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Genetic Engineering: This is not the Time We Use it in Clinical Applications

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Abstract: The evolution of genetic engineering technologies have brought us to a point where we ask a lot of questions and there are many debates on whether we should be using innovative technologies like CRISPR-Cas9 in clinical applications in human embryos. This research essay will argue that no matter how much the technology grows, we have to be 100% sure about its consequences. In order to be sure, there needs to be deep research on those technologies. Do we know enough about the human genome to understand the impact of editing it? It is likely that some countries might consider using these technologies, but while these technologies are fast and cheap, there are consequences in modified embryos that might lead to mutation. This essay will state that scientists should communicate the power of technology and how they can be responsible in using it.

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I. INTRODUCTION

As genetic engineering technologies develop, they become extremely precise, cheap, and fast; but there are many issues with practicing them. There might be ethical issues, technical issues, or even lawful issues that must be considered before using them. Humanity should not risk, there must be conducted deep research on the genetic editing technologies. For example, it might be used in adult cells to be analogous of taking a pill, however, those are *individuals* and will not pass on to their children. It has raised ethical issues; whether those changes should be made in human eggs, sperm, or embryos. Studies show it is impolite to use them in clinical application for now. Practicing genetic modifying technologies should be postponed in order to investigate and be 100% sure about the outcomes.

A new breakthrough in gene modification could greatly advance our capacity to reshape human DNA. The CRISPR method works by using bacteria to recognize the presence of DNA, after which it generates two short RNA molecules. These RNAs then combine with a protein called Cas9 to form a complex. It is a nucleus and a type of enzyme that can cut DNA. When the RNA finds its target within the genome, the protein Cas9 eliminates the target DNA and thus removes the virus. For the past decade, scientists have been researching this environment, and realized that this tool could be engineered to a point where you can cut not just a viral DNA, but any DNA sequence at a precise location. Furthermore, it can edit not only the DNA, but also fertilized egg, sperm, or embryos. It can target many locations at once and has been improving rapidly which allows researchers do basic experiments more comfortably. However, the result is unknown; being careful is what scientist advise.

There are many debates on the use of new genetic editing technologies, but science does not stop the improvement. New technologies like CRISPR can be very useful in modifying early stage human embryos in peri implantation period. In fact, there might be an alteration even before the human embryo implantation in the mother's uterus; this stage is called blastocyst. However, there will be some complications. CRISPR-Cas9 can definitely be a useful tool to test the function of prospective genetic pathways. Many of the approaches are being practiced on a well-known mouse, "Despite the widespread prevalence of human *in vitro* fertilization as a means of aiding infertile couples, we still know very little about the molecular events of preimplantation development, implantation and early placental formation in humans", says developmental biologist Janet Rossant who has dedicated much of her career to research on the mouse blastocyst. At the University of Toronto, she has been known for her role in establishing stem cell lines and advancing research on the mouse genome. Rossant emphasizes that molecular, morphological, and timing differences between mice and humans may play a major role in early pregnancy loss and influence the generation of pluripotent stem cells, which are crucial for advancing stem cell–based therapies.

According to Rossant, there are many practical hurdles to the potential of using CRISPR to study human embryo development. For example, many authorities prohibit the creation of human embryos. Many countries ban gene editing techniques that can potentially pass on to other generation. Nevertheless, researchers found ways of using CRISPR to make changes in human diploid zygotes. However, Rossant notes that these methods are still limited by less than perfect efficiency, as well as issues like

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mosaicism and unintended allelic variants, which keep their clinical use a distant goal.

In November 2018, a Chinese scientist named He Jiankui performed a disturbing experiment. Media from all around the world reported that Jiankui used CRISPR to engineer twin girls to make their DNA immune to HIV infection. He is confronted by a Scientific community and one of the Nobel laureates, David Baltimore stated, "There has been a failure of self-regulation by scientific network". The problem with a Chinese scientist editing genes is not the genetic engineering itself, but the use of it without scientific evidence supporting the safety of CRISPR-Cas9. Raposo reports that neither twin carried the intended 32-base pair deletion in the CCR5 gene; instead, each embryo displayed variants of differing lengths. Raposo says, "These novel mutations have not been previously shown to prevent HIV infection and may even be harmful. " It might cause a serious problem on the structure of human cells. The presence of original and edited cells will lead to a phenomenon called mosaicism, and off-target effects that could cause other unanticipated changes in the genome.

The boom from the scientific network has left only one thing in place - the precautionary principle. After Jiankui's experiment, many countries have banned genome editing in humans. However, a professor in medical law, Vera Lucia Raposo, states that research has not been completely banned. She claims, "It has been allowed when its aim has been to obtain additional data on the procedure's safety." We should not be in a rush. We recognize the need for caution - not only to avoid irreversible genetic errors, but also to ensure sufficient time to address the legal and ethical challenges that accompany this field.

Editing human genetics might be a big problem when it comes to being healthy and maintaining a strong immune system. Humans have an incredible immune system that can fight back and save the person. However, if we take a person with a transplant, everything turns to the dark side. The transplanted cells meet the originals, that initiates the immune response that leads to transplant rejections. As there is no effective way to fully prevent rejection, doctors try to reduce the likelihood of this issue by ensuring the pair are as histologically compatible as possible and by administering immunosuppressive drugs. However, "we can administer drugs that suppress immune activity and make rejection less likely. Unfortunately, these immunosuppressants leave patients more susceptible to infection and cancer" says Sonja Schrepfer from the University of California, San Francisco. The immunosuppressants can alone cause further problems.

After Jiankui revealed his study, a World Health Organization expert panel began developing guidelines for future CRISPR research and its ethical use. Scientists worldwide, including CRISPR co-inventor Feng Zhang, have urged a global moratorium on germline editing. As Jenny Straiton, editor at Future Science Group, explains, this would involve halting all ongoing germline editing projects until an international framework is established.

A Chinese scientist tried to implement new changes into twin babies which broke not only Chinese regulations, but also international ethical conventions. The issues raised include weak scientific value, excessive risks compared to benefits, improper ethics review, invalid consent from participants, and breaches of regulations. Besides these ethical issues, there are also off-target technical problems with CRISPR-Cas9 such as mutation, mosaicism, and on-target mutations with unwanted consequences. A researcher from the Dunedin School of Medicine at the University of Otago noted that off-target mutations may lead to defects, disabilities, or even cancer in some cases. Because these side effects are difficult to detect and evaluate, predicting, preventing, or managing their consequences remains highly challenging. Furthermore, these germline gene editing techniques may be passed onto other generation which might result in unforeseen effects. "Though there are different views on this, it warrants serious consideration, considering how many aspects of genome modification remain uncertain, and how much remains unknown about the nature of gene functioning." says Jing-ru Li, from Dunedin School of Medicine, UofO. There is still more research to be done. And as technologies develop, there should be discussions on how we are going to regulate it.

As genetic engineering technologies evolve, it is gaining the power to engineer desirable traits in humans. Danielle Simons, a senior research scientist at Stanford University School of Medicine, gives an example of a recent study. A team of scientists conducted genetic testing for muscle-related traits among volunteers in a resistance-training program. The test assessed whether individuals carried a genetic predisposition for muscle strength, size, and performance. Findings revealed that participants who received positive results were more likely to attribute improvements to their genetics rather than their own efforts, perceiving the changes as beyond their control. Thus, being aware of genetic background is important.

So called "designer babies", that has been included in the *Oxford English Dictionary,* has been raising debates for the past couple of years. According to Simmons, enhancements in embryos for trait selection raises moral issues involving both individuals and society. "First, does selecting for particular traits pose health risks that would not have existed otherwise?", she says, "The safety of the procedures used for preimplantation genetic diagnosis is currently under investigation, and because this is a relatively new form of reproductive technology, there is by nature a lack of long-term data and adequate numbers of research subjects. Still, one safety concern often raised involves the fact that most genes have more than one effect." For example, in the 1990s researchers identified a gene associated with memory. Altering this gene in mice significantly enhanced learning and memory but also heightened pain sensitivity. Dr. Simmons further raises the ethical question of whether parents should be permitted to modify their children's genes to select specific traits, given that the children cannot provide consent. What if a child grows up with strong muscles, but dislikes music? Would this affect the way a child feels about its parents?

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When it comes to genetic engineering, people ask a lot about what humans will be defined as such? The technology that we enjoy very much is not as valuable as our own biology. A technology and healthcare futurist, Jamie Metzl strongly believes, "Starting to see all of life, including our own, as increasingly manipulable will force us to think more deeply about what values will guide us as we begin altering biology more aggressively". According to Metzl, genetic engineering tools touch the source code of what it means to be human and therefore must be regulated. It is not easy to control them. Technology grows to the level where governments cannot keep up with the abilities of such tools.Meltz argues that to prevent harmful outcomes, each country should establish a national regulatory framework that aligns both with international best practices and with its own cultural values and traditions. "We also have to start developing global norms that can ultimately underpin flexible international standards and regulations." he says "We urgently need to start preparing for what is coming". One thing that humans have an advantage of and certain is that they are able to make appropriate decisions about their lives in ways that was impossible to do in the past.

The future is uncertain, but we must prepare for the worst. Genetic editing could easily shift from being a health or lifestyle choice to becoming a pill for survival. Meltz points out "It's not that hard to imagine future scenarios when humans would need to genetically alter ourselves in order to survive a rapid change in our environment...preparing responsibly for these potential future dangers may well require we begin developing the underlying technologies today."

The Hell scenario from *Radical Evolution* by Joel Garreau describes many things the genetic technologies can be used in the future. Genetic engineering is a complex process. "The genetic basis of human nature is not only so complex as to defy the best efforts of Mao or Pol Pot to shape it," (75) says Steven Pinker, a Harvard University professor. Pinker argues that individual genes rarely produce beneficial effects. For instance, no single gene determines mathematical ability or athletic skill, nor is there a "musical talent" gene—or simple genetic cures for conditions such as schizophrenia, antisocial personality disorder, or bipolar disorder. According to Pinker, the reality is far more complex, involving numerous genes interacting through feedback loops. He also stresses that predictions about technologies as intricate as genetic enhancement are highly uncertain, as they depend on overcoming technological, psychological, and sociological challenges.

In addition, Bill Joy, a legend in the computer programming and innovation industry, has some ideas about genetics, and scientists who are using them. He believes that scientists should control themselves, being extremely cautious about creating anything that can uncontrollably replicate itself. "Scientists do not believe they can do their work if they have to consider consequences..." he says, "Scientists and technologists must take clear responsibility for the consequences of their discoveries." (68) And it is true. No one knows where this GRIN technology will bring us. But there is only research that needs to be done in order to discover more about genetic engineering and its applications in humans.

II. CONCLUSION

Do we know enough about the human genome to understand the impact of making changes to it in the development of embryos? As new technologies become cheaper and faster, scientists are disturbed since it is not appropriate to use CRISPR technologies in clinical application in human embryos. Some people with a sufficient amount of wealth might want to do it. But they are only shouting "we are going to try it before we understand it." There will be many issues both technical and ethical. Unintended genetic consequences can turn off a gene very important to biological functioning. When this happens in human beings, it might actually create new genetic diseases; and the twin girls would have been genetically healthy. And since it is unstoppable, we have time and internal values to make correct decisions about how these technologies might affect our children and community.

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