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Legal Concerns Related to Creation of Mutant Babies and Need for International Regulatory Framework

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Abstract

Recently, the world has witnessed a biotechnological spectacle in which a scientist named He Jiankui brought the genetically modified embryos to terms. After the birth of mutant humans, Lulu and Nana, the leaders in the scientific community are emphasizing to carefully proceed with genetic engineering. In this regard, the imminent concerns are to address procreated human mutants. The birth of mutants presented an urgency to establish designed to designer liability and demands for a Mutants' Code. The current study advocates to set standards for the producer of mutant babies in case of default. Taking the inherent rights of babies intact, what remedy they can avail if they have been produced just for the sake of publicity, fame or mere experimentation. There is a new subject of law available now, and indeed, it is to be addressed in a timely manner; otherwise, one can see the quests of producing marvel characters in real life. The technology is likely to develop far more rapidly than the legal precedents can emerge to legislate it, but the jurisprudence and practices from international law can set bars beforehand for the potential impacts.

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Introduction

Starting from Asilomar conference in 1975 to Second International Summit on Human Gene Editing in 2018 (Baylis 2019), it took few decades to see what the world gathered to stop (Hurlbut 2019; The National Academies of Sciences, Engineering 2018; Nuffield Council on Bioethics 2018). Referring to the Dr. He Jiankui claim of successful procreation of two genetically modified babies, there is a transition in mentality from not doing to do it properly.(Nuffield Council on Bioethics 2018; Ormond et al. 2017) The scientists in the Second International Summit on Human Gene Editing agreed to find a technological transition discourse based on human dignity and human rights to proceed with the research of human gene editing (National Academy of Science & National Academy of Medicine 2017; Nuffield Council on Bioethics 2018). The technology inherits with it, not only the extinction of various incurable diseases but enhanced capabilities. This includes longer life, stronger selves, and potentially can acerbate a rift of competition in society. The intrinsic deviation of procreative beneficence (Savulescu 2001) will ultimately raise the threshold of ‘normal’ and compel an upgrade to cope up with the enhancing needs.

With Lulu and Nana, seems the debut of realization of those Marvel Comics concepts of fictional legislative bills such as ‘Superhuman Registration Act’, ‘Mutant Registration Act’ and others including ‘Vigilante Registration Act’ first appeared in the Uncanny X-Men series (TRUSHELL 2004). These marvel concepts once considered as science fiction, now as Fredric

Jameson (1991) said, are the pre-inurement of the dominant issues of postmodern culture. The powers bestowed to humans via technology enabled them to manipulate the source code of human anatomy. The acquired expertise tempting the scientists to redesign the human. There is an urgent need of designed to designer liability which though seems a fiction but is likely to be an imminent need soon. The Chinese Scientist He Jiankui using the CRISPR-Cas9 tool edited the genome of two embryos. He then inseminated those two embryos into a woman, and the pregnancy successfully resulted in the birth of twins which are considered as the world first germline genome-edited twins, genetically modified humans or mutant humans (Cyranoski and Ledford 2018).

CRISPR-Cas9 is very efficient tool to perform germline gene editing in human embryos and has made it possible to produce mutant babies (Saleem, Khaskheli, and Fareed 2019). However, absolute accuracy is sometimes reported to mitigate during the experimentation (Fu et al. 2013; Pattanayak et al. 2013). Although the mitigated changes can still be used to do experimentation but this minute change in terms of human species demands for more safety requirements (Veres et al. 2014; Smith et al. 2014). The marvel He has done, irrespective of ethical and other contingencies, was already anticipated by experts and along with it was the rising concerns that it will be used for non-medical reasons (Ledford 2015b). Although there are existing national and international regulations to regulate the research on genome editing but all prohibit the procreation of edited embryos (Araki and Ishii 2014). The birth of Lulu and Nana unlocked the new domain of legal research which is beyond the ethical standards of the past and started a new chapter in legal development where there is a need to draft new laws that may appropriately address the mutation in human beings. There is no clear boundary between cure for

disease rhetoric and enhancement rather the apprehension of genetic classism,(Sanz 2014) procreative beneficence and eugenics are real and known to the world. The article specifically emphasize on devising a cosmopolitan legal framework addressing the phenomena of genome editing the ethical and legal issues before and after the editing of the human germline genome.

The novelty of the study makes it significant since it addresses the humans born after a successful attempt of mutation in one's genome. The mutant humans born with their features and traits changed without their consent, as at that time they were not be able to give consent, are potentially declared as new subjects of law and ask a question, which in futuristic perspective hold significance, that why they are different? It is a novel concept which may seem absurd right now but is undeniable. It creates a plethora of controversies containing criminal law and tort law hybrid liabilities which are challenging the moral and legal responsibility (Smolenski 2015). The need to draft laws for mutants is urged to define the tracks of social inclination specifically to counter the genome editing phenomena from a counter perspective in which one in whatever time in future will be compelled to justify himself with a legitimate reason for doing the gene editing in human. In the absence of any potential law, there would be many mutants which may not be announced publicly and kept secret till any complication unveil them. The CRISPR/Cas tool is very convenient that there is no need for huge amounts of money and highly professional and scientific skills to perform the experimentation even on human genome. To counter the temptation of ease and cheap, we need laws with grave consequences for every attempt. The article only provides an imaginative futuristic perspective that may compel to highlight the need for proper laws that specifically address mutants and narrate culpable liabilities for those who do the mutation.

The article provides the feasibility of CRISPR technology to build claims about its significance and promises it hold for its disruptive nature in Part one. The second and third part address the pre and post mutation ethical issues and highlight the insufficiency of such ethical debate at this point of time when in fourth part signify the imminent need for devising a legal framework to regulate the genetic engineering in human genome. Part five emphasize on the need and importance of international regulatory framework taking international law as an overarching legal order to reach a consensus with conclusion at the end.

CRISPR-Cas9 an easy and cheap method to edit DNA

Discovery of CRISPR CAS 9 tool

In late 2012, Charpentier and Doudna introduced a programmable system, CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) Cas 9 (CRISPR-associated protein 9) system, to edit genome (Jinek et al. 2012). The CRISPR-Cas9 tool is an RNA-guided nuclease adapted from the bacterial species named Streptococcus pyogenes has function to precise genome modification in mammalian cells (Cho et al. 2013; H. Wang et al. 2013; Horvath et al. 2010). The CRISPR-Cas9 tool can also be used to perform editing in Humans (Singh, Schimenti, and Bolcun-Filas 2015). The first study which demonstrates the use of CRISPR/Cas9 tool to modify genes in early-stage of human embryos to edit out a blood disorder was published in early 2015 by a Chinese scientist Huang Junjiu (Liang et al. 2015). In 2018, Dr. He Jiankui revealed the results of his secret experimentation in which He and his team procreated Lulu and Nana with their genome edited. The technology is developing so rapidly that even the more compact systems are on the verge to break in such as CRISPR Cas X and Y,

which remove the defects of the Cas 9 and also broaden the experimental and manipulation fields (Burstein et al. 2016).

Previously used tools and mutation

The science and technology have developed to the extent that it can introduce mutation in the genes and can also identify mutations. The availability of nucleotide polymorphism and high-throughput screening with TILLING (Targeting Induced Local Lesions in Genomes) has made it easier to identify mutations in a targeted gene (Nordberg et al. 2018). A great leap has been passed in precision, user-friendliness and cost with CRSIPR-Cas9 from the other previously available tools for gene editing such as the zinc finger nucleases (ZFNs) and the transcription activator- like effector nucleases (TALENs) (Ishii 2017). Although, the problem of off-target mutations still exit along with 'mosaicism', where only some cells carry the desired edit (Holm 2019), but the world is ready to get go with the gene-editing technology to apply on human subjects and treat the genetic diseases. The motivation is evidenced with the statement of Dr Tedros Adhanom Ghebreyesus, Director-General of World Health Organization (WHO), in the second meeting of the Committee on Effective Governance and Oversight of Human Genome Editing held in 2019, He said;

> *"Since our last meeting, some scientists have announced their wish to edit the genome of embryos and bring them to term. This illustrates how important our work is, and how urgent. New genome editing technologies hold great promise and hope for those who suffer from diseases we once thought untreatable. But*

some uses of these technologies also pose unique and unprecedented challenges – ethical, social, regulatory and technical(Reardon 2019)*."*

Reason for such statement and why the experiment is not so successful

The pivotal of his statement is the CRISPR-Cas9 technology after a Chinese scientist Dr. He Jiankui performed experiments of editing the genome and procreated two baby girls, which faced a global condemnation by the scientists working on gene editing (Cyranoski and Ledford 2018). Dr. He failed to satisfy the scientific community about the purpose of his experiment and his study has not yet published.(Cyranoski 2018) However, CRISPR-Cas9, has already compelled the scientific community about the commitment of cure it can provide for various genetic diseases. According to the WHO, the monogenic diseases or those caused by an error of a single gene are around 10,000 of which some are fatal and others significantly impair the life quality such as thalassaemia, sickle cell anemia, haemophilia and cystic fibrosis(WHO 2019). There is a variable trend in the world about the use of genome editing technologies and its application bear issues which are legal, ethical, cultural and religious (Nordberg et al. 2018).

There are standards for genome mutation but no legal framework for it

A contemplation of the statements made by the relevant authorities[1] on the experiments of Dr. He summed up in the statement of the Second International Summit on Human Genome Editing excerpted as 'the procedure was irresponsible and failed to conform with international norms'(Yotova 2020). The statement rather implying complete prohibition caution for a careful use of genome editing on humans and requires fulfillment of standards prescribed for it

[1] Chinese Academy of Medical Sciences, the French National Academy of Medicine and the Academy of Sciences and the UK Nuffield Council on Bioethics.

(Cavaliere 2018). There is no sufficient framework or international norms regulating the genome editing in place right now (Cyranoski 2019b) and the whole debate is revolving around how to do it properly (Yotova 2020). There is no discussion addressing the post genome mutation scenario when it has already been done and we have two babies who, according to the conventional definition, be termed as Genetically Modified Organisms (GMOs)(Melo-Martín 2015). The manuscript takes the ethical and legal issues from the perspective of before mutation and after mutation making it the novel study in the field of biomedicine and propose a uniform ultra-national framework to address that subject.

Beyond the Ethical Issues

Morality inform the ethical decisions(Bauman 1994) and the decisions in biomedical industry is based on well calculated risk/benefit assessment specifically in which the former is lesser and later is greater. The ethical concerns arise from the genome editing differs in different countries with difference in culture but the universal concern that worries all is the safety, use of embryos in research and informed consent. The most pressing concern before the mutation is the surety about the safety of mutation(Holm 2019). The safety issue arises from two possibilities; the first one is off target mutation and the second being mosaicism. The off-target mutation is the edit of genome at wrong place and the procreation of such missed target edited embryo can lead to unpredictable changes in the resultant human. Similar unpredictability also prevails on mosaicism in which, some of the cells undergo successful edit while some remains unedited. The use of embryos in research especially the one used for procreation raises a pressing concern. Previously the ethical concern only revolves around the obliteration of embryos. With the

passage of time, the focus started to converge on viable embryos and the extent to which it can be developed and gestated after experimentation.

The safety debate is critical and it specifically address the risk/benefit estimation after the edits in genome(Brokowski and Adli 2019). Even after the successful attempt of replacing or editing an intended gene in the germline genome or DNA of an embryo, the safety concern only justifies the integrity and accuracy of the experiment but it does not satisfy the safety concern if the edited embryo procreated into human being. In order to declare the edit safe, one needs a considerable time that may last for decades or even generations to derive a reliable data about the causal relationship between gene expression in relation to other factors that shape biological outcomes in future (X. Wang et al. 2016). The unavailability of interpretable data combined with the limitation of CRISPR technology as mentioned above including off-target mutations and mosaicism, makes it difficult to precisely predict the future of edited organism hence hinder the accurate risk/ benefit analysis and complicate the decision to satisfy the safety argument. In order to collect more data and empirical evidence about the post-effects of gene editing in human beings, it is imperative to continue research on human embryos which present the second concern in the ethical debate at the pre-mutation stage.

The United States National Academies of Sciences, Engineering, and Medicine (NASEM) publish a thorough report on the editing in human genome and specified provisions that constitute compulsory sanction to carry out research on human genome. These provisions include; absence of any reasonable alternative; only restricted to a serious disease or a condition that is construed as harmful to one's quality of life such as permanent disability; restriction to the gene editing only for a disease not for enhancement; restriction to editing gene with a gene that is

already known and prevalent in population and have no negative affects; in the availability of reliable data and the health benefits of the procedure; ongoing, rigorous oversight during clinical trials of the effects and the procedure on the health and safety of the research participants; comprehensive plans for long- term, multigenerational follow up that still respect personal autonomy; maximum transparency consistent with patient privacy; continued reassessment of both health and societal benefits and risks, with broad ongoing participation and input by the public; and reliable oversight mechanisms to prevent extension to uses other than preventing a serious disease or condition"

All the provisions expressly provide a tacit approval to use the embryos for gene-editing purpose but after the secret experiment of Dr. He, the recurring debate again converged to the point where the experts are presented with a simple question that says; either to impose general prohibition of gene editing or devise a reliable legal framework to regulate the research. The emphasis is inclined to devise a legal framework because the CRISPR technology holds promising opportunities in the field of biomedicine. Further, coming back to the ethical problem of using human embryos in research, there is a mounting problem which is both ethical and legal; and that is about the informed consent(Brokowski and Adli 2019). The morality behind the informed consent is not easy to handle especially considering the 'reproductive rights' of individual and the Parfitian 'nonidentity' consideration. The in-depth argumentation about morality, safety and status of embryo in relation to Parfitian nonidentity consideration and freedom of reproductive rights warrant thorough discussion which can go beyond the scope of this paper, so to stay within the scope, we just take the legal aspects of informed consent which will be discussed in the section of legal issues.

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Post Mutation Ethical Issues

The primary advocated reason that entails a need to do gene editing in humans is to find a cure for genetic diseases (Corn et al. 2015; Jasanoff, Hurlbut, and Saha 2015). The purpose can be vital and lifesaving but the acceptance to manipulate the genome bring concerns regarding a collective but conceptual understanding that; to find a genetic cure is synonymous to allocating those with certain traits as a misfit in society (Ormond et al. 2017). It notifies to them a tacit exclusion and a collective loss of humanity. The developmental stage of gene editing lacks providing guarantees about healthy life after gene editing but ethically speaking and taking into consideration the social context; the hatred one receives because of disease could continue to persist with a different name; one could say, for instance, a repaired human. However, health is a compelling reason to perform gene-editing at the embryonic stage to get rid of disease-causing mutations which somatic alterations cannot control. It is also supported by Julie Steffan (2019)(George Q. Daley, Robin Lovell-Badge 2019) in an online published perspective as a replacement of preimplantation genetic diagnosis (PGD) but supported a theoretical claim for careful progression of the use of genetic engineering. The contemporary debate about gene editing is only addressing its application for disease eradication. It only includes a small part of the world community who knew the value and worth of this new technology and ignoring the remaining part of the population that has more Dr. He Jiankui minded people and are more curious to apply it.

One can justify holding an antithesis to support gene-editing as a guarantor of the good life of children such as Julian Savulescu (Savulsecu 2001). However, the limits of use of gene-editing technology contain exciting, lucrative business and dream realizing opportunities for both

business community and parents (Mulvihill et al. 2017). A time will come when people may prefer perfect off springs rather a baby who requires a post-natal alteration, quoting the example of aesthetic surgery in Korea, to attain the desired phenotype (Holliday and Elfving-Hwang 2012). The liberal eugenics could do conscious implications on human genetics (Lederberg 1963). In simple words, DNA provides the developmental blueprint embedded in the gametes which lead to the formation of an adult organism and the corresponding features (Lederberg 1963) for which any change in genotype is what one needed to achieve the desired phenotype. The study does not contemplate about being too futuristic when gene editing would be accepted as a solution for whatever someone wants in his baby. The custom-made babies with the success of gene editing may probably end the existing forms of discrimination but also has potential to give birth to a different discriminatory conception, including visual esthetics.

Another consequence could be a homogeneity in human traits in different societies based on the most favorite features acceptable in one society (Lee, Ahn, and Kim 2013; Comiskey 2004). Long-term perspective speculation of success of eugenics with genetic engineering purports to a world of dream characters not in culture but in appearance and an alarming shortage of gene diversity (Mary F Rogers 2012). Different societies may correspond to a similar set of appearances based on the preferred models of cultural appeals (Magro 1997). All these are the ethical concerns related to the gene editing and is taken with a futuristic perspective if the gene editing will be allowed for clinical application. However, yet there is no any legal framework specifically on international level that can address the gene editing as it is already taken as a choice by the world to choose but bears no sanctions. Further, ethically speaking the medical malpractice performed by Dr. He(Liu 2020) has implications for future progeny of the twin

mutants, how to address those implications and what risk/benefit calculation blueprint is designed to estimate the consequences requires to address the legal issues involved in human gene editing.

Legal Issues Related to Mutant Humans

The phenomena of gene editing have radically changed the understanding of fetus. The innovation in biotechnology has provided a solution for the cases in which life construed as harm and nonexistence as a benefit (Botkin 1988). However, it has also affected the very spirit of life, making it instrumental for parents to design. Legally speaking, the mutant baby can bring a suit of wrongful life (Botkin 1988) against parents and the institution carrying out the process. In contemporary practice, courts are hesitant to entertain and award general damages in wrongful life cases[2] where the negligence of doctor results in the birth of a child with specific heredity ailment but courts are inclined to award medical damages or recovery of medical expenses on the ground that there would be no such expenses if no negligence happened on the part of the doctor.[3]

However, contemporarily with no sustainable estoppel by a higher authority, who would be the principle responsible person to whom the mutant could sue for any complications they face as their life progress. The answer to this question warrants a philosophical debate of the core concepts regulating human rights(Brännmark 2017), principle of autonomy(Dunstan 1994), principle of primacy(Brännmark 2017) and principle of consent(Yotova 2020). The primacy

[2] Turpin v. Sortini, 643 P. 2d 954 - Cal: Supreme Court 1982
[3] Schroeder v. Perkel, 432 A. 2d 834 - NJ: Supreme Court 1981, Robak v. United States, 658 F. 2d 471 - Court of Appeals, 7th Circuit 1981

principle chants the well-being of human beings over the interest of science and society which is intrinsically linked with principle of autonomy. The autonomy signifies self-governance and confers an uninterrupted right to act on one's own judgment about matters affecting one's life(Dunstan 1994) and linked with principle of informed consent. An autonomous decision is synonymous to giving consent but in terms of genetic intervention there is no prior information and the person affected is also not available yet. In this case who owes the responsibility to give consent is a crucial question when it has implication for whole society. The question further entrenched with the conception that if at all an embryo is entitled to human rights? The Oviedo Convention includes the unborn child as a human being when the European Court of Human Rights (ECtHR) provides the human rights protection of 'right to life' after the birth of child. There is no homogeneous approach to the status of embryo and child which further complicate the matter of informed consent. Applying the principle of proportionality and precautionary principle of environmental law, the responsibility should be balanced between parents and the institution proposing to use the genetic engineering. The duty to care in this regard, may assume to have it modified to face the society, rather follow the path designed by mother nature even if it may increase the suffering and misery. The confusing situation that evolved with the potential suits of wrongful life as it is a deliberate manipulation of genome by parents at a stage before the commencement of pregnancy within the embryo and a resultant baby which during prenatal stage corresponds to the natural process of human race propagation but at post-natal stage begin an instrumental life designed by parents or others.

The primary or better to say a universal concern about the mutation in genome entails the liability to analyze the risk and benefit ratio to ensure the safety of the baby (Howard et al.

2018). It demands for a criterion to accord the responsibility in case of default. For instance, to make this point clear, if any of Lulu or Nana got any health problems subsequently in the course of their life development. Who will be responsible for such problems? How to distinguish either these problems arise because of mutation or otherwise? How to circumscribe the limits of informed consent? Also, how can parents give consent for a baby which is not part of them yet belongs to them as a thing, not as a being? If the courts will also award the medical compensation to the progeny of mutant humans? The question of informed consent is pivotal in this discussion. It is very important at this point about how research on germline genome modification in humans could be pursued in light of the substantial difficulties in ensuring adequate consent not only on the part of the experimental subject, but also on the part of the future generations that will be impacted by the intervention. The supporters of gene-editing present it as a universal rectifier of the diseased genome and extend this rectification to subsequent generations. The claim is very pleasing and satisfying, but the probability of unexpected outcomes is more probable at this stage of genome manipulation.

How much noble is the intentions of the first user of gene-editing technology; others may use it to pursue their desires in its application. Eugenic spirits are not new to the world (Kevles 2011), it was started when the science was not so developed and the only solution to improve the gene pool was sterilization which inhibits the progression of genes considered defective by the state (Buck v. Bell, 274 US 200 - Supreme Court 1927). With the CRISPR Cas 9, eugenics can get a more sophisticated form and the older wave of ‘eliminate the unfit’ of Nazi Germany can revive in a new spirit to ‘make the unfit, fit’ for the society(Yotova 2020). The National Academies of Sciences, Engineering and Medicine have highlighted certain paraments which if addressed, can

get-go with the gene editing in human beings (The National Academies of Sciences, Engineering 2018). Those standards require a sophisticated cosmopolitan research deliberation which is also proposed by many other scientists around the world (Araki and Ishii 2014; Hurlbut 2019; Saha et al. 2018). The technological transition is much faster than allocating sufficient time to observe the implications at each step of development. The genetic engineering in human also falls a victim of such fast pace where one can easily falls prey to it. The disciplinary experts designated by national institutions are willing to step forward but without required precaution ignoring the ingrained dignity and value of human worth. Quoting an excerpt from the Statement by the Organizing Committee of the Second International Summit on Human Genome Editing, "it would be irresponsible to proceed with any clinical use of heritable 'germline' editing at this time" (World Health Organization 2019) is a clear caution which intimates a need for the establishment of legal action against those who transgress the boundaries.

Need for an International Regulatory Framework

CRISPR/Cas9 is a powerful and intelligent tool which as Leah Ceccarelli (Ceccarelli 2018) expounded on Doudna's metaphorical examination of the words used to define the biotechnology with CRISPR/Cas9 as an autonomous agent with almost unlimited power to engineer the genome. CRISPR/Cas9 is personified as a powerful and intelligent agent that enables and allows for reshaping the human genome with its Godlike powers (Ceccarelli 2018). This claim is sound and based on solid foundations because it is not only cheap, but quick and also easy to use (Ledford 2015a). The predecessor zinc finger nucleases that cost almost 5000 US$ and were very expensive to play casually. The CRISPR Cas9 needs a guide RNA fragment, and all other components can buy off the shelf, when the total cost, including Cas9 enzyme, is 30 US$

(Ledford 2015a). Heidi Ledford, a senior reporter for Nature in Cambridge, Massachusetts, called the CRISPR/Cas9 as a disruptive technology and it is prevailing without very basic parameters(Ledford 2015a). Bo Huang, a biophysicist at the University of California, San Francisco(Ledford 2015a) said, "there is a mentality that as long as it works, we do not have to understand how or why it works." Emphasizing on this mentality CRISPR Cas9 and the updated versions in future has the potential to compel any passionate person to carry out experimentation to play nature.

Secrecy, in the course of first mutant human births adopted as a tacitly approved course of conduct to carry on the clinical application of CRISPR/Cas9 (Kofler 2019). The group of elders with authoritative institutional backing and appropriate technical expertise are appeared to give an open hand to those who want to explore this technology in its human implications (Kofler 2019). It was imperative to expose the first successful attempt of gene editing in human beings because although with some bitter consequences, but Dr. He has secured his name in history for his work. However, in the subsequent progression of this technology, one may not find any compelling reason to expose his personal adventures or endeavors. Taking secrecy as the best policy, the number of mutants may start to increase in our society day by day in the results of secret experiments. The conclusion of all discussion of this study converges to a solution of making laws which in case of any liability bestow grave consequences on the person responsible for his acts. Dr. He's secret experimentation imposes multiple criminal charges including violation of University rules and health measures, informed consent conflicts, forgery of documents (Saleem, Khaskheli, and Fareed 2019) and illegal medical practices (Liu 2020) but no

charge directly address the life of the infants after mutation and no consideration of their progeny(Cyranoski 2019a).

There are already existing multinational binding legal documents that address the application of biology and medicine within the scope of human dignity (Council of Europe 2019). Article 3 of the Additional Protocol to the Convention on Human Rights and Biomedicine of the Oviedo Convention prefers individual human worth over the sole interest of science and society (Council of Europe 2008). Similarly, Article 13 of Oviedo Convention addresses the matters of consent in a case where a person on whom the genetic testing is going to carry out, is not able to consent and authorize law to satisfy certain aspect to allow for the testing. The first and foremost is the safety of the person involved. In case of the first instance of gene-mutation, Dr. He claimed to give a permanent cure of AIDS (Jane Cai 2018) by doing mutation to the CCR5 genes which is the responsible factor to acquire AIDS (Tebas et al. 2014). This claim according to the precautions set by Oviedo Convention[4] imposes liability on Dr. He, because there are other safe methods to do safe and clean fertilization using Assistive Reproductive Technology (ART) by bathing off the sperm from the serum of infected individual and also by safe sex (Gilling-Smith et al. 2006). In addition, the health risk was not there at the time he experimented. He performed the experiments on the apprehension that they might catch the disease and bypass all the precautions that are sufficient enough to ensure the safety of the child. Avoiding the unnecessary details, the act performed was a clear violation of human dignity and human rights in the domain of state parties to the Oviedo Convention. Although the Oviedo Convention enumerate precautions for safe and dignified experimentation but it does not address the genetically

[4] The Oviedo Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (4 April 1997) ETS No. 164.

modified human being. The claim demands for post violation of Oviedo Convention framework because the Convention covers the ethical issues that stop at the verge of experimentation not the results of it; meaning thereby one perform all the experiments satisfying all the pre-requisites mentioned by the Oviedo Convention is synonymous to no responsibility on the parents or doctor in case of default. Tetsuya Ishii (2017) an expert of bioethics from Hokkaido University mentioned that "the nature is huge and one cannot play God in such an irrational way how Dr. He has played in his secret experimentation."

Additionally, there is no legally binding international document that addresses this phenomenon at a global level. The Oviedo Convention is just a regional document and does not allow for bringing in term the modified embryos. The World Health Organization (WHO) has established an expert penal on 14th December 2018 to develop a global standard to govern the human gene editing ("WHO | Gene Editing" 2019). The present study considers it a positive initiative similar to what the authors intend in this article to develop an International instrument which consists, not only the regulatory framework that prohibits the implantation of edited embryos but also prescribes standards and liabilities for national governments to impose exemplary punishment for those who violate the standards. It is important as David Cyranoski (2019), Asia-pacific correspondent for Nature magazine said, there would be more mavericks like Dr. He who for the sack of any compelling reason may try playing nature and it is no wonder now to hear another instance of birth of the mutant baby (Cyranoski 2019a). The immature attempts to delete the disease in society may create another difference which though for the public at large bring another annoying aspect or ailment. It may soon require a screening system to ensure the

normalcy of a newborn to protect the population from perspective quests of maverick scientists and curious parents the same as PCR testing required for cross-border movement.

Conclusion

The idea is no more hypothetical, and any discussion about access is yet speculative. However, it must likely to be expensive and with selective permeability of socioeconomic differences. Genetic disease, once a universal common denominator, could instead become an artifact of class, geographic location, and culture. As Jennifer Doudna(Jinek et al. 2012), the inventor of CRISPR/Cas 9 system once suffice in Napa Conference that, "maybe there will be a time when it would be considered unethical not to do genome editing in the germline for certain applications." The state owes equal responsibility if it is one person or the whole community, and proper grounds should be prepared beforehand to address it. The need for a statutory code of conduct is essential at this point of scientific development to caution the scientists and researchers about the inveterate consequences regarding their experimentation or clinical application of gene-editing. In the beginning, every new technological wonder becomes a focus of extensive debates involving ethics and other aspects of social importance. Once Louise Brown, the first 'test-tube baby,' was born, there was similar debate addressing the ethical aspects of invitro fertilization as is regarding gene editing. However, the only difference needs highlight in germline gene editing is the probable future implications that can not only affect the individual but the subsequent generations. The baby with edited genome is a mutant in its definition, because it has a natural development but not a natural formation. The formation is human emphasized and manipulated in a certain way to appropriate the desired changes irrespective of the reason for appropriation. Concluding with the words of Craig Venter, the author of "the sequence of the human genome"

published in Science in 2001, that "the question is when, not if." This study extends it to use for both the application of technology to make mutant humans and drafting of the code that address mutants. Concluding with an intriguing question, if Dr. He Jiankui does not expose his experiments and mutants, how will we come to know about them? The world needs to think about it with a solution-based approach.

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