting any risk-creating activity, with risk defined both in terms of known hazards and unknown possibilities. With germline editing, one cannot confidently predict all the consequences, whether of introducing deleterious traits or by losing unanticipated benefits to retaining particular alleles. The absence of means and mechanisms to predict risk and benefit, and lack of regulatory oversight increases uncertainty on the capacity to make decision on what to pursue and what not to pursue as economic interest gains upper hand with devastating consequences. Regulatory uncertainty of genome editing may undermine confidence in the technology which may stifle innovation in Africa.

In this context of conflicting ethical, scientific and policy advice, African governments have failed to create any binding policy. What principles underlying governance and potential applications for germline editing or what frameworks might provide appropriate oversight for these

technologies? What kinds of public policy strategies would African governments adopt to regulate genome editing technologies? Would they adopt *no regulations* or the *laissez-faire* approach or the default state to genetic modification, which is the libertarian position of leaving such decisions to the market place? That is, the government should not interfere with the market forces that influence procreation? Or would they adopt regulation which would consist at creating laws that directly ban germline engineering research or application. That is, government regulation of genetic modification in order to protect important values, such as social justice and the welfare of unborn children. A ban because there is something inherently wrong with genetic modification, that there are inevitable, unavoidable, and undesirable consequences associated with modifying the human genome [37].

Adopting regulation would imply that the morality of genetic modification depends on an adequate understanding and evaluation of the medical, social, economic, political, and biological consequences. Considering the immense power of genome editing technologies, it is imperative that efforts are made by scientists and African governments to understand the ramifications and to ensure that they are used in an ethically responsible way for the benefit and progress of humanity. African governments are faced with the challenge of ensuring that adequate regulations and laws on bioethics are put in place to control genetic modification in order to maximize its benefits and minimize its harms. It would be illusory for Africans to think that new technologies are somehow 'value-neutral' or 'value-free'. What we too often fail to grapple with, is that technology is value-laden from start to finish. From the innovator's intuition of a desired end to the development of the practical means of achieving that end — as well as its application, distribution, ownership and ultimate impact on society and the world at large — choices about technology are inextricably intertwined with value judgments at every stage [18].

4. Human Embryo Research and Embryo Ethics

Embryo ethics considers issues of research with the development, use and destruction of human embryos. Since the discovery of pluripotential, infinitely self-replicating stem cells, embryo research create therapeutic approaches for the treatment of debilitating, chronic and incurable life-threatening diseases such as Parkinson's disease, Alzheimer's disease, diabetes, and spinal cord injury. Despite the worthy ends of embryo research, it is highly controversial because they are derived from human pre-implantation embryos. Critics have argued that their use is wrong because it involves the destruction of human embryos; others worry that even if research on embryos is not wrong in itself, it will open the way to a slippery slope of dehumanizing practices, such as embryo farms, cloned babies, the use of fetuses for spare parts, and the commodification of human life [38]. Embryo research is morally impermissible because it involves the unjust killing of innocent human beings. Does the destruction of human embryos in research amounts to the killing of human beings?

The scope of ethical issues on embryo editing oscillates around the distinction between research and reproduction or whether there is a moral distinction between creating embryos for research purposes and creating them for reproductive ends; between therapeutic and reproductive gene editing, between gene editing for treatment and for enhancement, and for gene editing to correct inequality versus to increase inequality. Should the modified embryo used in research be implanted for reproduction? The fundamental ethical and legal problem resides in how to reconcile a Universalist understanding of human dignity, including that of the human embryo and human genome editing research. This is guided by the fact that scientific practices and technological applications are not harmful to humanity or does not encroach on human dignity. That scientific progress is put in the service of improving opportunities for human beings to express their best and most humane selves.

Any scientific activity that undermines human dignity and flourishing would be a cultural contradiction. This sensibility underlies the nearly universal condemnation of the use of human beings as mere means to scientific ends. Thus, the challenge of advancing genome editing research for alleviating serious debilitating medical conditions which is compatible with safeguarding ethical values and promotes the unconditional respect for human dignity, which in turn translates into unconditional protection of human life, including the human embryo, and the firm repudiation of any eugenic distinction between 'life worth to live' and 'life not worth to live. That is, resolving the moral problem which brings into tension two moral principles: the principle which enjoins the prevention or alleviation of suffering, and the other which enjoins us to respect the value of human life.

The central challenge is the conflict of preserving human dignity and promoting genome editing research in Africa. That is, the use or destruction of a human embryo for a 'purpose not serving its preservation'. Another major ethical concern is that of people misusing this technology to intentionally modify the genome to make "designer babies" with enhanced characteristics. Research ethics is not only about ends but also about means. Even research that achieves great good is unjustified if it comes at the price of violating fundamental human rights. Further, the microinjection of genome editing system into one cell-stage embryos requires human embryos for research use. This raises the questions if embryos are persons possessing the same inviolability as fully developed human beings, or potential persons, or divine creations, or subjects of moral 'harm', or the beginnings of human life, with intrinsic value, or organic material with no more moral standing than other body parts?

Opinions on the moral status of the human embryo are deeply trivial. Many argue that although an embryo does not currently have the characteristics of a person, it will become

a person and should be given the respect and dignity of a person. The criteria for 'personhood' are notoriously unclear; different people define what makes a person in different ways. Those who believe the embryo has equivalent moral status to a grown human person, think research involving the use or destruction of human embryos is likely to be unacceptable, or acceptable only in a limited range of circumstances. A human embryo in some jurisdictions is an entity determined by a particular point in time (e.g., Australia, Canada, Singapore) or, established by its capacity to develop into an individual or a human being (e.g., Belgium, Japan, Germany, Netherlands).

Most religions, especially the Roman Catholic, Orthodox and Conservative Protestant Churches conceive life's beginning, or *ensoulment*at conception. They believe the embryo is a unique being that will never be duplicated. Biologically, the embryo is an organism, in charge of its own integral functioning, enduring and developing over time. The embryo is not a potential human being, but an actual human being. As a human being, the embryo should be protected by human subject research regulations. It has the status of a human being from conception and no embryo research should be permitted. Judaism and Islam argue that the embryo does not have full human status before 40 days. Other Muslims believe that *ensoulment* of the embryo occurs at 120 days and research is permitted on embryos to that point. However, most scientists think a *human* embryo is indeed, human, biologically alive, and capable of development into a human being. As embryo it has no such status. That is, at that stage of human development, it does not have the characteristics which qualify it for human rights. In spite of the fact that they may have been unique, as embryos they have less uniqueness than they will have when fully grown into adults, much of whose uniqueness is not a result of genetic factors, but because of cultural influences, family, education, and individual choices.

Further still, in most Western countries, embryo research is prohibited above 14 days. Before day 14, the embryo has no central nervous system and therefore no senses. But in China, the human embryo is not regarded as human being and the moral status of embryos should be lower than that of a human life after birth. However, what is ethically problematic about embryo research is the fact that they are unable to give consent, and have no choice over the alterations inflicted upon them. Embryos cannot decide for themselves whether to undergo genome editing. The belief is sustained by the argument that embryos at this stage are simply composed of largely undifferentiated cells, lacking any form of sentience, self-awareness or self-will. Embryos are not the kinds of beings for whom consent and choice are relevant concepts. While the powerful institution of medical research seeks to further its cause through influencing public opinion, law and public policy on the virtue of destroying human embryos in medical research. African conceptions of what constitute the human embryo or its germline and the moral status of an embryo are not clearly elaborated or clearly defined.

African views on embryo policy and whether the human embryo has any intrinsic moral value and the use or destruction of embryos in research are not succinctly outlined. Their perception on the rightness or wrongness or ethical acceptability of the use of embryos for research is lacking. Does a human being begin with conception? Does a human being begin with birth? Does a human being begin after birth? When do Africans perceive the human embryo as human being and at what moment do they consider the moral status of embryos should be lower than that of a human life, before or after birth? It is evident that African attitudes about the moral and legal significance of embryos and fetuses, and about the appropriate degree of human control over its environment and its destiny, have been shaped by different histories and religious traditions distinct from others. If Africans think the answer to the above questions is obvious then the danger is we are merely reflecting uncritically the ideas of our culture and values. While Western countries make decisions on the moral status of embryo based on their traditional philosophical principles and ethical values, a difficult problematic situation will occur when Africans would want to redefine the issues according to their traditional principles and cultural values. It would be a mistake to allow others capture the advantage of designating the views, whether more or less radical, as reactionary on the one hand or hopelessly utopian on the other.

Furthermore, many are of the view that there is a duty to use genome editing quickly to eliminate serious, potentially fatal conditions. But what restrictions should be made on studies using human embryos so that the technology could not be used unthinkingly, in ways that harm patients and society, today and in the future [14]. Also, with the growing trend in the need for organs, tissues and embryonic stem cell for research and the case for rapid use of genome editing technology to save lives. And as human trials get under way, a serious problematic issue arises on the regulation of embryo research and embryo gene editing for research versus reproduction. Under what conditions and restrictions can these cells be isolated and used is presently high on the political and ethical agenda, with policies and legislation being formulated in many countries to regulate their derivation. The challenge of regulating Crispr-Cas9 technology into clinical settings and to have a well-regulated system that is able to make the distinction between research and reproduction [6]. Some researchers after castigating the stupidity of dignity claim that a truly ethical bioethics should not bog down research in red tape, moratoria, or threats of prosecution based on nebulous but sweeping principles such as 'dignity,' 'sacredness,' or 'social justice.'

Further, the view is advanced that Western countries already have ample safeguards for the safety and informed consent of patients and research subjects [32]. Acceptably, some technologically advanced countries have developed ethical and legal mechanisms (guidelines, codes and regulations) which, over time, have served to regulate, or at least try to diminish, the amount of harm posed by new technologies. However, with the unpredictability of CRISPR-

Cas9, the international regulatory landscape of genome editing is still evolving and no country in the world has stringent regulation specifically for genome editing technologies, even if most countries would not prohibit somatic gene editing, but nearly all countries prohibit germline gene editing.

Most countries advocate for a complete ban on gene editing for enhancement of human beings due to reasons of safety based on the current insufficiency of scientific understanding. Although the bans are not encoded in laws, the ruling that research on human embryos is permitted, but the transfer of modified embryos to a woman's uterus is not, has been described as a "Rubicon" for researchers in the world and medical communities. There is also the challenging issue of making a distinction between research and reproduction. That is, whether the modified embryos are used for purposes of research or implanted in the uterus for reproduction. Regulations clearly stipulate that gene manipulation on the human gamete, zygote and embryo for the purpose of reproduction should be banned. This is because existing regulations cannot take account of the current–and future–realities of genetic modification and foreseeable harms. The different consequences of human genome modification in either somatic cells or the germline, and the modification of the ecosystem through gene drives, call for different ethical and policy evaluations [28].

Many countries in the world are still facing the challenge of developing effective policies that both respect the ethical standpoint of diverse publics and enable the exploration and application of biomedical technologies. With the possibility that germline modification will be practiced in the clinical setting, prohibitive policies in the world vary across regulatory systems. The different regulatory categories include: 'legal prohibition', 'prohibition by guidelines', 'ambiguous' and 'restrictive'. Some countries ban it under law on assisted reproduction, while others ban it under gene therapy or bioethics law. Some countries appear to be ill-prepared for germ line genome editing because their relevant regulations are based on conventional genetic engineering, or because the regulations are enforced by guidelines rather than legislation [16]. Some ban any research; some allow only lab research but not pregnancies; some have no policies and unenforceable guidelines. Where legislation has been adopted either prohibiting or restricting germline interventions, it is mostly accompanied by criminal sanctions ranging from hefty imprisonment terms to fines (e.g., Australia, Belgium, Brazil, Canada, France, Germany, Israel, Netherlands, and United Kingdom) [15].

In the US, the National Institutes of Health won't fund germline research but private funding is allowed. In the NIH statement, there are some relevant prohibitions, including a prohibition against federal funds being used for the creation of human embryos for research purposes or for research in which human embryos are destroyed, a prohibition on FDA review of research in which a human embryos is created or modified to include a heritable genetic modification, and policy that the NIH Recombinant DNA Advisory Committee will not consider germline alteration proposals [42]. Germany strictly limits experimentation on human embryos, and violations can be a criminal offence. In the UK, successive parliaments have established the principle that early human embryos do not have the same legal or ethical status as born people, and that certain experiments are permissible so long as development does not exceed a certain point (usually 14 days). In the original act, the creation of hybrid embryos, the cloning of embryos and the genetic modification of embryos were prohibited. However, the 14 day legal limit is increasingly contested with opponents advancing claims that it would soon be disregarded and that society would, over the years, descend down a slippery moral slope in which limits on embryo research were insidiously slackened until it proceeded without any control.

By contrast, in China, Japan, Ireland and India, only unenforceable guidelines restrict genome editing in human embryos. In France and Australia clinical use is banned while rules in countries like Russia and Argentina are "ambiguous". Many researchers long for international guidelines that, even if not enforceable, could guide national lawmakers [26]. Although most countries prohibit germline gene editing, there is still serious inconsistency in the global regulation of human genome modification. Some of the enacted prohibitions can be rendered ineffective or inadequate in practice. This inconsistency in global regulations may have an erosive effect over time—so that a procedure accepted in one country slowly becomes the standard of care, smoothing the way for it to jump across borders.

Furthermore, regulations in many countries have not kept pace with the science. Around the world, laws and guidelines vary widely about what germline, or hereditary, research is allowed. The nerve-centered issue is the demarcation between qualified human life, life that is endowed with rights and dignity and an entitlement to constitutional protection, from mere biological life that may be utilized for purposes of research and treatment. That is defining human embryos as *bios* (qualified life) and not as *zoe* (mere biological life) [5]. Scientific understanding and precision in legal definitions of what constitutes a human embryo and/or its germline are essential to developing coherent policies. Many basic issues of right and wrong on when life begins and ends, what constitutes human dignity and how the scope of human responsibility to future generations can be defined, are still deeply contested.

Further, there is no consensus on the status of the human embryo (or even on what is an embryo), no consensus that embryos may be created for research or that they ought to be available for research. There are no legal framework that draws a line between what is permitted and what is not by allocating constitutional rights to human embryos in vitro, defining what a human embryo is, and ruling out practices that involve a violation of these rights. In addition, with global trends in research and as research moves to other locations of the world without robust regulatory safeguards and control mechanisms, how do we control harm and the potential of exploitation? How do we control if the line

between researches versus reproduction in germline genome editing in Africa would not be blurred? Scientists in China reported carrying out the first experiment using CRISPR gene editing to alter the DNA of human embryos, potentially impacting the germline. The Chinese experiments amplified concerns that new gene editing technologies which are inexpensive, accessible and precise, could be applied in humans suddenly. If in coming years future generations of Chinese children are born with far superior mental and physical abilities, would Western parent not request same for their children?

Furthermore, though the prospect of using embryonic modification clinically lies further into the future and the possibility of doing human embryonic modification is still premature, altering human genomes could create inequality and discrimination in the distant future. Although the principle is that genetic technologies must not exacerbate existing social inequalities, or create new ones. Germline modification can profoundly perturb ordinary biological function and introduce new, harmful genetic variants into the gene pool. The technology might further inequalities and bring greater harm to those on society's margins, including the disabled, minorities and other vulnerable people. If proven safe for human use, germline modification could exacerbate prejudices against the disabled and widen the gap between those who can pay for such therapy and those who cannot.

The challenging issue is the idea that in the years to come embryonic editing would not be carried out principally to develop new kinds of human beings. Researchers could divert their attention from curing hereditary diseases to editing supposedly desirable traits into a person's DNA. Some scientists or researchers might use the new technology to introduce germline genes for enhancement of offspring. This will result in humanity sliding swiftly down a slippery slope to the creation of generations of "improved" or "enhanced" humans with bigger muscle masses or higher IQs. The technology behind genetically engineering humans would be used for designing the master race. It will inevitably come to be used to introduce, enhance or eliminate traits for non-medical reasons. Genome editing with its potential to clear deleterious traits from the family line could promote cruel notions of genetic superiority and inferiority. This would lead to the slippery slope problem, which is, the point where the goal of eliminating a genetic disease in a potential child slides ineluctably into the goal of improving that potential child. It could be harnessed to craft "designer babies," who are more intelligent, beautiful or athletic and to "edit" embryonic cells to change an inherited trait forever.

The goals to stay young forever, become more beautiful, and never sick, and stay productive indefinitely. That is, a future human population that will gradually become physically healthier, more robust, and intellectually superior to any generation. However, designing a human person may be seen as an infringement to the innate freedom or right of liberty and equality, we have as human beings. As human beings, we've got a unique identity, and that identity, a very important part of it, is our biological inheritance, our genetic identity. While today's ethics will advocate against designer babies, once the technology is perfected, future ethics will evolve to endorse it. The gene rich or wealthy parents of the West could choose to modify some desirable preferential traits of their children and this may open the door to an era of high-tech consumer eugenics.

They could give them special abilities like superhuman mentality, omniscience, omni-linguism, night vision, and power augmentation, among others. Given these superhuman abilities, there is an intense conflict between both social groups. The rich can enhance the capacities and capabilities and might develop a separate superior community of different species since the line between therapy and enhancement is now fluid. The line between altering traits for medical reasons and enhancement is "inherently blurry and subjective," and fertility clinics that "offer the latest upgrades for offspring" and even nationalistic rivalries among countries using the technology. They can choose to improve their species to become more resilient, smarter and less vulnerable. Some parents might want to use the tool to "prevent or cure" things like dark skin or homosexuality, "instead of looking for social changes to make people see each other as more equal [21].

Furthermore, germline alteration for enhancement of desired traits of the 'perfect child' or 'designer babies' implies that the change is permanent, present also in the perfect child's eggs or sperm, and so will be passed on to future perfect children. The technology could be used to insert new types of discrimination and new inequality into the world. Unequal access to such technologies could lead to genetic classism and eugenics consisting at manipulating human genetics in order to improve on a population. This would inevitably give rise to doctrine of social advancement through biological perfectibility leading to speciesism, if the technique proves safe for human use. We could also be experiencing a rise in intersection of reproduction and expansion in baby farms, with white embryos grown in young African women. Many young women hired by commissioning clients from within and across borders navigate relationships that often cross boundaries of race, class and nationality. This plays the function of preservation of racial hierarchy which would in future disregard and denigrate the humanity of African women. It is not implausible that African women could lose the ability to make genetic decisions about their own progeny.

Further still, the history of eugenics movement should serve as warning for Africa and a reminder of how vulnerable persons became target for racial hygiene. Africans have historically been categorized as extremely vulnerable populations with diminished moral status, low socio-economic status, less human dignity and low regard for human rights. Generally, they are medically, politically, economically, socially, technologically disadvantaged. African communities have historically suffered from the

racist social applications of genetic theories and germline engineering offers another opportunity for racism to manifest, veiled as science. There is absence of adequate discussion addressing the issues of vulnerability as part of the human condition of African families, groups and populations. Also, the situation where mechanisms of social protection are declining and lack of ability to cope with their negative consequences, they may become easy targets for experimentation. Historical designation or characterization of vulnerable persons as inferior feeble minded and cases of abuse to promote eugenics, cleansing the gene pool of deleterious genes or purification of human race should serve as a poignant reminder to humanity about the misuse of technological possibilities.

Additionally, there is risk that gene editing technology will be further perverted for state-mandated population genetic engineering as a form of social control or used by dictators and other egomaniacs to 'improve' the genetic characteristics of the next generation. As scientific power increasingly augment the possibility for maximizing long term species power, while also providing the best optimum means to achieve long term viability of the species. There is the challenging issue that Africans are still largely lacking in the ability to survive an encounter with a potentially hostile alien race; the ability to control the climate; the ability to provide global security; the ability to control and defeat pathogens, which constitute a serious challenge to their survival in the face of serious technological power and advances. Further still, they are increasingly viewed as people who fall short of some technically achievable ideal and considered as "damaged goods". With the globalizing trends in research introducing global health inequality, the complex political and economic problems, and challenges related to distributive justice or benefits sharing of innovation.

Moreover, the challenging issues related to the marginalization of African communitarian and humanistic values in favor of capitalist liberal economic ones. There is growing vulnerability in African communities related to neo-liberal, global economic policies as globalization created an asymmetry of power. The globalization model is powered by the operation of a dominant market-driven logic," shifting policies away from maximization of public welfare to the promotion of enterprise, innovation, and profitability. This logic changed the nature of state regulation, "prioritizing the well-being of market actors over the well-being of citizens" [22]. Rules and regulations protecting society and the environment are weakened in order to promote global market expansion leading to exploitation, precariousness and exclusion. To counter this trend, Africans need to be interested in the ways communitarian values may guide policies and practices in new technological innovations, as well as in pitfalls decision-makers must be careful to avoid. Africans should ensure that these technologies must be controlled and regulated so as to comport with our shared values.

5. The Need for Engagement and Empowerment

The biggest challenge of today and now is how to encourages, researchers, society, government and industry to work together to facilitate dialogue about the sorts of values that innovations in genome editing technologies promote, and the sorts of values that we hold and want to advance in the community. Setting up decision-making systems and procedures in advance is the best way to ensure that ethically appropriate decisions will be made. Responsible innovation requires public involvement and consideration of ethical, legal, and social implications. This involves identifying common goals important to scientists and the wider public through timely and detailed consultation among diverse stakeholders. It requires the establishment of an open, international, collaborative and regulated research framework. Yet, there is still a serious challenge to set up mechanisms for community engagement and empowerment in Africa into informed and democratic discussions. Since Africans are required to make informed decisions and choices on germline modification and the modification of the human gene pool. Informed consent must take local and regional values into account and enable true decision-making on particularly sensitive use of cells and DNA from certain sources [4]. Africans need to assert their convictions about human beings, life, and dignity, and social, economical, and political order in the discourse of society.

Till date, ethical justifications for the applications of the technology are moot until it becomes possible to demonstrate safe outcomes and obtain reproducible data over multiple generations. Most people around the world are still uninformed, unaware and have little or no knowledge about germline editing and genetic technologies. People know very little about altering genes in unborn babies and on issues related to the use, prevention and treatment of serious debilitating diseases. Furthermore, people are not opposed to the fact of scientists trying to improve (genome-editing) technologies since they belief in the near future, there might be compelling reason to use the technologies. That is, a rare situation where scientists eliminate a fatal disease, which a child would have otherwise inherited. Even the precise effects of genetic modification to an embryo are still impossible to know until after birth. Lack of knowledge and information implies it may be a very high-risk thing to do, messing around with the genes of unborn babies.

However, preventing an illness by repairing DNA is a noble motivation and way to use science. Given the uncertainty accompanying science, research is supported by the belief that a cure can come out of it. But as scientific knowledge advances and societal views evolve, the clinical use of germline editing should be revisited on a regular basis. There is the issue that instead of making "better" humans, genetic modification could make people who are even sicker or cause them to die. Additionally, germline gene editing is a society altering technology and a political issue which cannot be reserved for scientists to make decisions exclusively. We

need to put in place robust mechanisms of accountability for both the social and technical concerns. In most discussions, scientists usually focus on technical questions about safety and effectiveness while sidestepping the ethical, social and political dimensions of the debates.

Further, legitimate concerns regarding the safety and ethical impacts of germline editing must not impede the significant progress being made in the clinical development of approaches to potentially cure serious debilitating diseases [25]. An ethical approach to risk requires us to evaluate the possible consequences both of action and of inaction, and to realize that we are responsible for harms caused by the latter as well as the former [8]. There is need for a systematic, coherent, universally applicable framework that allows well-regulated laboratory research, with strong ethical oversight, to proceed. Rather than a call to a generalized moratorium, or banning, of this type of research, efforts should be placed on establishing an open, international, collaborative and regulated research framework [44]. Discussion on new scientific advance should be informed and enriched by continued research to understand and refine these techniques in a laboratory, under strict regulatory limits and scientific scrutiny. Many of the questions that the public and policymakers will rightly raise can be answered only if researchers are actively investigating the techniques, testing a variety of hypotheses and advancing their own knowledge. A moratorium on research would be a moratorium on this understanding [30].

Further still, there is crucial need for more research since without further research we will never be able to establish the safety and efficacy of these hereditary altering procedures. The science is moving at lightning speed and regulatory changes may happen only after a high-profile gene-drive release. Regulation, if and when it comes, might need to be adapted to the local situation, to existing legislation and to cultural and religious normative frameworks. It become obvious that engendering more trust in science is best achieved by encouraging the people involved in the genesis of a technology to actively participate in discussions about its uses. A democratic debate that associates all stakeholders to deliberate on risk associated with innovation and which values ought to be protected and which sacrificed must accompany science. Involving the public directly in choices about research that could influence the very nature of human existence — what might be termed the sciences of the existential [39]. Bioethics enables us identify and critically evaluate the various ways that people think we ought to provide health care and use genome editing technology.

However, people and their circumstances are different in many ways, and how they ought to live will vary in many respects. As such, a truly deliberative process which engage today's world is that which integrate diversity and conforms to the bioethical principles such as: *multidisciplinarity*– to gather all human sciences and activities that are relevant for bioethical questions; *interdisciplinarity*– to encourage dialogue and to find a mode of cooperation between all these disciplines; and *transdisciplinarity*– to overcome mutual differences, that is, to unify differences into a unique, bioethical view focused on questions that cannot be unraveled from the perspective of *one* science or *one* area; *Pluriperspectivity* – the 'unification and dialogical mediation of not only scientific, but also of non-scientific, that is, a scientific contributions, including diverse ways of reflection, diverse traditions of thought and cultural traditions, that is, diverse views that rest on cultural, religious, political and other particularities [12]; [19]; [43].

Additionally, as echoed by the editorial of *The Lancet* in 2015, careful progress and debate, bringing in all stakeholders, will be needed to craft appropriate use of genomic information in the evolving landscape of clinical practice, and to set appropriate boundaries for high-risk, high reward methods for genome engineering. Even today's scientists need to be better prepared to think about and shape the societal, ethical and ecological consequences of their work. Scientists need to engage with governments and invite informed public discussion to draw up rigorous guidelines that govern research and clinical procedure. Systems must then be put in place to ensure that these guidelines are followed [41].

6. Conclusion

The possibility of changing humanity by modification of the human germline or human gene pool is nearby. Would the possibilities offered by medicine lead humanity into a dark tunnel or would humanity entertain these possibilities responsibly depends on the choices we make. Despite the popularity of genome-editing techniques, researchers are still grappling with the known unknowns of the technologies. There is still need for further research on genetic editing technologies, approaches to improve the safety and efficacy of these technologies, basic research into gene functions, development of disease models, and clinical research on somatic gene therapy applications to enable the public and populations of the world to make informed decisions. The scientific community, regulators, ethicists, and the public still have to grapple with the challenging issues that should be resolved before reproductive applications.

Furthermore, scientists should seek to keep the international community, policy decision-makers, the media, and the general public informed and aware of innovative inventions. Such awareness is essential/fundamental for making informed decisions after open discussions on the potential risks and benefits and for fostering public debates. This is the best way to ensure that society and science harmoniously progress together. In the near future, it is expected that a more involved bioethical and democratic deliberation would take place. Giving the plurality of our backgrounds, our moralities, and our narratives, bioethics must open the new way to a more interactive, integrative and pluriperspective approach to deliberation. A global bioethical deliberation is one that incorporates values and principles such as multidisciplinarity, interdisciplinarity, transdisciplinarity, pluriperspectivity and integrativity. One

in which the general public will have a greater say in how science will proceed and which addresses the crucial issues central to life, survival of human species and environment, the preservation and protection of human dignity and human rights.

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