Gene Editing of Human Embryos Using CRISPR/Cas9

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Honors Capstone

Gene editing of human embryos is an interdisciplinary topic regarding science, ethics, religion, socioeconomics, and law. The overall goal of gene editing for human embryos should be to treat genetically inherited diseases. This can be a questionable thing to do to a human both ethically and religiously. To make matters worse, gene editing of human embryos may potentially be used for cosmetic or physical reasons not pertaining to medical problems. There are many possibilities of harm to humans due to the current misuse and effectiveness of human embryo editing. The price of gene editing in human embryos may also be expensive, making it accessible only to the wealthy. In order for gene editing of human embryos to be acceptable, proper national and international laws need to be in place with scientific support that it is a safe thing to do. It would be ideal if the cost of using the technology was relatively affordable, yet this may not be attainable in the beginning due to lack of funding. Even with laws and science to support gene editing of human embryos, it will still be both ethically and religiously controversial. Overall, the lasting effects that gene editing of human embryos will have on the human race is unknown. There are many religious and ethical opinions against gene editing using Clustered Regularly Interspaced Short Palindromic Repeats/CRISPR associated protein 9, CRISPR/Cas9, due to its potential harm, cost, and the lack of knowledge pertaining to its effects on the human genome. However, extensive scientific research to perfect CRISPR/Cas9 methods and strict regulation of its use to treat genetically inherited diseases is necessary and will lead to health benefits that outweigh these current negative opinions.

CRISPR/Cas9 is a relatively new way to genetically engineer organisms. CRISPR/ Cas9 is a mechanism found in bacterial cells that is used to attack viruses as a defense mechanism. The Cas9 is a gene that encodes for a protein which cuts a specific sequence of double stranded DNA. In order for the Cas9 protein to know which area of the genome to cut, CRISPR has a

built-in guide RNA which guides the protein to the desired area. CRISPR leads the Cas9 protein to the area of the virus's genome that it wants to cut in order to stop the virus from doing any damage to the bacteria (Crossley 2018). Scientists discovered how this system works in the bacteria and realized that it can be applied to the human genome and other organisms as well. They decided to modify this function in bacteria in order to achieve the goal of cutting animal or human genomes by adding on the ability for it to correct the genome as well. Scientists can attach a different guide to CRISPR in order to pick which area of the genome that it targets so Cas9 can then cut the area that they want to edit. The desired sequence of DNA to replace the cut-out sequence is also injected into the cell so that it is available to be incorporated into the genome. After this is done, the repair mechanisms within the desired gene can fix the double strand break in the DNA and incorporate the new strand of DNA (Crossley 2018).

The specificity of the CRISPR/Cas9 mechanism is what makes it capable of treating genetic diseases that could be cured if certain sequences of DNA were altered. Some of the diseases that CRISPR/Cas9 has been tested on are, Barth syndrome effects on the heart, Duchenne muscular dystrophy, hemophilia, β-Thalassemia, and cystic fibrosis (Cai et al. 2016). CRISPR/Cas9 can be applied to developing treatment for these diseases but also to better understand the genetic implications of the diseases as well (Cai et al. 2016). This is due to the fact that the genetics of the disease must be extensively researched prior to developing a successful method to treat it with CRISPR/Cas9. Increased knowledge of disease is another benefit of gene editing outside of its desired impact to treat genetic diseases. Other classifications of diseases may also be able to be treated using CRISPR/Cas9 such as HIV and other immune system diseases which can be transferred from person to person or to offspring. Due to the nature of the CRISPR/Cas9 technique, the best human diseases it could treat would be those that are only caused by one

mutation in a gene (Cai et al. 2016). This would make targeting the specific area of the genome quite easy and only require CRISPR/Cas9 to fix. Diseases that have more than one area of the genome mutated would make it more difficult for CRISPR/Cas9 to effectively target all of these areas, however, it would still be possible. The number of genes that CRISPR/Cas9 would have to correct may also make the treatment more expensive because the treatment would be more complex. The number of genes that cause certain genetic diseases may unfortunately be a limitation for CRISPR/Cas9's use due to the difficulty in correction and increased price.

CRISPR/Cas9's use on human embryos still requires research since the creation of this new editing mechanism. So far, studies have shown that CRISPR/Cas9 is successful at editing the desired area of genes within the human genome (Herai 2019). It is important to know early on that it is possible for this technology to properly edit the human genome in the desired target area. The Cas9 protein has been shown to successfully target the CFTR locus involved with cystic fibrosis. This locus is a region of a gene that is involved with making a protein crucial for regulating mucus thickness in the body. This is the area of the human genome that is not functional in cystic fibrosis patients, so they do not have a working form of this protein. CRISPR/Cas9 successfully fixed the mutation in this gene and thus a functional protein was able to be made allowing mucus thickness to be regulated (Pellagatti 2015). This is an important study that shows the medicinal impact CRISPR/Cas9 can have on society. Cystic fibrosis is a genetically inherited disease that currently has no cure. If CRISPR/Cas9 has been shown to successfully fix the cystic fibrosis mutation, it would be extremely beneficial to continue testing it so it could potentially be use on humans. This study was performed using human adult stem cells (Pellagatti 2015), and the impacts it would have if it were performed on human embryos would be even more significant. If the gene editing occurred in the human embryo this would

allow the offspring to grow up without ever having to suffer from cystic fibrosis related illnesses. The main goal is that CRISPR/Cas9 "…targets a particular gene enabling the alteration of deleterious and disease-causing genes in certain genetic disorders. These are the changes in the germline intended to be passed on to the next generation so that the devastating and disease-causing genes can be eradicated forever" (Krishan et al. 2016). This would be the ultimate objective for diseases like cystic fibrosis, in order to prevent future generations from suffering from the disease. The methods to use CRISPR/Cas9 need to be refined and tested on the genetic diseases it will be used to treat in order for it to have this impact on society. However, the current research regarding its success so early on is indicative that this will one day be achieved.

More research needs to be done regarding how CRISPR/Cas9 may impact the areas of the genome it is not meant to target. Most of the studies that pertain to CRISPR/Cas9 now only focus on how it impacts the target area of the genome. New research has discovered that CRISPR/Cas9 may have "off-target" effects on the genome and other areas of the genome that were not meant to be targeted (Herai 2019). This is a problem because although the CRISPR/Cas9 may effectively fix the desired mutation, it may cause another one somewhere else in the genome. These problems are beginning to be researched more in order to develop solutions for the off-target effects. One potential way is to develop a "switch" for Cas9 to be turned off and stop the expression or formation of the cutting protein once the initial fix in the genome has been completed. This would prevent Cas9 from continuing to cause off target double strand breaks in other areas of the genome (Herai 2019). Other possible ways to stop off target effects is to first ensure that the target gene will be "suitable for the intended genetic manipulation" (Kimberland 2018). Another important factor that will help to reduce off target effects is to properly select a guide RNA that has a good "on-target cutting efficiency" and selectivity of the target gene

(Kimberland 2018). There are also certain Cas9 proteins that have been proven to be more precise in cutting the DNA strands which would reduce the chance of it cutting areas of DNA at off-target sites (Kimberland 2018). These are just some of the various techniques that can be implemented in order to increase the effectiveness of CRISPR/Cas9 and decrease the chances of it causing breaks in undesired areas of DNA.

Despite the potential for CRISPR/Cas9's effectiveness for editing the human genome, many people do not find editing the human embryo ethical . They believe that this technique will be abused and lead to the development of "designer babies" and that it is unnatural (Baumann 2016). This means that instead of using the gene editing technology to fix genetic disorders in human embryos, people will use it to give their babies desirable attributes. If "designer babies" became the goal of gene editing in human embryos, it would lead to a growing sense of inequality within society. The unedited people would feel inferior to the people who were edited to be more cosmetically pleasing. Using laws to regulate the usage of using CRISPR/Cas9 to edit the human embryo is something that can prevent this. Strict laws would be necessary to prevent using CRISPR/Cas9 to enhance physically attributes unrelated to genetic disease. This would eliminate the ethical problem of "designer babies" in regard to CRISPR/Cas9. Those from a bioethics background believe that gene editing of human embryos goes against the laws of nature no matter what it is being used for, and therefore should not be used. This is due to the fact that the universe itself has a natural order in which certain diseases belong and editing the human embryo defies this order (Baumann 2016). Using CRISPR/Cas9 to create "designer babies" would be an unnatural thing to do but using it to treat a disease would not be. This ethical opinion of CRISPR being unnatural can be applied to many medical procedures today, such as

abortion, as none of them are truly natural events. CRISPR/Cas9 should be treated as any other medical procedure that is used to treat a disease would.

Although there is hope for improvement of off target cuts when using CRISPR/Cas9, currently the editing of human embryos has not been shown to be significantly successful or efficient in several research studies (Baumann 2016). This is a problem because it's not ethical to use technology on humans that may potentially harm them. However, with more research these problems can be fixed. Scientists who are able to carry out research on human embryos are already working towards solutions for the various problems CRISPR/Cas9 is experiencing when editing the human genome. Once these problems have been fixed the ethical issues regarding its potential failure will be obsolete, yet there are still ethical issues that will remain with its success (Ormond et al. 2016).

A major issue that can arise from gene editing of human embryos once it is successful is how the technology may impact future generations that were modified without consent (Ormond et al. 2016). This ethical issue is not novel to CRISPR/Cas9, it can be applied to many medical decisions made today before and when a child is just born. Parents also have the right to make decisions for the child up until they are 18 years old which limits the freedom that children have in medical decisions as well. Besides this, it is hard to believe that a child would want to be born with a genetic disease that hinders their quality of life rather than without one. There is a major difference between, "non-existence and existence with a disability, which is not an exact parallel to comparing existence with and without genetic alterations" (Ormond et al. 2016). This is a very important point because although there are genetic alterations occurring when CRISPR/Cas9 is used, the overall result is curing a terrible disease. Therefore, when discussing the idea of

consent with CRISPR/Cas9 for this purpose it should refer to curing a disease rather than just genetic alterations.

Eugenics, the idea of creating a perfect race, is another ethical concern with CRISPR/Cas9 usage on human embryos. The ethical problems regarding eugenics truly arise when, "there is the potential for "enhancement" that goes beyond the treatment of medical disorders" (Ormond et al. 2016). This problem is not relevant to CRISPR/Cas9 if it is only used for fixing inherited genetic diseases. Previously in the United States those with mental disease were deemed unfit to reproduce, therefore eugenics was promoted through sterilization (Fischer 2012). In the case with CRISPR/Cas9, these people with inherited mental illnesses would still be able to reproduce because CRISPR/Cas9 would be used to fix the mutation in the human embryo. CRISPR/Cas9 would just be used to treat these diseases like any other medical treatment that exists today. Strict laws would need to be in place pertaining to how CRISPR/Cas9 could be used to ensure that the ethical concern of eugenics is not a problem. It would also be impossible to use CRISPR/Cas9 to perfect every imperfection in the human race. As mentioned before, it would be difficult to use CRISPR to treat diseases caused by many genes. In order for it to promote the idea of eugenics it would have to be able to eradicate every genetic disorder or imperfection to exist.

Countries such as Belgium, Sweden, the United Kingdom, Slovakia, Germany, Austria, Italy, Ireland, the United States, and China currently have inconsistent laws regarding the research for CRISPR/Cas9 which influences how they ethically perceive it. Actively doing research is necessary to perfect this technology to edit the human genome and thus improve how society perceives it. Research and the results from the research influence the public's opinion on the new technology that could potentially be introduced into the medical field. The research that is

actively being done to test the usage of CRISPR/Cas9 is performed on embryos that cannot be used to produce viable offspring. Belgium, Sweden and the United Kingdom are more open to gene editing of non-viable human embryos, whereas Slovakia, Germany, Austria and Italy are against it. This reflects how culture also influences the opinions towards CRISPR/Cas9 and the laws that apply to its usage in various countries. The countries that allow gene editing on human embryos are Belgium, Sweden and the United Kingdom. Whereas Slovakia, Germany, Austria, and Italy are very opposed to using human embryos for gene editing. Other countries, such as Ireland, have no regulation on gene editing of human embryos (Kosilkin & Kalinichenko 2019). The United States and China also do not have specific laws that regulate human germline gene editing, which is the editing of genes that may be inherited (Baumann 2016). Although they do not have a law regarding gene editing of human embryos, "…any attempts to establish such a pregnancy would require the approval of the U.S. Food and Drug Administration, and any clinical use is prohibited by the Chinese Ministry of Health guidelines" (Baumann 2016). Therefore, it would be unlawful to edit a viable human embryo in these countries to create a pregnancy. The countries that have more experience researching with CRISPR/Cas9 are more likely to have more experiments where it has been successful. As a result of this, these countries may have a more positive opinion towards the new technology. In the countries where the research is not allowed, the public may not trust the technology due to the lack of scientific research to support its potential health benefits and usage. The different cultures, government, and religious background of these countries may hinder their likelihood to support gene editing of human embryos. However, if research is very successful using CRISPR/Cas9 it may alter their opinions in order to benefit society. Research plays a major role in determining how the society will view the effectiveness and impact of CRISPR/Cas9. It would be beneficial to have

international laws that regulate the research of CRISPR/Cas9 to be consistent throughout the countries (Kosilkin & Kalinichenko 2019). This would allow the countries to collectively work towards the same goal of researching CRISPR/Cas9 in order to improve its effectiveness. Moreover, it would be beneficial to oversee the research that every country is doing to develop an overall consensus about where the current research is at for CRISPR/Cas9. The international regulation would also help to ensure that each country is properly using CRISPR/Cas9 and that no one is attempting to use it to create cosmetic changes.

The effectiveness and success of gene editing is something that could be fixed with more research and experimental trials on animals. However, federal funding is something that gene editing research relies on. Governments have not been providing federal funding in order to limit the research and experimental trials for CRISPR/Cas9. This is a way that governments have been regulating gene editing (Dohn 2019). It is argued that instead of limiting funding to regulate gene editing, the United States government should provide federal funding for human embryo editing for better regulation. If the government provides funding, it will allow the research to be under full scrutiny of the public and the National Institutes of Health (NIH) regulations. Right now, the research that is being done is not subject to these specific regulations and this may lead to more ethical problems (Dohn 2019). If the research is not uniformly regulated throughout the U.S. by the NIH, some intentions may be to promote “designer babies” rather than the correction of genetic disease. Currently, there is only one law in the U.S. that relates to “heritable genetic modification”, and the purpose of this law is to restrict federal funding to human embryo research (Dohn 2019). With any new scientific technology, people argue similar things referring to the unnatural aspects of the procedure. Nevertheless, the technology continues to be used and researched until it is accepted by some (Baumann 2016). The United States should provide

federal funding for research on human embryo editing in order to prevent the research from going elsewhere and for the wrong reasons (Dohn 2019). The United States funding for CRISPR/Cas9 research on human embryos is essential due to the many benefits it will provide. However, before federal funding can be approved, further research to prove the benefits of CRISPR/Cas9 is needed for policymakers to develop laws and guidelines pertaining to the technology. This will ensure that policymakers understand the true impact CRISPR/Cas9 will have on society and the applications of the gene editing mechanism that need regulation (Gutmann & Moreno 2018).

CRISPR/Cas9 was unethically used when a Chinese scientist, He Jiankiu, edited two human embryos that were born with an edited CCR5 locus to provide HIV resistance. This scientist did this unlawfully, unethically, and in secret which is currently causing many people to push for more laws regarding CRISPR/Cas9 usage (Enriquez 2019). Although he did it unlawfully, perhaps if China enforced their laws more strictly to regulate gene editing this would not have happened. People want to ban the usage of CRISPR/Cas9 after the unethical actions of Jiankiu, “But criticisms of the potential use of human germline genome editing clinical applications vastly overlook the advantages of germline modification…” (Enriquez 2019). Implementing stricter laws for CRISPR/Cas9 would be better than to just ban the research all together. The ideal foundation of law regarding use of CRISPR/Cas9 would be to permit the use of the technology to cure genetic diseases, and to prohibit the use of it for “cosmetic or enhancement purposes; and uses involving modification of traits that raise concerns of discrimination already prohibited the law” (Enriquez 2019). Therefore, the laws that should be implemented for the use of CRISPR/Cas9 should support the idea that it is a technology to be used for medicinal purposes only. Currently the laws regarding gene therapy do not apply to

germline gene editing, which is the editing of hereditary gene. The Food and Drug Administration will have to acknowledge this when developing regulations for CRISPR/Cas9 and recognize that germline gene editing (GGE) is different than the current gene therapy available now (Enriquez 2019). The FDA cannot ignore the potential cosmetic use for CRISPR/Cas9, and they must develop laws that prevent the use of this technology for these reasons. If the FDA does not recognize this when developing new laws, the cosmetic use for CRISPR/Cas9 may, "fall beyond the agency's regulatory reach" and they should "assert authority over the regulation of all type of GGE products" (Enriquez 2019). Regulation of all types of germline gene editing by the FDA will ensure that it will not be used for cosmetic purposes, and that it will only be used to treat genetically inherited diseases.

It is necessary to develop laws about the use of CRISPR/Cas9 in order to limit the ethical problems that may arise from its use, but religious beliefs reflect yet another opinion. Many people are concerned that gene editing of human embryos, "will play god and precipitate backlash from nature that could be devastating" (Peters 2017). This concern relates more to using CRISPR/Cas9 to create cosmetic enhancements. Limiting the usage of CRISPR/Cas9 to genetic disease should not categorize it differently than any other medical treatment for a disease. CRISPR/Cas9 does not "play God" any differently than the artificial medical treatments or procedures that exist in the world. Other theologians are concerned "that genetic manipulation might violate the divine image in the human species" (Peters 2017). However, it only changes the human health of the populations. This should not qualify as violating god's image in humans:

> …if gene editing has the potential for improving human health…. then the divine image of God at work in us will lead us to toward embracing CRISPR's benefits. If we think of human society as the divine image on earth, then our creative advance in human health and ecological health through advancing medical technology would be a morally fitting expression of that divine image (Peters 2017).

Using CRISPR/Cas9 would ultimately be an expression of the divine image currently in humans to promote health and the overall common good. This technology should not be considered to violate god similarly to how other technological advances do not. All religions do not have the same belief towards technology, but regarding God in relation to human nature, CRISPR/Cas9 should not be a problem. This is true only if researchers and scientists do not abuse the technology. Pope Francis, for instance, believes that gene editing is not bad as long as the technology is not used to manipulate the genome without good reason (Francis 2015). There is no reason that the human genome should not be allowed to be genetically edited in order to improve the wellbeing of society (Peters 2017). With the separation of Church and State in the United States, the government will have to properly regulate the usage of CRISPR/Cas9 so that its applied only to genetic diseases in human embryos. This will ensure that the Church continues to support the usage of CRISPR/Cas9 and the betterment of society.

Upon the success of CRISPR/Cas9 with the laws to regulate it and extensive research, the cost of its use will become the next concern. If the technology is expensive this would lead to problems for lower income families. At the beginning of its release, "CRISPR-based products, such as gene therapy, are likely to be costly" (Baumann 2016). This would make it difficult for everyone to access the health benefits it could provide. Fortunately, most of the CRISPR/Cas9 research funding comes from the government. This means that everyone paid for the technology's extensive research in order for it to be effective. The government used society's tax money to fund CRISPR/Cas9, therefore, they should not be allowed to deny certain people in society access to its health benefits (Brokowski & Adli 2019). Despite this, CRISPR/Cas9 will likely be expensive upon release to society. There may be potential for the price of it to decrease overtime, but this is not commonly seen with current gene therapies in use today. A potential

way to fix this problem would be, “future investments in genomic research and the health care system in order to create and deliver benefits for society as a whole” (Baumann 2016). This would hopefully decrease the price of CRISPR/Cas9 for the entire public upon its release. Besides this, in order to diminish the cost of CRISPR/Cas9 the types of genetic diseases that it can be used to treat can be limited to the most common ones. If many people are impacted by the genetic disease it would increase the likelihood of funding for the companies and make CRISPR/Cas9 cheaper to use on the public (Baumann 2016).

The implementation of CRISPR/Cas9 into the medical field still requires extensive research and guidelines as time advances. However, this new genetic technology has the potential to greatly improve the health of society overall. Once the methods to use CRISPR/Cas9 on human embryos have been perfected to their maximum success, several genetic diseases will be curable. This is a major feat in medicine because most of the diseases CRISPR/Cas9 can be used to treat currently have no cure. Editing genetic diseases out of an embryo will ensure that from birth the human being will not have to suffer from a horrible genetic disease. This is another benefit from using CRISPR/Cas9 on human embryos, because it will diminish the amount of time the person has to suffer from their genetic disease. Most of the negative opinions towards CRISPR/Cas9 refer to the results from previous and current studies. These studies are a work in progress to perfecting CRISPR/Cas9 and cannot be used to fully determine the ethical implications of using this technology on humans. It will take many more research efforts, experiments, funding, and laws to truly grasp how ethics can apply to using CRISPR/Cas9 on human embryos. The technology has been shown to be successful in some research studies and this cannot go unnoticed so early on in its development. Time will provide researchers to fix the problems that are causing ethical strife, such as lack of effectiveness. More government

regulation of CRISPR/Cas9 will ensure that it is used for the proper reason, to treat genetically inherited diseases, rather than for cosmetic reasons. It will also ensure that scientists do not unethically use the technology on viable human embryos so early on in the research stage. Laws that regulate CRISPR/Cas9 on a national level are important, but so are those on an international level as well. International regulation would be crucial for research advancement by unifying nations, thus maximizing the potential success of the technology. After this is all achieved, the success of CRISPR/Cas9 will depend on how it is made available to the public. The most common inherited diseases should be deemed most important for its use, and this will help to diminish cost of treatment. Once CRISPR/Cas9 is made accessible to all people who can benefit from it, the positive impacts it will have on these people and their offspring will outweigh any current negative outlook on the technology.

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