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AN ETHICAL FOUNDATION FOR GENETIC THERAPY AND GENE EDITING (CRISPR)

A Dissertation

Submitted to the McAnulty College and Graduate School of Liberal Arts

Duquesne University

In partial fulfillment of the requirements for
the degree of Doctor of Philosophy

By

Nikolija Lukich

May 2021

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Nikolija Lukich

2021

AN ETHICAL FOUNDATION FOR GENETIC THERAPY AND GENE EDITING (CRISPR)

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ABSTRACT

AN ETHICAL FOUNDATION FOR GENETIC THERAPY AND GENE EDITING (CRISPR)

By

Nikolija Lukich

May 2021

Dissertation supervised by Dr. Gerard Magill

There are many steps involved in the process of introducing CRISPR-Cas9 into the current health care system. This dissertation provides an ethical foundation for the uses of CRISPR-Cas9 genetic therapies and editing techniques, which organizations can utilize when implementing these new technologies. Multiple components must be examined, including the practical application of the concept of autonomy, which benefits from the inclusion of personalism and care ethics as it aims to provide a more effective method upholding the right to independent decision-making. In addition to individual considerations, population-based decisions and public health tools are explored, connecting the human right to health care with the challenges that are experienced in implementing an expensive treatment. These considerations are especially important when working with vulnerable populations in research, as well as when genetic therapies are used at the beginning and end of life, when patients can be most at risk. Reflecting on how an organization currently implements new technologies as well as Pre-Implantation Genetic Diagnosis, is immensely useful and can provide further guidelines when

considering genetic editing. Taking practical implications into account is crucial so that organizations can begin the process of considering their use of CRISPR-Cas9 and the education of stakeholders. The dissertation also mentions fears about future uses of genetic editing, which could allow individuals to enhance their unborn children and promote transhumanism and eugenics.

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Chapter 1: Introduction

With the advances being made in genetic therapies and genetic editing techniques involving CRISPR-Cas9 technology, health care organizations are faced with the task of safely and ethically making decisions about and using these interventions. The thesis of this dissertation is to present an ethical foundation for genetic therapy and gene editing (CRISPR) that organizations can utilize to guide decision making.

The ethical foundation is presented in chapters two to five in which key aspects of bioethics that must be considered when engaging genetic interventions are discussed. Chapter two will discuss the principle of autonomy and the important requirements that need to be met in order to accept a patient's or a substitute decision maker's autonomous decision. Chapter three will review population health resolutions that reflect public health needs. Chapter four will explore the methods by which vulnerable populations and those who cannot consent for themselves are approached for research. Specific religious considerations contributing to vulnerability in decision-making will also be discussed. Chapter five will explore the integration of clinical and organizational issues in genetics. Finally, chapter six will describe the future of genetic therapy and gene editing in order to explain the implications that CRISPR-Cas9 has for human enhancement and transhumanism.

When an advancement in science is announced, it generates excitement, as well as doubt. Research is conducted before a new technology or intervention is implemented within the medical field, and if the findings are generally positive, society accepts the advancement as a new step toward curing disease or furthering our knowledge of medicine. Few discoveries have sparked as much controversy and enthusiasm as the CRISPR-Cas 9 tool has recently, both for its uses in genetic therapies as well as genetic editing. Particular attention was paid to the CRISPR-

Cas9 tool due to a Chinese scientist's admission to using the tool to edit the genes of an embryo resulting in the birth of genetically-modified twins, a feat never accomplished before.¹ Currently, much of the literature about CRISPR-Cas 9 falls into one of two categories: scientific research or predictions and high-level philosophical discourse often leading to the discussion of eugenics. Both research and discourse are valid and necessary as they will continue as genetic therapies and editing techniques using CRISPR become a real option for health care patients. This dissertation aims to provide guidance to organizations undertaking the implementation of these new practices, and sets to provide foundational information which considers various ethical and practical aspects of this new technology.

The scientific literature on this topic is abundant due to ongoing research studies and clinical trials being conducted around the world. Investigations have described CRISPR-Cas9 and the impact that it has had on specific diseases. Many genetic therapy projects have been allowed to proceed because they involve somatic cell therapies, as opposed to others that affect the germline. The process of how CRISPR-Cas9 can edit a genome will be explained briefly in this dissertation. While many studies demonstrate the positive outcomes of this new technology, other experiments have garnered intense criticism. In 2018, a Chinese scientist, (He Jiankui, 2018) made headlines after announcing that he had modified the genome of two embryos, and allowed them to gestate until babies could be born. The concept of modifying an embryo's genome is forbidden around the globe, and the research that emerged was met by collective shock and criticism. Many ethical questions were raised, not only about that particular scientist, but also about the idea of the door now being open for genetic editing to proceed. Currently there is a gap in the literature with regard to how an organization or community should consider the eventual provision of this type of medical service.

This dissertation acknowledges that genetic editing and therapeutic techniques are occurring and will one day be a possible option for many patients. It will take the information acquired from the scientific research and combine it with ethical analysis in order to establish how the introduction of these techniques can be acceptable and effective. Ethicists debating the implementation of CRISPR-Cas9 either argue that it can be used as a helpful technology to reduce disease prevalence and further the control we have over our own genetics, and, by extension over humanity, or focus on the negative consequences we could face as a society if and when the use of CRISPR-Cas9 extends to modifying germ lines. Once the technology becomes available, it is commonly predicted that it will result in a resurgence of the eugenic movement, which promotes, in turn, to the creation of a morally superior human race based on ‘superior’ traits. As a result, the concept of humanity would have to be re-examined and human rights may have to be modified within a eugenic framework. Furthermore, vulnerable or impoverished populations would see the gap between themselves and the wealthier class widen.

Although these concerns are valid and potentially realistic, we cannot ignore that the use of CRISPR-Cas9 is increasing among scientists and researchers, and will continue to evolve and demonstrate further benefits. With the recent development of work in China described above, organizations and societies must be prepared to determine the best way to implement these new technologies. This dissertation will provide that foundation which will include considerations regarding how vulnerable populations are included in the discussion, and how organizations determine and align their values to the implied goals of genetic therapies and editing techniques. It is expected that the dissertation will contribute to the ongoing discourse in this subject area and provide a practical approach to considering and implementing this new technological advance.

Introduction

Scientific developments have now presented the health care field with the possibility of genetic editing for both humans and embryos. Although science is a long way from perfecting the techniques involved, ethical analysis that focuses on a practical approach to healthcare implementation must be conducted as soon as possible, so that both patients and medical professionals will be prepared to deal with this new breakthrough once it is safe to use. Numerous issues, such as decision-making, public and population health, and vulnerable patients in clinical practice and research, must be considered in order to gain an extensive understanding of how genetic therapies and genetic editing will affect them. Techniques such as Pre-Implantation Genetic Diagnosis and the implementation of research studies using CRISPR are already being employed, and it is crucial that the medical field examines how the ethical implications of these practices affect patients, families, staff, and society.

Chapter 2: Autonomous Health Decisions

A: Relational Decisional Autonomy

It has been determined in Western health care that patients who receive medical care have the right to autonomy.² This translates into capable patients being able to make their own decisions regarding their health care. These choices must be respected, even if a medical professional disagrees with them.³ Autonomy is best manifested when a patient provides informed consent. It is important to recognize that autonomy in the context of health care is a negative right, in that a patient can either give consent or refuse it when offered a particular medical intervention. This right does not, however, always give patients the opportunity to demand a specific treatment.⁴ With regard to genetic editing, for instance, the possibility for patients to request this new technology as a treatment may become more common, blurring the line between the positive and negative aspects of the right of autonomy.

Informed consent is considered to be valid when a capable patient provides it. A capable patient is able to understand the treatment options available to them, and appreciate the impact that their choice would have on their individual life.⁵ A physician or other health care provider is responsible for determining whether their patient is capable of making decisions, and to evaluate their ability to communicate their choices.⁶ In situations that deal with sensitive and controversial information, such as those considering the use of new genetic therapies or editing techniques, the relationship between a physician and their patient is crucial. It would be beneficial to apply the concepts of personalism and care ethics to these relationships to demonstrate the ideal manner in which to foster a positive relationship between a patient and their health care provider. Positive and open relationships lead to better healthcare, proving the need for the examination of the ethics of care and its utility.⁷

If a patient lacks the capacity to make their own autonomous decisions, a substitute decision maker (SDM) is appointed to make choices on their behalf and provide consent when necessary.⁸ SDMs are frequently spouses or family members, or individuals who have been assigned Power of Attorney by the patient while they were still considered to be capable. It is crucial for substitute decision makers to understand the nature of their role, and to think about the patient's choices as opposed to their own. SDMs are required to provide consent for treatments that are in accordance with previously-expressed wishes of the patient, or make decisions that are in the patient's best interest. How best interests are determined can vary from person to person, especially when a physician and a SDM, or patient, disagree with each other.⁹ When discussing genetic therapies and editing technologies, for instance, SDMs must be very careful when providing consent on behalf of an incapable patient. They must have detailed

conversations with the medical or research team to ensure that these types of interventions would satisfy the goals of the patient, and would be in line with the patient's core values and beliefs.¹⁰

B: Parental Decision Making for Children

Children are typically considered to be incapable patients due to their inability to appreciate many of the choices surrounding medical care. In the United States, the age of consent is 18, with the exception of some situations in which the age of consent is lowered for mature minors.¹¹ In other countries with similar health care principles, such as Canada, specifically in the province of Ontario, there is no formal age of consent, but children are often deemed incapable at a young age. When children are considered to be incapable, their substitute decision maker is usually one or both parents. A relationship between a parent and their child's physician should be the same as that between a doctor and their patient. Health care providers who need to get consent for treatment must still discuss all relevant information about a child's diagnosis, prognosis and treatment.¹² A parent has an autonomous right to make decisions on behalf of their child which are in their best interest. Providers need to always practice caution when accepting consent from parents. Even though it is assumed that parents will make choices that are in the best interest of their child, and are able to make decisions that comply with their child's lifestyle, that may not always be the case.¹³ Issues arise when there is a disagreement between a child and their parents regarding a medical decision. There are methods that physicians can employ to attempt to come to a consensus, but providers must always consult the appropriate legal guidelines in order to determine whose choice to follow.¹⁴

Another aspect that frequently influences parental decision making, particularly with regard to experimental treatments, is the family's economic status. In the United States, health

care is not ‘free’ and parents may have to determine if they can afford their child’s medical care.¹⁵ Other needs, such as buying groceries or paying home bills, may take priority over health care, resulting in inadequate access to medical services.¹⁶ Poverty and other socioeconomic factors, however, cause more than just financial problems, and providing necessary health care to children has become an important priority to health care systems, global organizations.¹⁷

Added pressure for parents comes with having to decide about the life of an unborn child. When undergoing genetic testing, or procedures such as amniocentesis, future parents are typically seeking information that will help them make a decision about their unborn child’s medical care.¹⁸ Parents could also choose preventative measures, such as Pre-implantation genetic diagnosis to ensure that their future child is not subjected to living with a particular disease, such as Huntington’s.¹⁹ Any form of seeking information or risk management in which parents engage is a form of non-maleficence and beneficence. Their main goal is to reduce or eliminate harm, and thereby, increase the benefit that a child experiences.²⁰

It is important to recognize, however, that parents who choose to undergo genetic testing or therapies for their unborn children are imposing their own values onto their children, which may be very stressful for a parent.²¹ Added stress occurs when parents are faced with choices that go beyond disease prevention. With new genetic editing technologies becoming more popular and accessible, parents may be presented with the option of manipulating their embryo’s genome to enhance certain traits that would ideally benefit their child.²² While some parents may choose to edit whatever they can, other parents may feel selfish for choosing and imposing their own opinions of what is beneficial on their future children.

Chapter 3: Population Health Decisions

A: Right to Health Care across Populations

Whether new and innovative technologies that may be able to cure disease and prevent it should be available as part of any citizen's right to health care may be open to discussion. While a new technique may be accessible in certain hospitals, for example, its cost may prevent most people from being able to afford it. It may be more beneficial for a country or government to focus on ensuring that all of its citizens have access to basic health care resources, and to reallocate their funding for this purpose, rather than provide more services to a smaller number of people. A government or policy maker has to decide how to either reduce the cost of procedures while maintaining a high level of quality, or only allow those individuals who can afford expensive medical care to attain these services.²³ Therefore, it may be determined that humans have a right to healthcare, but not a universal right to costly treatment. While cost plays a significant part in how individuals access health care resources, standards of healthcare need to be determined by each country, since it seems to be impossible to create a universal level of healthcare.²⁴ Each country or region must base their decision on the amount of money, the number of resources and staff that are available, as well as accessibility when determining the standard of health care that will be available to all of its citizens.²⁵

While genetic editing tools can be immensely helpful for parents in order to identify anomalies or improve the life of their unborn child, there are significant hardships in accessing these tools.²⁶ Access and affordability can be difficult features to deliver for any new technology or treatment, especially while they are still in experimental phases. Accessibility and affordability of health care in general is an ongoing problem in the United States, even though it is agreed upon that health care is a basic human right. The WHO released its definition of health as complete physical, mental, and social well-being and not merely the absence of disease and

infirmity.²⁷ This definition is morally pure and ideal, but may not be totally realistic in all parts of the world, due to factors such as poverty, economic distress, or environmental concerns. The same issues still exist in developed countries, as well, and are cause for concern. As a result, medical tourism may increase, which entails people from developed countries seeking care in countries that provide care at a lower cost.

B: Disease Prevention across Populations

As explained previously, new genetic therapies may be used as preventative measures for individuals who wish to eliminate a certain disease from their genome. Disease prevention has been practiced throughout the world in diverse ways, and while this new technology varies in terms of what it targets, it accomplishes the same goals as other methods of prevention. Public health interventions exist in order to reduce or eliminate the prevalence of serious medical conditions and to promote a healthier society, making prevention the highest priority for public health units.²⁸ Numerous diseases have become easily preventable with ongoing scientific innovation. For example, vaccinating young children can avoid fatal illnesses, such as polio and rubella, and increased awareness and screening capabilities can catch cancer early, leading to better health outcomes. While a government may have a goal of curing diseases, it would be equally beneficial to invest in disease prevention efforts which would preclude many individuals requiring curative measures in the future. This would ultimately benefit individuals physically, and society, economically.²⁹

Disease prevention techniques have been successful in improving the health of a population. However, it can be challenging to decide how to implement these efforts, and to determine who is responsible for doing so. Public health inherently focusses on a community,

which removes any individual decision-making, and considers how to collectively improve the health of a large group of people. Public health efforts are frequently considered to be paternalistic and employ the ethical theory of utilitarianism, which promotes the best outcome for the most number of people, or whatever is best for the greater good.³⁰ This implies that individual citizens should be required to do what is best for all those around them, such as receiving a flu shot in order to encourage herd immunity.³¹ Nonetheless, we live in a culture deeply rooted in autonomy, as explained previously, which usually results in individuals making choices that only affect themselves.³² In order to balance an individual's interests with those of their community, libertarian paternalism, or a paternalistic "nudge" may be exercised. This is a theory that values the autonomous rights of an individual to make their own decisions, but also includes a small level of government influence that takes into account the overall best interests of a community.³³

The potential to use genetic therapies as a preventative measure is still in its early stages, but perhaps public health officials and agencies should begin to consider how they might use these technologies to benefit the community as a whole. Since techniques, such as PGD and the use of CRISPR are solely focused on individual concerns at the moment, it will take some time to be able to make the use of these procedures common and accessible enough to eliminate diseases or disabilities from an entire community.

Chapter 4: Vulnerability in Health Decisions

A: Vulnerability in Research Subjects

With any new technology or treatment, research and clinical trials must be conducted to ensure the safety and efficacy of the intervention.³⁴ Individuals who consent to research are

inherently vulnerable, since they are accepting a reasonable or sometimes high level of known possible risk with no guarantee of benefit.³⁵ While clinical trials are subject to rigorous process to ensure safety, there must be additional safeguards in place to monitor the level of risk and the response from participants along the way. This is especially true when conducting research on vulnerable populations, such as children, the elderly, or disadvantaged individuals.³⁶

In order to address the inherent vulnerability of taking part in a clinical trial, researchers must obtain informed consent from the patient or their SDM, the same way that consent is required for a medical treatment. Participants must understand all of the potential risks and benefits associated before providing consent.³⁷ When conducting a clinical trial, an investigator must also explain how the experimental treatment may specifically affect the patient, both physically and mentally.³⁸ Informed consent makes it evident that a respondent or their substitute decision maker has made an autonomous decision to participate in research, based on all the required information having been provided.³⁹ By offering their consent, a research participant indicates that they fully understand any possible harm that could occur and that they are able to appreciate the purpose of the research as well as the possible impact of their contribution.⁴⁰

Another factor that affects the vulnerability of research subjects is whether a positive and trusting relationship with their researcher is in place. An investigator has an obligation to communicate with trial subjects in a manner that makes information meaningful and clear, since they may not have the same understanding of the purpose and benefits of the study. In addition, a scientist has the duty to present significant and troubling risks for participants. By demonstrating that a risk-benefit analysis has been done, the researcher can predict safe and ethical research, and assure their patients that vigorous preparation was undergone in advance.⁴¹ The success of high risk research, where the results are unknown, depends significantly on a positive and honest

relationship between the physician and their patient, or the researcher and their subject.⁴² Maintaining communication and sharing progress demonstrates to the participant that their vulnerability is known to the researcher and that it is being considered throughout the clinical trial.⁴³

Particular populations are more vulnerable than others, either because of their inability to consent to participation, or because of their current life circumstances.⁴⁴ Examples include pregnant women and economically-disadvantaged populations. These groups deserve to be part of research that may benefit them, although they are often excluded due to their vulnerabilities. In the case of pregnant women, they will be the target population for some genetic research when it eventually involves fetuses.⁴⁵ Additional safeguards must be put in place for this population in order to ensure safety as much as possible. In this situation, the relationship between the researcher and a pregnant woman should be a strong and trusting one, which leaves no doubt that both the woman and her unborn child will be cared for.⁴⁶ It can also be difficult to conduct studies with minorities and ensure that the research remains ethical. Usually, minority populations experience a lower quality of care, poorer healthcare outcomes, and have less access to health care than normalized populations, making it the mission of research to learn why these inequities occur.⁴⁷ Improvements that could be made in order to encourage economically disadvantaged populations to take part in research include simple modifications to a research study to ensure that all participants feel comfortable. This can include simpler language explaining the medical facts, or translating the information into other languages.⁴⁸

Additional safeguards must be put into place with vulnerable populations who are not capable of making their own decisions, such as children and patients with dementia. Both of these populations have the same rights as capable patients do.⁴⁹ They are able to autonomously

withdraw from an experiment at any time if they feel uncomfortable, and they are not required to provide a specific reason.⁵⁰ In these situations, substitute decision makers must be well-versed in the risks and benefits of a study and how it could impact their loved one. Along with their medical status, the patient's values should also be taken into account.⁵¹

B: Vulnerability at the Beginning and End of Life

Individuals at the beginning and end of their lives are more vulnerable, mostly due to their inability to make decisions and care for themselves. The requirement for a substitute decision maker to make choices on behalf of a patient increases, which amplifies the vulnerability of the incapable patient, since they cannot speak for themselves and an autonomous wish directly from the patient cannot be heard.⁵² When discussing these populations in the context of decision making for genetic editing or genetic therapies as research or treatments, certain factors influence how choices are made, as well as the reasons behind them. The substitute decision makers have to carefully consider them to ensure that appropriate choices are being made – choices that are in line with previously expressed wishes or values, or that are in the best interest of the patient.

A patient or SDM is often influenced by their religion when making decisions about the beginning and end of life. Islam and Catholicism, specifically, have very clear directives regarding procedures at both of these times, which can guide the choices that are being made by patients or SDMs. Parents, for example, may have to consider terminating a pregnancy for a variety of reasons, and would turn to their faith for guidance. Islamic and Catholic views outline how to proceed in these scenarios, as well as what exceptions can be made. They also have detailed discourse regarding when a life begins, which could assist a couple in making a decision

that is in accordance with their values. Both of these religious doctrines can also provide some information on the acceptability of genome editing, particularly using embryos. Since IVF is strongly prohibited, the use of embryos for research, or in the context of Pre-Implantation Genetic Diagnosis (PGD), it is implied that genetic editing would also be condemned. However, there may be an opportunity to eliminate the need for some abortions if this technique was more widely accepted.

These religions also have extensive beliefs pertaining to the end of life, and can further assist patients and families when making choices about death. In particular, SDMs for patients nearing death typically have more information on which to base decisions, as most family members are aware of their loved ones' values, wishes and religious beliefs. Sometimes this is not the case, however, and a choice has to be made that is in the best interest of a patient. At the end of life, there is always caution taken not to hasten death, so that an individual is not tasked with being responsible for another's death, but rather that a patient either dies naturally or on their own terms (in the case of withholding or withdrawing treatment). The ability to choose one's own terms by which to die extends to the practice of physician-assisted death that is available in some states. Currently, a patient must be capable to choose this procedure, but in the future, incapable patients may be able to indicate in an advance directive that they would like a loved one to decide for them to die. Physicians are generally against this provision, since it is always difficult to predict what one's own wishes will be in the future.

Genetic therapies and editing techniques may be able to solve some of the issues that patients or their substitute decision makers face in the situations described above. These therapies may be able to correct an anomaly in a fetus or slow the progression of a fatal disease, making the choices easier for an SDM. Genetic therapies and technologies may be able to alleviate guilt for

parents who are faced with a known genetic anomaly. For example, if a couple knows that their unborn fetus has a particular genetic disorder, they may be able to correct the abnormality before birth, thereby avoiding the need for abortion.⁵³ This may require a religious couple to make a compromise and use artificial reproductive techniques. At the end of life, it is difficult to implement any sort of reversal process for aging, but a genetic therapy may provide hope to a patient that is dealing with a serious illness. An adult with cancer who previously believed they were facing a death sentence, may be able to be treated using a genetic therapy, which would prolong their life and cure their disease. Genetic therapies would not address the vulnerability of these populations, but they would provide assistance to patients and families when making decisions, and ensure that autonomous wishes would be upheld as much as possible.

Chapter 5: Integration of Clinical and Organizational Issues in Genetics

A: Clinical Issue: Pre-Implantation Genetics Diagnosis (PGD)

A procedure that is being used more frequently in medicine is Pre-Implantation Genetic Diagnosis (PGD). Pre-implantation genetic diagnosis is a technique used to examine an embryo's genes ex-vivo, in order to identify whether it carries a gene for a specific disease.⁵⁴ Often PGD is used when parents have an autosomal recessive or X-linked disorder, a familial history of one, or when mothers are over the age of 35. In all of these examples, parents want to know that any of their future children will not have the same disease or will be healthy.⁵⁵ PGD is carried out using of In-vitro Fertilization (IVF).⁵⁶ In most circumstances, a specific disorder is being targeted, and if an embryo is shown not to contain a gene that codes for that illness, it will be implanted into the uterus, with the certainty that the child will not have the disease.⁵⁷

When using PGD, the autonomy of both the parents and the unborn children should be considered. An embryo is unable to communicate its wishes, therefore, informed consent from the embryo's perspective cannot be provided. There is also a question about whether an embryo is considered to be a person with rights, and, as such, have moral status.⁵⁸ As a result, the autonomy of the parents is most relevant.⁵⁹ Individuals typically choose PGD to prevent their child from having a particular disease which they deem harmful.⁶⁰ Some critics of PGD claim that doing this is selfish. Individuals have the right to reproduce, but when parents begin to interfere with natural development, they may be doing it for their own interests.⁶¹ However, it could be argued that parents actually do have the right to employ PGD if they believe that it will free the child's life from suffering and improve the overall quality of it.⁶²

In addition to autonomy, beneficence and non-maleficence should be considered. Proponents of PGD believe that the use of the technique also promotes both of these principles, since a child would benefit from not having a potentially debilitating disease, and future suffering would be eliminated. In the future, when the uses of PGD may change to choosing non-medical traits, further ethical questions may arise. This will be considered in chapter six. Non-maleficence is also promoted due to the elimination of harm when parents choose to prevent an illness from occurring in their child.⁶³ Moreover, some scholars believe that by not using PGD to avoid known genetic diseases, parents are actually causing their children harm.⁶⁴ Similarly, non-maleficence is supported through the present uses of PGD, but future uses for genetic enhancement may change this viewpoint and require additional oversight and management.

Once PGD becomes more accessible and affordable, parents will gain more control over their child's genetics which will, in turn, influence their future. Many scholars discourage the use of this technique to manipulate social traits, in order to avoid the advancement of forms of

eugenics and the rise of discrimination. Gene editing is faced with similar concerns and numerous scholars are concerned that the use of gene editing and genetic therapies to create “designer babies” will become the norm. This topic will be discussed in a chapter six.

B: Organizational Issue: Emerging Genetic Technologies

A prominent issue for organizations with regard to genetic therapies and editing techniques has revolved around creating a plan for implementation within their institution. Since gene therapy is a relatively new technology, its implementation into healthcare has been limited. Clinical trials are the main source of access to gene therapies.⁶⁵ In the course of experiments (if they occur in the medical facility) or once clinical trials are completed, it would be necessary to apply appropriate steps to ensure a smooth and effective process of implementation. Primarily, an organization would need to be certain that the appropriate staff was highly trained in gene therapy techniques and had the ability to discuss the implications with their patients. This may require the creation of skills clinics in order to teach physicians and technicians how to perform techniques, as well as how to analyze results. It is expected that researchers who are conducting the clinical trials would be able to share their knowledge with their colleagues; to make the technology widely available.⁶⁶

In the initial discussions surrounding possible implementation of a new technology such as genetic therapy, patient safety must be considered. Patient safety must be implemented at all levels of an organization, both institution-wide and among the individual employees who are directly responsible for preventing errors when possible, and creating a safe environment. All employees, but especially those in direct contact with patients, must have an increased level of knowledge in order to maintain patient safety. A patient always assumes that their health care

providers have been trained in safety measures which allow them to treat their patients appropriately, as well communicate effectively so that the patient can make an informed decision.⁶⁷ Keeping patients safe also includes evaluating the risks involved in medical treatments, especially novel technologies. While clinical trials provide information about medical risks, an organization should think about how a patient or community may be exposed to risk in other ways.⁶⁸ Not only individuals can make errors that may endanger patients. Patient safety should be dealt with at an institutional level through the implementation of strategies and mechanisms to control the various risks associated with medical practices.⁶⁹ This also promotes the organization's accountability to the community it serves.

An organization will also have to determine whether a new technology aligns with their core values and is able to achieve its institutional goals.⁷⁰ The primary priority of medical organizations is to provide excellent care to its patients, and this is often reflected through a mission statement. In addition to this main focus, an organization's mission statement is able to reflect other values it has, such as religious abidance or outreach.⁷¹ Upholding the mission statement at all levels of the institution allows the community to hold it accountable and to ensure that its values are being upheld as well.⁷² By insisting that all levels of the organization follow the mission statement and associated guidelines, it can be ensured that ethical decision making will be encouraged in order to create a positive moral culture, both internally and externally.⁷³ This also implies that any procedures or interventions offered within the hospital uphold these values and are considered to be morally acceptable..⁷⁴

Although gene therapy shows immense promise in treating and curing disease, the most significant issue preventing its full realization is its high cost. Gene therapies that are on the current market cost approximately between \$500 000 and \$1.2 million for a single treatment.⁷⁵

As a result, there is fear that individual patients will not be able to afford this life-saving technology. One option that may help patients is a personal payment plan, where the organization can make arrangements with patients to pay in installments.⁷⁶ It would also be helpful if health care institutions encourage insurance companies to cover such treatments as these, since they could help cure disease and save lives.⁷⁷ This is an important aspect for organizations to consider when implementing a new technology, and it should explore options that can be made available to patients in order to uphold its values of providing excellent care.

Chapter 6: Genetic Therapy and Gene Editing (CRISPR)

A: Genetic Therapy and Gene Editing

This dissertation has explored the many aspects of genetic therapy and gene editing interventions that must be considered before and during the implementation into health care institutions. It is evident that genetic editing is becoming a realistic method of treating a variety of patients. Research using gene editing within gene therapies is showing positive results, and illnesses such as childhood cancers, could be cured in the near future.⁷⁸ The use of the CRISPR-Cas9 or Clustered Regularly Interspaced Short Palindromic Repeats, is the easiest and most cost-effective method of editing the DNA of mammalian cells. CRISPR was discovered as an immune system in archaea and bacteria designed to fight viruses, and was modified to act in human or mammalian cells.⁷⁹

Since this technique is still in its beginning phases, research is still being conducted all over the world. It is primarily being studied using ex-vivo cells in laboratories, using pluripotent stem cells or somatic cells.⁸⁰ Embryos are also beginning to be used to study hereditary cells, but researchers can only manipulate embryos for a certain number of days due to common protocols

and legislation.⁸¹ Destroying them early before development reaches a state ready for implantation ensures that research abides by the international agreement that germline edited embryos not be implanted with the goal of a successful pregnancy. As previously mentioned, one researcher in China, Dr. He, did not follow this rule and used the CRISPR technique to alter the genome of multiple embryos, resulting in twin infants being born.⁸² While this was heavily frowned upon by other scientists, it is expected that this course of study will reach that point in the future. Although the CRISPR technique is mainly being used in laboratories, it is becoming more common to conduct research and use the technique in hospitals with patients, bringing hope to many individuals suffering from incurable diseases.⁸³

It is more accepted and straightforward to conduct research using somatic cell therapies. Somatic cells are those that are not passed on between generations, and only affect the individual whose cells they are in the present. Editing somatic cells is often referred to as gene therapy. During cell replication, a person's DNA can experience small changes and the body's mechanism of recognizing these mistakes does not always catch each difference. If multiple genes have some sort of alteration, it can lead to the emergence of a disease, such as cancer or haemophilia.⁸⁴ Illnesses that are caused by one single mutation are easier to target, as opposed to others that are created by multiple gene mutations.⁸⁵ Targeting somatic cells ensures that no future generations are affected by the changes from gene therapy, and cause fewer ethical challenges.⁸⁶ From an ethical perspective, a medical treatment that only affects an individual and not their descendants avoids the issue of advanced consent regarding hereditary gene therapy. A patient who seeks out gene therapy can make an autonomous decision based on their beliefs and values.⁸⁷ The informed consent process would be the same as with all other treatment choices.

Hereditary Cell Therapy, however, poses some more challenging ethical questions. Unlike somatic cell gene therapy, which allows an individual to decide whether to manipulate their genome for themselves, heritable genome editing requires prospective parents to choose a specific genetic path for their future children.⁸⁸ Hereditary gene therapy also uses the CRISPR-Cas9 technique to edit the genes of an embryo. This then alters all of the embryo's genes as well as any genes that would be passed on to future descendants. For example, parents may choose to edit a gene that causes Huntington's Disease if a family history exists, so that no future generations, including their child, will suffer from Huntington's.⁸⁹ Concerns have been voiced with regard to this form of human intervention. For example, some have questioned the effects of a novel technology on humanity, and whether humans should be able to intervene in the genetic path of future generations. This may alter the way that we uphold human dignity and view an individual's unique qualities.⁹⁰ A significant ethical concern with regard to hereditary gene editing is how to balance individual benefits with potential benefits of the general public, once children with edited genomes begin to be born. While individual children and parents may benefit, the utilization of this editing mechanism may cause social and cultural harm.⁹¹

As this new technology becomes more readily accessible, it is crucial that organizational oversight, as well as public engagement occurs. Organizational oversight ensures safety and efficacy. A mechanism should be put into place for appropriate follow-up procedures to be instituted for each patient, in order to track side effects and general status.⁹² Organizations must also perform frequent cost-benefit analyses to reflect on how the technology is being used, and which patients have the best access. If gene therapies prove to be immensely successful at treating cancer, it may be valuable for hospitals to invest in the technique to make certain that their patients have access to this treatment, despite its higher cost.⁹³ Since this intervention

directly involves patients and the public, they should be involved in the decision making process. A community member may have questions or need clarification about how the hospital plans to implement policies for a new technique, and whether everyone will have access to it. This promotes trust and transparency between the hospital and the community it serves.⁹⁴ It also allows the institution to clarify any misconceptions that the media may have reported.⁹⁵ As genetic therapy and editing become more common and transition to being used for enhancement, the public will need to collaborate with scientists and health care centers to hold them accountable for the choices they are making that will impact society.⁹⁶

B: Human Enhancement and Transhumanism

As it becomes possible for researchers to alter or edit an embryo's genome through germline modification, the possibility of genetic enhancement will become more plausible. Once embryonic research is better understood and accepted, scientists may be able to target specific genes that are not solely medical.⁹⁷ Since scientific research has proven that genes affect personality and character traits, such as intelligence, empathy, and athletic ability, there may come a time when parents who can afford it will be able to choose which genes their offspring will have, in the hopes that their child will grow up exhibiting the desired qualities.⁹⁸ This could lead to "designer babies," but there is scientific evidence that children are not pre-destined to a specific future based on their genetic makeup. Environments and parenting styles seem to have more of an influence on children than their genes do.⁹⁹ Nevertheless, serious concerns persist.

It was brought up earlier that eventually the CRISPR technique will be improved and the possibility for all parents to have access to it for both medical and social reasons is entirely plausible. This concept, that a significant population of people could be genetically modified,

frightens both academics and the general public alike. Some philosophers believe that enhancing human beings should be prohibited because it would change ‘human nature.’ It is also feared that gene editing will only be available to parents who can pay for it, further increasing the gap between the wealthy and the poor.¹⁰⁰ Others believe there may not be as many threatening concerns relating to gene editing, and that it should be allowed and promoted so that more effective human beings can be created.¹⁰¹

Many bioethicists that do not support enhancement believe that pursuing it will interfere with human nature, and that any threat to a human’s makeup should be avoided at all cost.¹⁰² Human nature is an inherent part of the identity of all humans, one which dictates how we act and make decisions.¹⁰³ As a result, enhancing the genes of future children, an unnatural act, may disturb this human nature.¹⁰⁴ In order to truly modify human nature, the human species as a whole would have to change. While this concern is valid, it is expected that the feared outcome of a new set of human beings in our lifetime is unrealistic, since only a small number of humans will be able to afford this new technology.¹⁰⁵

However, if enhanced humans do become more prevalent, scholars are unsure about what this enhanced human’s moral status would be compared to unedited individuals. We would need to alter our conception of morality in order to accommodate enhanced individuals. It would have to be determined whether allowing the creation of ‘post-humans’ would be morally acceptable, and whether it should eventually be made mandatory. Few scholars agree with this line of thought and most believe that society would collapse if this line of research continues.¹⁰⁶ If post-humans become a reality, however, there is the potential for some people to have a higher moral status than we currently have, which would lead to concerns about human rights. Scientists and philosophers would have to question whether post-humans would be entitled to their own set of

human rights, different from the ones we have now.¹⁰⁷ They fear that ‘mere’ humans would not be able to exercise the same level of moral reasoning as post-humans, which would reduce their status to disposable humans, akin to animals, and would certainly result in little respect being shown to them.¹⁰⁸ The current scientific literature frequently ignores this concept of a changed morality, but it is important for these discussions to take place to ensure that we are prepared when enhancement becomes a reality.

In addition to the moral and philosophical concerns that must be considered with regard to germline editing, practical concerns should also be addressed. The majority of literature discussing genetic enhancement and transhumanism expresses worries that genetic editing will lead to eugenic acts, which would create significant justice issues around the world. Eugenic practices can be detrimental and highly unethical, but they may not be as negative as they are often considered to be.¹⁰⁹ In any case, an attempt to avoid them should be made through organizational and ethical oversight so that further risks, such as creating a wider divide between the rich and the poor do not occur.¹¹⁰ A neutral group should be formed that is able to consider multiple perspectives and determine the risks and benefits associated with the creation of post-humans. This group must also include representatives from the public, which ensures that scientists, philosophers, and politicians do not make unilateral decisions without appropriate stakeholder engagement.¹¹¹ Ideally this would address much of the discomfort regarding the potential of genetic enhancement and bring assurance that the practice will be conducted safely and fairly.

Chapter 7: Conclusion

When a new technology that has the potential to change the manner in which we cure disease emerges, its many facets warrant close examination. Genetic therapies and editing techniques are

providing hope with regard to a range of medical issues, including the elimination of cancers, and the improvement of children's lives before birth. However, there are many issues associated with such applications that also need to be considered, such as how these developments will affect organizations, public health initiatives, and populations around the globe. Despite concerns held by scientists and philosophers alike, these technologies will undoubtedly become part of the health care system.

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¹⁰⁹ Christopher Gyngell and Simon Easteal, “Cognitive Diversity and Moral Enhancement,” *Cambridge Quarterly of Healthcare Ethics* 24, no.1 (January 2015): 66-69, doi: 10.1017/S0963180114000310.

¹¹⁰ Buchanan, *Beyond Humanity?* 51-54.

¹¹¹ Buchanan, *Beyond Humanity?* 255-258.

Chapter 2: Autonomous Health Decisions

Decision making in Western healthcare revolves around autonomy, the right of individual patients to choose what they feel is best for them. Autonomy is realized through the need for informed consent from a patient or their substitute decision maker. Capable patients have the right to choose whether they accept a treatment or not, but substitute decision makers have a more difficult role, because they are acting on someone else's behalf. Being a parent further increases this often-stressful process when a child's life is at risk. Making decisions, however, can be challenging, especially when considering the implications of an experimental technology, such as genetic editing treatments. Ultimately, genetic editing and CRISPR-Cas9 research requires autonomy and informed consent to proceed and for knowledge to be gained. This supports the need to examine the concept of autonomy theoretically, as well as in practice, as it differs in various geographic regions. For example, decision making may look slightly different between the USA and Canada, both developed Western nations.

A: Relational Decisional Autonomy

The roots of decision-making are in the principle of autonomy and, in practice, informed consent provides an ethically sound process for making choices. There are other ethical components that must also be included in the scope of autonomous decision making in order for it to be executed more appropriately. This discourse is also required so that substitute decision-making can be performed ethically. In the process of exploring autonomy, it will become evident that autonomy and substitute decision making are better understood and practiced with the addition of the concepts of care ethics and personalism, because they are more respectful of an individual as well as those around them. The dichotomy of autonomy and care ethics also applies to health care providers and their relationships with their patients, describing how physicians, in

particular, should communicate with their patients during decision-making, as well as how the relationship between physician and patient can thrive.

The concept of autonomy is the right of an individual to speak for themselves and to make their own informed decisions, based on their own reasons and needs. These decisions must be acknowledged and adhered to, even though some may disagree with them. Each country, state, or province may have their own legislation outlining the concept of autonomy in health care, as well as the preferred definitions and associated stipulations that health care providers must follow. For example, the United States and Canada are both developed nations with similar health care resources, but have each implemented different legislation regarding informed consent. In the US, each state dictates the criteria for informed consent and substitute decision makers, most often stating that an individual must be 18 years of age in order to make their own decisions unless they are deemed a mature minor¹. In Canada, various provinces make these distinctions. In Ontario, there is no legal age of consent for making a treatment decision – a patient must simply be capable of understanding and appreciating their treatment options, as judged by their physician.²

It is considered a human right to have the autonomy to make your own decisions. A capable individual is able to choose how they treat their body and for which interventions they provide their informed consent. Autonomy differs from the human right to liberty, in that a person can have unlimited liberty, but little decision-making autonomy, and vice versa. The simple distinction between liberty and autonomy is that liberty is a political concept, whereas autonomy is a moral one.³ Furthermore, autonomy is the act of free will, and liberty is freedom without the interference of a third party. It is difficult to compare the two concepts when it comes to medical decision-making, as autonomy is more applicable than liberty as a general concept.⁴

Historically, autonomy stems from past research trials that have exploited individuals without their knowledge or consent. As a result, laws exist that protect subjects from exploitation or harm. Policies are created to avoid repeating historically unethical research events.⁵ Documents, such as the Nuremberg code and the Declaration of Helsinki, were put into effect to ensure that the human rights of all individuals were upheld.⁶ They also emphasize the importance of the responsibility that investigators have to educate themselves about what makes research ethical and legal.⁷ Outside of the research context, history has seen the field of healthcare ethics evolve and focus greatly on autonomy and informed consent, and the concerns associated with those concepts. The Kennedy and Mondale hearings resulted in the formation of commissions and new laws that would protect patients, as well as doctors and medical staff.⁸ Furthermore, the National Commission and the Kennedy Commission provided guidance to create a specific set of codes, but allowed for flexibility for particular patients. The published documents outlined how the United States as a country thought the issues should be handled, as well as how the medical community ought to act, but still allowed for freedom within a healthcare setting for each individual patient to receive specialized and personal care. They addressed the concerns of both society and government, and set the stage for future policy creation.⁹

As suggested by Beauchamp and Childress, in order for an autonomous decision to be accepted, three conditions must be met: proper intention, a complete understanding of the situation, and the making of choices free of external deciding influences. If these stipulations are met, a decision can be deemed thorough and valid. It can, therefore, be respected and honored.¹⁰ There are also situations, however, where autonomy may not dominate in decision-making, primarily if an autonomous decision will directly harm another individual. In these cases, autonomy can be overridden by a physician or healthcare provider, and another choice can be

made that is more appropriate and not harmful.¹¹ Before making another choice, however, the provider should consult with the necessary legislation and protocol about overriding autonomy. A healthcare worker must respect autonomy when they are sure that a patient is capable of making a decision, and has done so free of coercion.

In order for a patient's autonomous decision to be respected, an individual must be deemed to have adequate decision-making capacity with which to provide their informed consent. A capable patient is able to understand simple medical facts about the procedure or treatment to which they are consenting, and able to appreciate the effect that the medical intervention will have on their body and on their life.¹² This definition allows a physician to easily evaluate a patient's capacity and clearly affirm the role that autonomy plays in the decision-making process. There are, however, situations in which a doctor can judge a particular patient's decision to be irrational and, therefore, overturn or not follow the autonomous decision of a seemingly capable patient. An example would be if a patient requested a leg amputation with no signs of distress or infection to the leg – they simply state that they have no more use of their leg. This case would allow for autonomy to be overruled because of an irrational desire, and the same could apply to an irrational fear.¹³

Furthermore, some authors believe that rationality should be combined with competency in order to view a patient's decision about a medical intervention as valid and acceptable. It is argued that an individual who makes a rational decision is considered capable.¹⁴ In practice in the United States, these theories are combined and a system with three levels is used to deem a patient capable: a patient's ability to understand, a patient's ability to evaluate, and a patient's ability to communicate.¹⁵ These three steps demonstrate that a patient has the appropriate

capacity to make their own medical decisions, and it also shows that they can make a rational decision that works best for their lifestyle and adheres to their personal values.¹⁶

A healthcare worker who is assessing a patient's capacity must keep all of the above mentioned elements in mind when determining whether an individual is capable of making treatment decisions. In addition to these theories, there are certain tasks that a patient must complete to show a provider that they are capable. In order to demonstrate that a patient truly understands their condition and all possible treatment options, they are asked to paraphrase their situation, or recap any discussion they have had with their physician. This proves that they have been able to process all of the medical facts associated with their condition, and rephrase them in a personal and meaningful way. To express an appreciation for their circumstances, a patient is asked to articulate all of their treatment options, and the subsequent expected result of each. This includes the recommended treatment, as well as alternative methods, and what would occur with no treatment at all. A patient's ability to evaluate their diagnosis is demonstrated through their personal ability to weigh the risks and benefits of all of their options, and decide on the best treatment that corresponds to their values. If a patient can make the same choice repeatedly and maintain a level of consistency over a period of time, they demonstrate their ability to evaluate. In addition, when a patient can recognize and articulate all of their options and decide upon one of them, it shows their ability to communicate.¹⁷

A capable patient's decision is only accepted, however, if they provide their informed consent. An individual has the right to receive all the necessary information associated with their diagnosis, and to discuss all of their options with their health care team. This ensures that a final treatment choice is an autonomous one. An effective and honest discussion leads to a more trusting relationship between a physician and their patient, which presumably would result in a

higher standard of care in which both the patient and their physician have some level of control. There is a sense of equality between the two main participants, as they both share a common goal of providing relief to a patient.¹⁸ Informed consent also ensures that doctors are legally covered, as they allow a patient to make a decision for themselves, free of coercion and seemingly with no level of paternalism.¹⁹

When assessing a patient's capacity, a common issue may arise when dealing with informed refusal of a treatment or procedure. A patient can decline a treatment for personal reasons that do not correspond with a doctor's opinion, or even a "reasonable person's" preferences. These reasons can be religious or value-based, and should be respected. If a patient can prove that they have decision-making capacity, by being able to understand, evaluate, and communicate their choices, they should be able to make their own decision regarding care. Informed refusal is often mistaken for incompetency, especially if a physician disagrees with the patient's choice. To have to prove to an excessive degree that they are making an informed choice free of coercion, and, for good reason, is disrespectful and harmful to the doctor/patient relationship. Although it can be difficult for a physician to accept a patient's decision, they must do so in order to uphold the patient's autonomy.²⁰

Healthcare is currently heavily influenced by Beauchamp and Childress' theory of principlism. Autonomy, one of their four principles, now drives decision-making and hospital policy to ensure that a patient's rights are upheld, as was described above.²¹ Therefore, the field of healthcare has become primarily focused on the individual patient, to ensure that they are making their own choices and providing their consent for interventions with which they agree. Many proponents of principlism agree that autonomy should be the major driving force within healthcare, in order to ensure that basic human rights are being maintained.²² For example, a

capable patient has the right to consent to experimental treatment, regardless of their physician's opinion or preference for a safer option. Autonomy, however crucial it may be, cannot be the only concept on which healthcare relies, however. It needs other theories or tools to ensure that patients are receiving the best care possible.²³

Introducing care ethics may be helpful for patients when considering their options and allowing others to help them make decisions. Further detail on shared and substitute decision making will be explained below. Since autonomy is one of the most prominent components of medical decision making, it must be acknowledged, and it may, in fact, need to be re-established to include care ethics and personalism. This enhances the currently known concept of autonomy and makes it stronger in practice. By adding a relational component, autonomy becomes more applicable to individuals and results in well-rounded decision making.

When we think about autonomy and the effect it has on individuals within the health care system, we must also consider the types of care that influences choices being made. Care ethics can be a useful concept and tool when discussing relational decisional autonomy. The ethics of care focusses on particular individual and community relationships.²⁴ It emphasizes the importance of dealing with situations that do exist, such as the bond between a patient and physician, a mother and her child, or the government and individuals diagnosed with AIDS.²⁵ These relationships are specific, and all of them require explicit and varied types of care. Similarly, bioethics deals with particular connections between people, society, and states. By recognizing who is involved in the work being done, either those doing the work or those benefiting from it, bioethics incorporates care ethics within its methodology to ensure that requisite services and theories are being implemented. Many ethical theories that are used to guide clinical decision making usually apply to humans in general, are frequently hypothetical,

and do not take into account particularities. However, healthcare cannot be an abstract construct, nor can care be provided in an abstract manner. A level of particularity is required to provide appropriate and targeted care.²⁶

Furthermore, care ethics emphasizes the importance of care, on both an individual and societal level. Every human being requires care at some point in their life and relies on the care of others in order to shape them into functioning human beings.²⁷ People also expect a level of care from the medical field, when they seek aid for an illness. There is an assumption that hospitals, clinics, or physicians will all be able to provide an adequate level of attention to maintain or re-establish a suitable level of health. Our dependence on such medical support throughout our lives demonstrates its importance, and the value that care theory can provide. While autonomy is the driving force in healthcare today, patients and providers must also acknowledge a human's need for dependence. Ironically, autonomy would not be possible without the care of others.²⁸ The ethics of care allows individuals to analyze situations from the perspective of care and to confirm a human being's reliance on care.

Care ethics is, therefore, a compulsory component within healthcare designated to ensure that services are effective and useful. Providing care, either for one individual or for the population of an entire country, does sometimes require referral to abstract or general moral theories, but its application must always be implemented with an aim to provide specific care.²⁹ Even though those who are discussing bioethical theory may not be responsible for the care themselves, they must ensure that their theories are applicable to a field that is accountable for the medical wellbeing of numerous citizens.³⁰ This may be difficult, however, since it has been proven that not all bioethical discourse can be applied to all patients or individuals around the world, even though they are human beings, and as such, moral agents. This implies that care ethics may be

more suitable for specific healthcare situations, as opposed to common bioethical theories, such as deontology and utilitarianism.

i. Substitute Decision-Making

Any individual who is deemed not to have adequate decision-making capacity must be appointed a substitute decision maker (SDM) who provides consent for them. A substitute decision-maker acts on behalf of a patient, making decisions based on how the patient would have, and the surrogate's own autonomy should not be considered when providing consent. It must be understood that acting as a proxy entails simply being a voice for an individual, often a loved one, who is unable to speak for themselves.³¹ However, it is not uncommon for an SDM to consider the effects of a decision on their own life when considering the autonomous wishes of an incapable patient. This is common at the end of life, when choosing whether to forgo or withdraw life support; when a surrogate must also think about how a significant decision, such as this, will impact a family. Withdrawing life support can be difficult, but if it is in conjunction with a patient's previously-expressed wishes, the act of withdrawing can also be beneficial for a family as it brings closure to a loved one's life and the burden of care disappears. It is never permissible for an SDM to act solely based on their own wishes, especially if their opinions differ from the patient on whose behalf they are acting.³²

The way that a substitute decision-maker is chosen can vary, depending on whether the patient chooses an individual or whether one is appointed after the patient loses capacity. For example, a patient has the right to appoint a durable power of attorney for health care to make any decisions on behalf of the patient if they are deemed incapable. This is a form of advance directive, and the selected individual does not need to be a family member.³³ This can be done to

ensure that the elected SDM shares the same values as the patient or has been made aware of the patient's values and wishes, and that they are able to make decisions for the patient in a stressful and potentially emotional time.³⁴ Without the selection of a specific individual, the surrogate automatically becomes a family member or loved one (in accordance with a hierarchy in local legislation) or is appointed by the court or government.

A completely incapable patient is one who lacks any capacity to make a decision. For the most part, this includes patients who are permanently unconscious, such as those in a persistent vegetative state. It also includes patients who may be conscious, but are heavily sedated, or individuals who are mentally unstable and not aware of their surroundings or able to make any decisions regarding their care. Substitute decision makers who act on behalf of completely incapable patients must be careful to ensure that they are acting based on what their loved one would have wanted while they still possessed a level of decision-making capacity.³⁵

It is hoped that patients, especially completely incapable ones, had the opportunity to discuss their preferences with their friends and family while they were able to express their wishes clearly. It is helpful if a patient has an advance directive which provides healthcare workers and families with guidance about an individual's wishes.³⁶ This almost completely eliminates the need for a substitute decision maker to make major decisions about a patient's health. Although it is essential that there is an appointed individual able to provide consent for less significant treatments, or any not listed in the advance directive, there is no question as to what the patient wants. The document acts as a representation of the patient's informed consent and, as Kelly explains, acts as an "ace of trump" in that the directive is the first and only indication of the patient's autonomous choices.³⁷ However it should be remembered that an advance directive may not be a legal document in some jurisdictions, and an SDM is still required to confirm a

final decision. Information should also be gathered about when an advance directive was created (does the patient still hold the same beliefs in the current moment?) and whether the patient was capable when creating the document. If the SDM can prove that the patient had since changed their mind from the instructions on the advance directive, or was not in sound mind when it was created, physicians have a duty to act on a choice made by the SDM in accordance to the patient's new wishes.

When a formal advance directive does not exist, a substitute decision-maker must make decisions on behalf of the patient. There are standards to which a surrogate must adhere, in order to ensure proper health care for an incapable individual. The 'Substituted Judgement' standard emphasizes that a proxy is only voicing the previously expressed opinions and wishes of the incapable patient. The SDM, in this instance, is able to provide some forms of proof of what the patient preferred which demonstrates to a physician what a patient would have done for themselves. This can be difficult, especially in circumstances where an SDM is unsure of the patient's wishes in a specific situation. This is solved using the 'Best Interests' standard which stipulates that a surrogate is able to make a decision based on the best interests of the individual patient, or of a reasonable person. Ideally, a substitute decision maker would be able to combine these two standards to make a suitable decision on behalf of the patient. Based on values and an evaluation of a patient's lifestyle, a decision can be made that is best for that specific patient.³⁸ There may also be legal resources, such as the Health Care Consent Act in Ontario, Canada, which specifically outlines how an SDM should use the "Best Interests" Standard to make a decision.³⁹

A patient can have a limited capacity, however, and still be deemed incapable of making their own medical decisions. One example of a patient with limited capacity is an individual

suffering from dementia, who only experiences lucid thoughts and awareness some of the time. Patients with these diseases often have advance directives that explicitly state their wishes for the future, but without this type of document, a substitute decision-maker has a difficult role.⁴⁰ These patients sometimes have the ability to be aware of their surroundings, and make small decisions about everyday tasks, such as meals or activities, but they are not aware of their condition or able to make any decisions regarding proper medical care.⁴¹ A proxy not only has to consider the wishes of the patient before the progression of their disease, but also how they would react to a treatment or choice in the present time. They must still act in the patient's best interests, but also keep in mind that although the patient may be confused, they are able to feel pain and be aware of the people around them.⁴²

When dealing with situations that involve patients with limited capacities, but who are aware of their condition and surroundings, such as mentally disabled patients, it is best if a surrogate works with the patient to make medical decisions.⁴³ Even if the incapable patient is unable to rationalize or process their condition and their options, they are able to understand the words and facts that are provided. The dual decision-making is most effective, because the incapable patient feels included and respected, and that their autonomy is being acknowledged. By using a substitute decision-maker, it is ensured that a proper decision will be made that is in the best interests of the patient. If both of these individuals agree, proper consent can be provided for effective medical care.⁴⁴

There is an importance in maintaining autonomy in these types of situations as much as possible, since it is considered a human right and promotes human dignity. When an incapable patient, such as the one with dementia just mentioned, who is progressing into the late stages of the illness, becomes unable to speak for themselves, they are still a human being who deserves to

be respected. While they may not be able to make their own decisions, their autonomy should be considered.⁴⁵ This is where care ethics may be helpful because it does not revolve around autonomy. It emphasizes that particular relationships should be considered, as opposed to one blanket theory that can be identically applied to the general public.⁴⁶ These particular relationships between patients and their SDMs should ensure that patients are treated as individual human beings, who have specific values and needs, and not simply as a set of symptoms that need curing. This is an important component of compassionate patient care, leading to a trustworthy and effective relationship between care-giver and recipient.⁴⁷ The relations with their care-givers must include trust and compassion, which raises the notion that SDMs, as well as patients when they are capable, should rely on those around them for support in decision making.

Autonomy is often regarded as solely focusing on what an individual chooses for themselves, but it is almost impossible for any person to be completely autonomous and independent. All human beings are dependent on others for at least a part of their lives.⁴⁸ Autonomy allows patients to make their own choices, but it also requires that they accept care and support from those around them. The care from others allows autonomy to be as prominent as it is in healthcare today. Bioethics promotes autonomy and principlism, since it puts patients in charge of their own care, but it fails to acknowledge dependence as being part of autonomy. The ethics of care recognizes this relationship and stipulates that the two must rely on each other to ensure the ultimate goal of adequate healthcare.⁴⁹

In reality, many patients might include their family or close friends in the decision-making process. While this is expected, it is important to understand the role of a support system – they are not acting as substitute decision-makers for the patient, nor should they be coercing the

patient into making a particular choice. The concept of coercion can seriously impact a capable individual's ability to make a decision that is reflective of their own wishes. If a patient is coerced, their consent is not considered autonomous, and is, therefore, invalid, since an outside party has influenced their decision. Coercion directly removes an individual's freedom to make their own choices. Extreme coercion involves direct threats towards a patient, such as a physician threatening to stop treating the patient if they do not follow their orders.⁵⁰ It is crucial that informed consent is free of external pressure and that doctors are aware of any ways coercion can be present in the decision-making process.

Furthermore, patients may feel coerced and pressured by their family, or certain sections of society when making decisions regarding medical treatments or procedures. It is possible for family members to coerce a loved one with a direct threat, for example that care will not be provided unless a certain procedure or treatment is undergone.⁵¹ Usually, however, there can be external pressure from a family, by which the patient is persuaded to choose an option, because they want to please their family. This can occur with elderly patients in nursing homes wanting to please their grown children, or feeling that their own autonomous decision is not as valued as their children's.⁵² It can also be applied to children wanting to please their parents by undergoing something that they feel uncomfortable taking part in, even if they are above the legal age to make their own decisions, or have the capacity to consent on their own.⁵³ Although a healthcare worker must still accept consent from a patient who has been pressured by an outside influence, they are able to acknowledge this pressure and try and counsel their patient to do what is truly their autonomous choice.⁵⁴

Society also uses coercive techniques in various forms to try and influence the general public to make certain healthcare decisions. For example, the FDA requires that cigarette

packaging has images and warning labels about the serious harmful effects of smoking. They believe that these powerful visuals may influence people to stop smoking in the hope that they think about their health.⁵⁵ Offering monetary rewards for participating in studies, such as ones aimed at weight loss is another example of coercion.⁵⁶ Although an individual may believe that they are making an autonomous choice, there is a level of outside influence that persuades them to make a decision with which society or higher organizations agree and encourage. These types of tactics are not direct coercion, as they do not pose direct threats, and allow a level of autonomy for each individual. They still, however, include a level of manipulation hoping that a patient will conform to society's goals and wishes.⁵⁷

It is of great concern to researchers and medical practitioners that vulnerable patient populations exist and are being coerced or heavily influenced as they make certain medical decisions that do not truly reflect their personal values or wishes. Vulnerable populations can be comprised of children, the impoverished, or prisoners, among other vulnerable groups.⁵⁸ This concern also extends to participation in medical research in which these groups are manipulated or studied in which they are convinced to participate and which may not be directly therapeutic, or solely for the common good of society.⁵⁹ This is a problem, because all individuals have autonomous rights if they are deemed capable, and persuasion or direct coercion from outside influences should not be allowed to interfere. Children are an example of a vulnerable population, because their decision-making capacity is not considered developed enough to provide informed consent. Other vulnerable populations may be influenced by insurance companies, access to healthcare institutions, or by elements of society to conform to a certain standard of care, even though they may feel they deserve better, or they prefer another method of

treatment. For example, a patient with depression may feel as though therapy would be beneficial, but most settle solely for a prescribed medication.⁶⁰

Ideally, an SDM or a capable patient would partake in shared decision-making with their healthcare team. This method, where doctors and substitute decision-makers/patients collaborate to make medical decisions, is effective, because it combines the scientific knowledge and recommendations of a physician, with the personal values and preferences of the patient (by means of their surrogate). By using a shared decision-making model, SDMs and patients are able to use the support of physicians or nurses or other healthcare workers to guide them into making a suitable proxy decision.⁶¹ Shared decision-making is especially useful when a substitute decision-maker is appointed by the courts or government. This would occur if the incapable patient did not have any family or close friends that could act as a proxy decision-maker. A court-appointed guardian has no prior relationship with the patient, and relies on the ‘best interests’ standard to make decisions. By interacting with physicians, who are more familiar with the patient, the guardian is able to make appropriate decisions for the incapable individual. Sharing information and recommendations would lead to what is ultimately best for that specific patient.⁶²

It is also important to think about a potential power imbalance between a patient and their substitute decision-maker, for example, between parents and children, or those with dementia and their caregivers. As an individual with Alzheimer disease (AD) progresses through their condition, for example, care becomes more and more necessary. Often a son or daughter feels responsibility to care for their parent with AD until it becomes too much of a burden. At this stage, many patients with Alzheimer Disease are transferred to a nursing home or hospice, where they can receive constant care and support.⁶³ In either of these situations, patients become

less and less aware of their true surroundings, which can tire out their care-giver as they become more responsible for their safety. This burn-out is common.⁶⁴ Tronto discusses four phases of caring, the fourth being care-receiving. This phase consists of patients, for example, being perceptive to the care they are receiving and understanding its necessity.⁶⁵ In the case of an AD patient, they may not realize why they require care and do not demonstrate appreciation, but frustration instead. A patient may not understand why there is another individual helping them get from one place to another, when they believe they are capable of doing it themselves.⁶⁶ In reality, the patient does require extra support, but they are unable to understand this fact. The lack of acknowledgment of 'care-receiving' can make a care-giver feel as though they are not caring enough and make their job extremely difficult. In these situations, finding enough patience to uphold autonomy when making decisions for incompetent patients can be challenging, albeit necessary.

Although it may be difficult, respecting the autonomy of patients with Alzheimer disease, or others with incapacitating factors is essential. It is important to recognize that although they may be unable to make significant medical choices with regard to treatment, these individuals may still be able to communicate about treatment, such as indicating when they are in pain, and about daily activities, such as what time they would like to eat, which clothing they would like to wear, or with whom they would like to interact.⁶⁷ Allowing some liberties for these patients indicates to them that they are still being respected and that they are still leading meaningful lives with some level of control over their choices. This becomes progressively more challenging as their disease becomes worse, but there should always be some effort to provide opportunities for autonomous decision making. This also strengthens the relationship between a patient and their caregiver, and leads to better care. While there may be some level of risk involved if a

patient is allowed to walk around a nursing home alone, for example, it may be worth a possible minor physical injury if a patient can recognize that they are being cared for as a person, and not as a patient in an institution.⁶⁸

These freedoms also indicate that the patient is simply a person with a mental disability, and not a patient in need of curing. Often medicine focusses on cure as opposed to care, and in the case of dementia, cure is not possible.⁶⁹ A patient with Alzheimer disease will not improve mentally, and accepting that diagnosis can be difficult. Understanding that this disease is terminal can allow care-givers to recognize the necessity of their role. Therefore, care should be the primary goal of treatment. Treating the patient like a human being, and acknowledging their values and wishes demonstrates that their autonomy is being respected and their dignity is still intact. This personalist approach ultimately works best, so that these patients are able to maintain some control and attach meaning to their life.

When a decision must be made for an incapable patient, such as one with Alzheimer disease symptoms described above, a substitute decision maker must be appointed. The choice of who may act as a substitute decision-maker varies depending on the situation, but once chosen, they must always act on behalf of the patient and abide by their previously-expressed or presumed wishes.⁷⁰ The input of such individuals supersedes the simple solution of letting a physician determine the appropriate course of treatment. As explained by Shalowitz, a surrogate, who is a family member or friend is better able to predict and decide what a patient would have preferred than a doctor or healthcare worker.⁷¹ This implies that using a surrogate is the most ethical solution to the problem of a patient not being able to communicate for themselves. Ultimately, this is the best option to uphold autonomy and provide appropriate care for an incapable individual. It also requires a patient, if they are selecting this SDM, to acknowledge

that relationality is an integral part of autonomy, and that they will depend on the care of others in order for them to achieve their medical wishes.

An individual who has become accustomed to an individualistic society rooted in autonomy may find it difficult to re-frame their notion of autonomous decision making to include relationships beyond just having an appointed SDM. While needing care is universal among all humans, it can be challenging to acknowledge that as an adult, someone else will have to care for you and that you will be unable to care for yourself.⁷² Losing control over oneself is a common fear within society, and while appointing someone Power of Attorney or creating a living will or advance directive may comfort an individual through instructing others in what their autonomous choices would be, there must still be a sense of trust in others to do what is best in the event that their advance directive is not applicable to a particular situation.⁷³ Recognizing this need for care and accepting that it will become a reality is essential in order for autonomy to gain a new connotation that may be more applicable to real situations as opposed to hypothetical ones. Furthermore, even if a patient is not incapable, this new meaning of autonomy may encourage them to seek help from others in making a decision or gathering information, instead of adding stress to their own lives, carrying out every task, and making every choice alone.⁷⁴

ii. Provider-Patient Relationships

Care ethics, at its core, focusses on relationships, and can be aptly applied to the relationships between patients and their healthcare providers. Positive and open relationships lead to better healthcare, proving the need for the analysis of the ethics of care and its utility.⁷⁵ This relationship between patient and provider must include honesty, trust, and openness, to ensure that adequate medical services are being delivered. A patient should feel comfortable and autonomous, while a doctor must ensure that they are not being paternalistic, but, rather, honest

and helpful. Not all patient-physician relationships are so perfect, but striving towards this level of support should be a goal. By maintaining these components within a relationship, care is at the forefront, in addition to autonomy and trust. Trusting relationships rooted in care lead to a higher level of patient independence and may produce a better medical outcome, setting up both the patient and their physician for success.⁷⁶

It is certain that bioethics is based upon issues in healthcare, and that the ethics of care has always been a necessary component, even though it may not be formally identified as such. We need to care in order to work in or trust healthcare. Furthermore, by simply discussing the ethics of care and delving into how it is actualized in reality, all individuals who participate in the health sector may be able to truly understand the purpose of their work, and the motivations that drive them to do their job well.⁷⁷ It is obvious that healthcare professionals who do not truly ‘care’ about their patients or about what they are doing, do not provide successful or adequate service. Such an approach to their daily activity can damage the relationship with their patients and negatively affect their work. On the other hand, by recognizing that healthcare workers do, indeed, care and view their job as something beyond just earning a living, the ethics of care becomes a stronger theory that is a necessary component of effective healthcare.⁷⁸

The ethics of care maintains that everyone requires care in their daily lives, especially with regard to medicine. Joan Tronto presents a sequence of care that can be utilized when creating policy, or making a choice that must be focused on care and how it should be implemented or provided. She outlines four phases of caring, some of which were alluded to in the previous subsection: caring about, taking care of, care-giving, and care-receiving. This sequence includes separate steps that are all interconnected to make certain that the best level of care is provided.⁷⁹ While these phases describe how care should be approached, they fail to provide a normative

foundation upon which acts can be based. Simply having the responsibility to care does not constitute enough knowledge to understand how care should specifically be implemented.⁸⁰

While no ethical theory can provide specific guidelines regarding what to do in certain situations, Vanlaere and Gastmans present the idea that personalism may be the answer to the dilemma of normativity for care, and can, therefore, provide this vital component for this ethical approach.⁸¹ By combining personalism and care ethics, one is better equipped to provide effective healthcare. Care ethics already has contextual features that allow it to be applied to medicine, but personalism provides foundational methods with which to explain why individuals must be cared for, and why human beings must be considered as whole units. It is a characteristic of human nature to care, and by adding the component of what human nature entails, care theory becomes a more viable ethical foundation of healthcare.⁸² It may also give health care providers a deeper understanding of their responsibilities and duties that would influence the quality of care they provide and relationships with their patients.

The ethical theory of personalism, as the name suggests, focusses on the entirety of a person. It places emphasis, not only on a single aspect of an individual, but on the whole of the human being.⁸³ Louis Janssens outlines what it means to be a human being, in terms of what factors comprise each individual person. He postulates that there are eight dimensions that must be accounted for when considering an entire human being: a person is merely a subject, they possess corporeality, the material world consists of our body and the bodies of others, individuals are basically directed toward each other, humans are part of a greater social world, a person is called to know and worship God, we are all historical beings, and all human persons are fundamentally equal, but at the same time each is original.⁸⁴ While these components will not all be explained in detail, Janssens' theory will be referred to as an interpretation of personalism.

It is evident in Janssens' description that a human being has both subjective and objective dimensions, all of which must be considered. Personalism requires that an individual is a subject, but also that they are related to others, and require those relationships in order to flourish, survive, and sustain their status as a 'person.'⁸⁵ This all-encompassing method of thought is important to recognize. In Western medicine, autonomy is often cited as having the most value. Personalism acknowledges that a human being is a subject, but also puts forth that subjectivity, or autonomy, is not the most important factor. In fact, there is no single most important dimension; rather, all of the dimensions described by Janssens should be considered together. This point makes it clear that the entire human being is accounted for and considered when making decisions, and no single aspect of humanity is of higher value than the others.⁸⁶

Valuing all of the dimensions equally can be viewed as a positive way of thinking. However, personalism attracts some criticism because of its Christian roots. It is evident from Janssens' argument, as well as from that of other moral theologians, such as Augustine and Levinas, who was not truly religious, that God plays a significant role in the definition of a human being.⁸⁷ Christianity teaches that there is a human transcendence present in the lives of people, which influences the way they are perceived, as well as the decisions they make.⁸⁸ It is also clear, especially in the direct writings of Janssens, that there is a belief that all humans are creations of God, and that they should follow His teachings and guidance in order to live Christian lives.⁸⁹ Furthermore, this idea extends to the sacredness of human life, which can influence medical care. These religious considerations may be beneficial for Christians who are using personalism, but cannot be used as arguments for individuals and societies that do not believe in the Christian faith. While personalism does not rely on religion to enable it to stand as

its own theory, there may be hesitation to implement this theory on a global level, as the backlash against Christianity may overpower the non-religious ideas being put forward.

When care ethics and personalism work in tandem, the results are an ideal theory with which to approach and provide healthcare. Personalism can provide care ethics with a normative method for realistic implementation, and the two combined can enforce the notion that particular relationships must be acknowledged to provide patient-centered care. Care ethics and personalism must be added to autonomy in order for them to be applied in the medical world today, which heavily favors autonomy as the most important ethical theory for decision making.

Aside from caring for a patient and providing medical care, a physician's role when caring for their patients and aiding in the decision-making process is to provide proper guidance in order for a patient to make an autonomous choice.⁹⁰ To effectively fulfill their role, a doctor is expected to form a trustworthy relationship with their patient, to ensure that confidentiality and privacy are upheld and that the patient is comfortable enough to ask informative questions.⁹¹ This ultimately leads to better care, as a patient and their healthcare team work together towards the common goal of the patient finding relief. If a patient does not feel cared about or valued, they may not comply with medications, or may disregard any information given by their physicians.⁹² A trustworthy relationship is built upon proper communication and a doctor's ability to assess each individual's case in detail. A physician is expected to use prior knowledge to ensure that their relationship with patients is appropriate based on each specific patient.⁹³

Effective communication is the key to success for a patient-doctor relationship. One main role that a physician has is to educate their patient about their condition, provide a diagnosis and prognosis, and present any treatment options.⁹⁴ This can be stressful for a patient, and it is crucial

that their physician is able to present information in a way for the patient to properly understand and process their situation. It is also the doctor's responsibility to assess and tailor each relationship to fit the individual patient, to ensure that they are comfortable and able to provide their informed consent, should they choose to do so.⁹⁵ This promotes patient-centered care and demonstrates the use of care ethics described above. Usually, if a doctor is kind and forthcoming, and open to a discussion about goals and values with their patient, the relationship becomes a positive one, leading to successful care and future steps.⁹⁶ If a physician or resident seems burnt out and act as though they do not personally care for the patient, there may be a misinterpretation leading to problems in the future. It is important that physicians monitor themselves and also think about how they present themselves to their patients.⁹⁷

When providing necessary information, a physician should consider how a patient will react, and try and deliver the facts in a way that will make the patient most comfortable. When disclosing information, a doctor, for example, can either explain every last detail and risk related to a given procedure or treatment, or choose to omit certain facts that are either irrelevant or are thought to possibly cause more harm than good (by potentially scaring the patient unnecessarily).⁹⁸ However, physicians should be careful about making a subjective decision about what will harm their patient, and they should use their experience to make that determination. Problems could arise if the patient waives their autonomous rights, or does not trust the doctors sufficiently to have faith in their medical recommendations. It would then fall on the professional to use moral reasoning to make the best decision for their patient: either to explain differently, or to go to a substitute decision maker if the patient is incapable of making their own choice.⁹⁹

A physician may choose from one of three disclosure standards to present the proper information in order to obtain genuine informed consent. The “professional practice standard” involves outlining all information that a fellow professional would agree to be necessary; the “reasonable person standard” entails explaining what a reasonable person would find the most useful; and the “subjective standard” which requires the doctor to discuss information they feel is relevant to a specific individual patient. The best standard is one that combines the latter two which ensures that the proper facts are provided at a level that the patient can understand and which reflect their own lifestyle, and therefore allow them to make an informed decision.¹⁰⁰ A doctor must consider that a patient may not feel that all medical facts or drug chemistry will be relevant in their decision making process, and only significant and potential risks and benefits, as well as a simplified version of the science, are necessary. For example, patients who come from an impoverished community and who have little formal education will probably not be able to understand difficult medical terminology which will lead to an uninformed decision regarding their medical care if a physician does not simplify the language so the patient understands.¹⁰¹

It is also important that once a physician provides any necessary information and offers recommendations that they follow up with their patient and offer help in areas they can provide it. Although this is less applicable when discussing possible treatments and procedures, this practice should be implemented during general practitioner visits. For example, a physician can recommend to a patient that they stop smoking. They explain the risks of the action and the benefits of cessation, but it is rare for a physician to offer additional practical support. Although a doctor may be hesitant to prescribe withdrawal medication, it can still be beneficial for a patient who is trying to quit, to receive withdrawal support from their physician. Assistance of this kind results in the patient being more honest about their habits, and more likely to trust their

physician's advice. This ultimately motivates the cessation of smoking and improves the doctor-patient relationship.¹⁰²

In the past, paternalism was a common practice in medicine, where doctors made choices on behalf of their patients because a doctor's educated opinion was valued more than a patient's personal one. A physician knew what would provide the most benefit for a patient and that recommendation was accepted.¹⁰³ Now, patient autonomy takes priority over a doctor's opinion in making the ultimate decision. Nevertheless, paternalism is still present in society. Beauchamp and Childress emphasize the difference between hard and soft paternalism. Soft paternalism involves a doctor making a decision for someone who is unable to make one for themselves, such as a depressed patient who cannot clearly weigh their options or who gives uninformed consent. Hard paternalism consists of a medical professional directly interfering with a competent person's choice, because that choice differs from the medical suggestion. In other words, there is no respect for autonomy.¹⁰⁴ Soft paternalism can be morally justified. An extreme example is preventing a patient under the influence of drugs or alcohol from committing suicide. A presumably reasonable person would consider the interference morally acceptable, since the autonomy of the patient is compromised.¹⁰⁵

It is more difficult to justify hard paternalism. For instance, withholding a negative diagnosis because a doctor feels the patient would suffer from knowing their fate, is frowned upon, and discouraged. A physician's decision to withhold an aspect of the actual scenario from a patient in order to prevent unnecessary stress and resource overuse may be justified. For example, a patient with an anxious nature discovers he has a small thyroid nodule, which may or may not be cancerous. His general practitioner knows that these situations rarely end up being malignant, and does not believe the patient has any reason to be concerned, nor does he have any

reason to order extra tests at the present time. It can be accepted that the physician recommends yearly screening to ensure that cancer does not occur.¹⁰⁶ This case is one of paternalism, in that it involves a physician acting in a way that they believe will be most beneficial for their patient. It is also an example of how theory does not directly transfer to practical situations, as some would argue that a physician must explain all risks and possibilities to a patient, and that the patient then has an autonomous right to undergo further testing at any cost. This leads into the issue of futility, which will not be discussed at length.¹⁰⁷

There are additional definitions and interpretations of paternalism as well. Gert, Culver, and Clouser define paternalism as consisting of four parts: A physician must believe their actions will benefit their patient, a physician recognizes that their actions towards a patient are the kind that need moral justification, a physician does not believe that their action has the patient's past, present, or immediately forthcoming consent, and a physician regards the patient as believing that they can make their own medical decisions.¹⁰⁸ These four stipulations do not all have to be met for an action to be considered paternalistic, but it is important for doctors to reflect on their own thoughts and intentions before acting. This definition ensures that paternalistic behavior is always based upon good intentions that simply need to be justified. The definition also acknowledges that paternalism can be justified and unjustified and that there are certain situations where unjustified paternalism is permissible.¹⁰⁹

Paternalism should, indeed, need to be justified. A physician who is able to recognize that there is a possibility that a paternalistic action may be morally wrong, has the ability to analyze the action to determine if proper justification can render it permissible. A physician who can make judgements about morality can also judge whether they are being paternalistic, and try and avoid this kind of behavior. It is also up to each individual physician to determine how to deal

with these actions and thoughts. If a doctor believes himself to be virtuous, he can decide whether a paternalistic act would violate a moral ideal or moral rule. Another physician may identify more intensely with casuistry, which does not evaluate morality, but simply compares a current case with others from the past, and uses those previous cases to decide on a conclusion in the present.¹¹⁰ Furthermore, when a physician considers which philosophical theory (if any) they identify with, they can use it to determine whether they are indeed acting paternalistically. An act consequentialist always justifies and deems permissible paternalistic actions that would benefit a patient. Conversely, a strict deontologist stipulates that these actions are never permissible, and a common moralist argues that they are sometimes justified and allowed.¹¹¹

Paternalism, however, can lead to negligence, if all the proper information is not given to a patient in the process of making a decision. If a physician does not feel the need to disclose all of the risks of a procedure, it can be catastrophic if those very risks occur. For example, if a doctor does not explain the risk of vaginal delivery to a woman with a high-risk pregnancy, the birth may have complications that could end up being fatal for the fetus and the mother. This could also lead to court cases in which doctors are sued for simply not providing all the necessary information.¹¹² To avoid these situations, doctors must disclose any general risks associated with a procedure, but also explain any risks associated with a particular patient. This ensures that a patient can make a properly informed decision that they feel will be best for them. This further emphasizes the need for proper discussion between a physician and a patient that includes all relevant and necessary information, but not too many technical facts to overwhelm the patient.¹¹³

All things considered, paternalism, although it is often disapproved of, is sometimes beneficial when it is executed as persuasion or a ‘nudge’ in the right direction. It can be useful

for patients who are overwhelmed and unable to make an appropriate decision for themselves. A physician's previous experience can aid in persuading a patient to choose what their physician believes to be the option which is in their best interest, and which offers the best possible outcome. It can be difficult for a patient to think rationally in an emotional state, and having another outside voice that still cares for the patient is beneficial.¹¹⁴ Furthermore, when physicians voice their own personal experiences as self-disclosure, it can demonstrate to their patient that they do care more than just about the medical interventions, and are willing to share their personal stories to help the patient make the best decision for themselves.¹¹⁵

It has been established that autonomy must include a relational component to make it complete. Within healthcare, the most common relationship experienced by an autonomous patient is the one with their physician. As explained above, physicians have a duty to properly interact with and communicate with their patients. While paternalism needs to be considered when providing patients with information, care ethics can also be used to improve and maintain a positive relationship between a physician and their patient. When discussing duty and doing what is right, bioethical discourse considers deontology to be in the realm of individualized healthcare. Healthcare itself relies on others, both on individuals and collective societies, in order to determine that there is a duty to care and to provide medical aid to everyone.¹¹⁶ According to the World Health Organization, all individuals have a right to healthcare, inferring that governments and individuals have a duty to provide care.¹¹⁷ This is an example of care ethics as well. The duty to care can be included both as a deontological statement, but also through the ethics of care, which focusses on the particular relationship, in this case, between patients and their care providers. The connection between deontology and care ethics may not be as clear as in other areas, such as politics, but within healthcare, it is obvious that both of these moral theories must

rely on each other to provide a service that has been deemed essential for all human beings.¹¹⁸ In this situation, there may not be a universal duty for all individuals to provide care, but there is definitely a duty to care by those who choose to pursue a health profession.

In an ideal situation, all healthcare workers would be selfless individuals who truly wish to aid their patients and provide them with care. Getting paid and having an occupation are only additional benefits. However, it can be questioned if those providing care have an actual duty to do so.¹¹⁹ Deontology, in a philosophical context, focusses on individual reasoning and doing what is right. An individual has a duty to act in a way that corresponds to them being a moral person.¹²⁰ In the context of healthcare, separating care and duty can be difficult, since individuals do have a duty to care in order for them to make a living.¹²¹ There is little tolerance for treating patients badly and without respect, which are signs of inappropriate care. However, while individuals working in healthcare are essentially paid to care about others, there is also a notion that they feel they have a duty to care as individuals, regardless of their job. Often people train in health professions because they feel a responsibility and desire to care for others. Their duty to care as individuals and their duty to care as workers merge into one unified motivation to care.

Simply having a duty to care, however, is not enough to be a successful healthcare provider in today's society. In order to provide the best care through a personalist approach, by acknowledging that a person is more than just a set of symptoms, a physician or healthcare provider must be compassionate. Compassion is a virtue that is experienced through an emotion. It demonstrates a level of humanity which connects with their patients' personal lives.¹²² When an individual feels the need to act on their notion of compassion, beneficence is being exhibited, as one is trying to bring about added benefit to the other person in need. While compassion is a virtue, beneficence is a supererogatory addition that is not required of all individuals.

Empathizing with someone else is considered humanly positive, but going one step further and taking action is not always necessary.¹²³ If this idea is applied to medicine, it may be argued that providing some sort of care, such as assistance with dying, may be going too far. However, compassion may motivate a doctor to do just that.

It is evident that compassion should have a place within medicine. Physicians have an obligation to be compassionate towards their patients, as it is necessary to provide meaningful healing. Compassion is a virtue that some individuals display better than others, but it is also a virtue that can be taught.¹²⁴ All healthcare professionals have a responsibility to be well-versed in their medical specialties, but also have a duty to be able to interact with patients on a personal level. Insisting on compassionate employees emphasizes the other duties that are expected of those working in the medical field. Physicians, primarily, have a fiduciary duty to put their patients first, a duty to provide due care, and a duty to maintain confidentiality within their patient-physician relationship. These duties all require compassion to ensure that a patient is appropriately treated.¹²⁵ This promotes providing ‘good care’ that treats symptoms, but also improves the patient’s overall wellbeing.

Furthermore, the relationship between a doctor and their patient is strongly dependent on compassion. By demonstrating compassion, a physician is also recognizing the importance of a patient’s feelings, and by extension, their values. By displaying a level of empathy and acknowledging the hardships a patient is facing, more trust is being built that should lead to better care. It is crucial that a physician has the skills to be authentically compassionate to make certain their patient feels comfortable and supported.¹²⁶ However, it should be noted that while compassion is able to create a more personal bond between a physician and their patient, the relationship should not be symmetrical. While there should not be a sense of superiority from the

physician, the patient should not feel as though their doctor is unable to help them. A physician must stay objective while engaging in the subjective world of their patient. This further emphasizes that a physician needs to empathize and try to feel the exact emotions of their patient, but must be able to acknowledge their hardship and evaluate their suffering at a deeper level.¹²⁷

It is important to discuss the role of a physician and the type of relationship they should create with their patient. While it is crucial that a healthcare professional is compassionate and demonstrates their desire to care, the patient must stay a client and the relationship has to remain professional. Finding a happy-medium can be challenging; a patient must feel that they are being treated kindly and with respect, but a physician must remain objective and not become involved in their personal life or coerce them into making a decision that does not coincide with their values. A physician should acknowledge that requiring care is a universal experience as this simple recognition encourages empathy toward a patient.¹²⁸

However, the previously-described power differential must be considered, and a physician does have a task to complete, resulting in the physician having to accept that they may not receive a reciprocal amount of care in return. Tronto's four phases of caring model does include a section that explains the need for an acceptance of care by a patient, for example, but a physician's duty is to sacrifice this potential return in order to do their job. Carol Gilligan describes this self-sacrifice as 'mature care,' and feels that it is crucial in healthcare. However, van Nistelrooij postulates that mature care may be one method of characterizing this relationship, and that there is the possibility of dealing with the patient as a client, but also as a fellow human being in distress and in need of care. Appealing to the human instinct of helping others may be

more indicative of how a physician should approach their work, as opposed to simply doing their job.¹²⁹

Medical professionals train extensively to be able to treat ailments and cure disease, but many may find it difficult to see beyond a patient's diagnosis and details of the disease. It is crucial that patients are treated like human beings, and that their whole self is considered when being given medical treatment for illness. 'Good care' should be based upon the entirety of a person, and can include religious, cultural, and relational components, not just symptoms.¹³⁰ A physician has the responsibility to establish a trustworthy and positive relationship with their patients to ensure that these human dimensions are acknowledged and taken into account during treatment. By approaching medicine with the notion that appropriate care should be tailored to a 'person,' and not a patient, there is a better chance of success. This also upholds autonomy, to a degree. A patient who values their family's opinion, for example, may receive a better care plan if their physician is aware of their needs. Their autonomous choice may depend on others, and a doctor who can recognize this would be better at administering care. In healthcare, it is evident that personalism should always be considered in order to provide appropriate care.

It is clear from the discussion above that a physician is expected to exhibit empathy and compassion in addition to adequate medical skills when informing and treating a patient. In order to accomplish these goals, a doctor must be attentive. The primary objective of a consultation or conversation with a patient should be able to understand the personal narrative of an individual and to acknowledge their experiences.¹³¹ It may be routine to get a list of symptoms and run the corresponding tests, but it would be more beneficial to converse with the patient to better comprehend their biography and the events leading up to their ailment. Being attentive is another duty of a physician that allows a patient to feel as though they are more than just a collection of

symptoms, and it demonstrates an elevated level of care from a healthcare professional. While it may take more time to speak with the patient about more than just symptoms, it is valuable to do so to ensure that all aspects of their history and their experience is understood and realized.¹³²

Moreover, appreciating that every patient has their own unique history and set of experiences will aid a physician in providing better care. A doctor may learn new information about how a symptom appeared or certain events of a patient's life that may be harmful that would improve a patient's care, and also ensure that treatment is individualistic. It ensures that the informed consent process, in which a physician determines what information needs to be disclosed is more personal and ultimately leads to a decision that is right for a specific patient.¹³³ Not everyone fits into a pre-established mold, and patients' experiences are subjective, emphasizing the need for additional care to provide the best and most personal support for an individual. Furthermore, asking questions and gaining knowledge about a patient's background may be beneficial if a physician has not clarified their diagnosis, and allows for a patient to be considered wholly.¹³⁴ It also improves the relationship between a patient and their healthcare worker and garners trust, leading to better care.¹³⁵

B: Parental Decision Making for Children

As described above, medical decision-making can be a stressful, complex and difficult task when facing life-threatening diseases. Individuals must rely on medical information, but internal values and experiences also come into play when an autonomous choice about medical care is being made. Children fit into the previously defined category of patients who may have a limited capacity with which to make their own medical decisions. Children have some capacity, but in the US, their informed consent is only considered to be assent, and must be combined with

parental consent due to the legal age of consent in the United States. It can be difficult to assess a child's capacity as well as to determine that they are sufficiently capable of making their own medical decisions. It is often assumed that a child cannot understand and appreciate their condition and treatment options, which invalidates their consent for any medical interventions.¹³⁶ Even though children are seemingly unable to provide legally accepted informed consent, their autonomy should not be dismissed, however. The assent or dissent of a child can be reflective of how much a child understands about their situation and these wishes should be considered by parents and physicians. Extra care should be taken to ensure that a child's voice is heard and that they feel respected and included in any decision-making about their own condition.¹³⁷

Along with a child's assent or dissent, parental consent is necessary for all decisions involving children. Doctors must treat parents the same way they would a capable patient by discussing all relevant information about a child's diagnosis, prognosis, and treatment, as well as the associated risks and benefits.¹³⁸ A parent has an autonomous right to make decisions on behalf of their child, which they consider to be in their best interest. Since parents have a right to raise their children however they see fit, they also have the same right to make decisions regarding appropriate medical care. It is assumed that parents always act in the best interest of their children and that a parent or guardian knows their child's habits and lifestyle, and can decide whether a medical intervention will be beneficial or harmful.¹³⁹ A difficult situation can arise if a child and their parent do not agree about a treatment plan or procedure. For example, if the child feels uncomfortable undergoing a surgical procedure, but their parents insist that it occurs, legally, a doctor must listen to the parents, as long as there will be no direct harm to the child. Although this violates a child's autonomy, their lesser level of capacity makes it acceptable.¹⁴⁰

Neonates are also children, but differ from the above described minor since they have no capacity. Infants are not able to express their wishes in any form, aside from possibly being able to show and demonstrate when they are in pain or feeling uncomfortable. Furthermore, this communication may not be clear to everyone, and recognizing the suffering of a neonate can be difficult for inexperienced individuals.¹⁴¹ In the case of these patients, parents are making decisions for their children and acting with their best interest in mind. It is recognized that since infants are completely unable to communicate or exercise autonomy, physicians are involved in making decisions about medical care, providing parents with the ability to provide permission and assent, as opposed to full consent for care.¹⁴²

A parent acts as a substitute decision-maker, following similar guidelines as SDMs who have been described above. However, there are unique nuances in making decision for children which will be explored below. Along with medical opinions, the interplay of external factors influence how parents determine all of the options available to them in order to decide on the best course of treatment for their child. This ultimately affects their child's future quality of life. This section discusses how socioeconomic factors, religion, culture, and general personal values influence a parent's final medical decision for their ailing child.

- i. Parental Autonomy and Values

Parents are responsible for choosing options that result in the most beneficial care and should act with the welfare of their child in mind. When an adult makes a decision, they do so based on their opinions and values, and it is hoped that a surrogate would be able to apply those same values when making a choice for their child. It is difficult to employ this 'substituted judgement' model of surrogacy to children, since they often do not have the opportunity to express personal values and interests in their own medical care. Parents do not have the ultimate

right to impose their own values on their child and label them as being the same as their child's. This is especially true with infants, so the 'best interests' standard is employed.¹⁴³ Best interests can vary depending on how individuals define a positive quality of life, and in order to make decisions that are in the best interest of a child, personal values should be considered. A most common determinant involved in choosing the best medical option is the determination of harm, as parents want to prevent their children from experiencing injury and suffering.¹⁴⁴

Values frequently influence medical decisions, and parents making decisions on behalf of their child may use 'values' as a justification for their choices. Parents have, both consciously and unconsciously, established their own values, and live their lives to match them. However, they must consider that their personal values may not be the same as the values of their children.¹⁴⁵ In situations where a child is completely incompetent, as is the case with babies or fetuses, a parent automatically imposes their own values upon their child and assumes that their values are equal to those of their child. This can be difficult to oppose, since an infant is unable to disagree with their parent.¹⁴⁶ Healthcare workers should be careful to ensure that a child's best interests are considered, in addition to respecting the values of their parents.¹⁴⁷ If possible, they should consider the personal values of their patient in order to provide the best care for them. In scenarios where a child is able to communicate, either partially or fully, such as in the case of mature minors, there is greater ability for a child to apply their own values to make or voice their decisions regarding medical interventions.¹⁴⁸

However, some scholars argue that a parent has the liberty and the right to make the ultimate decision for their children with no interference from any other party. Since parents have a right to raise their children however they see fit, they also have the same right to make decisions regarding appropriate medical care.¹⁴⁹ It is assumed that parents would automatically

and always act in the best interest of their children and that a parent or guardian knows their child's habits and lifestyle, or is able to determine a hypothetical situation in which their child exercised 'good' behavior that corresponds to a happy life. Since it is regarded as a right or liberty, it can be included in parental autonomy, which implies that no one, whether it is a doctor or a court, should be able to override a parental decision, unless a parent is deemed incapable of making decisions. There is an added responsibility to decide whether a medical intervention will be beneficial or harmful.¹⁵⁰

Other researchers have suggested that instead of a 'best interests' standard, parents should use a harm-ratio standard to determine an appropriate medical decision for their child. Birchley argues, however, that a harm analysis should be used to inform the 'best interests' standard leading to a thoroughly thought-out decision. A harm analysis includes analyzing the amount of predicted harm associated with each intervention or treatment option made available to a parent.¹⁵¹ It can be assumed that the intervention with the highest benefit and the lowest harm is the best option for a child. However, this may not always be the case, and a harm analysis may not be the most suitable method for making a medical choice. For example, if all options for a child are considerably harmful, parents would have to consider the best interests of their child in order to make a choice that coincides with the predicted outcome.¹⁵² Using the harm principle to override a parent's decision is also questionable, should they pick a treatment option that causes more harm than benefit to their child.

In order to obtain informed consent from parents, doctors must treat them the same way they would an adult patient when discussing a child's diagnosis, prognosis and treatment.¹⁵³ Relevant information should be provided clearly by physicians who are aware of a child's medical situation. Furthermore, it can demonstrate an extra level of compassion if a physician is

able to comment on a family's personal values and how they might influence a medical decision. Healthcare workers who are able to relay this information and also be aware of entirety of a situation are more likely to build trusting relationships with their patients and their parents.¹⁵⁴ Once all information has been presented, and sufficient time has been given to process that information, a parent should be able to provide an informed decision. They should be able to demonstrate that they understand and appreciate their child's situation and the implications that could result for each treatment option. This ensures a competent decision that is truly in the best interest of a child.¹⁵⁵

Every individual is entitled to their own personal values and to having the liberty to incorporate them when making medical decisions. However, it can be difficult to assure oneself that personal values are important and crucial when societal pressure can still manage to greatly influence which medical decisions a parent is expected to make for their child. In the Western world, autonomy is considered to be one of the most important rights that humans have. The earlier section of this chapter outlined the concept of autonomy and how physicians should go about assessing a patient's autonomy and obtaining informed consent. A healthcare worker must respect autonomy when they are sure that a patient is capable of making a decision, and has done so, free of coercion. In order for a patient's autonomous decision to be respected, an individual must be deemed to have adequate decision-making capacity with which to provide their informed consent. A capable person is able to understand simple medical facts about the procedure or treatment to which they are consenting, and to appreciate the effect that the medical intervention will have on their body and on their life.¹⁵⁶

An autonomous choice, as alluded to in the last paragraph, is autonomous, because a patient is able to use their own reasons to make a decision. Personal values must be considered to

ensure that a medical decision feels right and is in accordance with personal beliefs. Common personal values include culture and religion; other values can include one's need or emphasis on family, as well as education levels and valuing information, and how human life is regarded. It can be difficult to understand medical jargon and information when it is presented in times of crisis. For this reason, personal values are useful in predicting possible implications for medical choices. They act as a filter, in addition to other external factors, that allow patients the opportunity to see how their medical choice will affect their own life, but also why they make the choices that they do.¹⁵⁷

Personal values differ for each individual, but decisions that involve a family may shift the decision-making focus away from the self to the other. Two components will be considered: how are medical decisions affected by considerations about a marriage, and how does a specific intervention affect a family that includes children and extended relatives. Many people value their family and recognize the importance of family as a major component of a happy lifestyle.¹⁵⁸ When parents are forced to make serious medical decisions for their sick child, familial considerations may influence which decision is made. For example, a mother whose unborn child may have a disability and she herself, is at risk during delivery, may fear that her husband will not be able to handle the amount of stress associated with raising a child who will need constant physical support because of a disability. Studies have indicated that divorce may be an outcome of this added pressure.¹⁵⁹ Moreover, parents who already have children, and are facing their possible death, may wonder if their family will be capable of dealing with grief and sadness over the death of an infant.¹⁶⁰ Studies have also indicated that families who include a disabled child, or who grieve the loss of a child together, end up stronger and are better suited to accept their situation, as opposed to trying to deal with difficult situations alone.¹⁶¹ These considerations

can influence how parents make decisions regarding serious medical interventions for their children.

Another possible factor that may influence decision making is the parents' level of education. In cases where one or both parents have university degrees or medical backgrounds, it may be assumed that they value scientific facts and medical information over emotional or personal influences. Although it is medical information, details about a medical condition can be a personal choice, some parents preferring a simple explanation of a prognosis and treatment options, choosing to use other values to make a decision rather than equipping themselves with a detailed 'education' about the condition.¹⁶² There may even be a risk that physicians will be more inclined to support parents with a higher education level. For example, a doctor may consider parents who are professors more rational and better able to make a decision that corresponds to the medical opinion, thereby creating a bias on the doctor's part for the more educated parents. This should not be the case, as healthcare workers have a responsibility to respect any of their patient's wishes and processes of decision-making, and provide information and support equally among parents.¹⁶³

Other personal values may also play a role in parental decision making. For example, when a parent makes a decision for their infant, they have to consider their own personal views on personhood, and what it means to be a human being. The concept of personhood often stems from religion, and decisions are often made based on religious views. For example, when discussing the beginning of life, there is some debate about when one becomes a person, and therefore attains moral status. Catholic doctrine maintains that life starts at conception, and embryos are considered to be people throughout a pregnancy.¹⁶⁴ Judaism teaches that one's soul appears once they take their first breath.¹⁶⁵ Attaining moral status is crucial, as it entitles a person

to human rights. In this case, a person has a right not to be killed intentionally, especially through a medical procedure.¹⁶⁶

The principle of double effect (PDE) is an essential component of religion-based decision-making. PDE is applied to situations when there is a question about an action that may produce multiple outcomes, some intended and others consequential. It asks the question, is it right to perform a procedure with an intended good effect that may result in an unintended but foreseen negative effect?¹⁶⁷ When using this tool, there are four conditions that must be met in order for the decision to be deemed acceptable: the act in question may not be wrong morally, the negative result may not actually produce the intended good action, the ‘bad’ effect must not be the intended effect, and the benefit must outweigh the unintended, evil outcome.¹⁶⁸

Religion, for the most part, is an acceptable decision-making tool, as choices can be justified through religious doctrine. There are scenarios, however, where religion is not a sufficient method for choosing a course of treatment. The most common example is an infant whose parents are Jehovah’s Witnesses. In this branch of Christianity, blood transfusions are prohibited in order to abstain from blood and to respect God, both of which are believed to be true in this religious sect.¹⁶⁹ A capable individual has a right to believe these statements to be true and opt out of blood transfusions, but an infant who has no sense of capacity has not been given the opportunity to choose their religious beliefs. If a baby is in a life-threatening situation and requires a blood transfusion, it can be considered immoral for a parent to prohibit this intervention based on their own beliefs. It is not fair to their child to have their parents’ beliefs imposed upon them, in the situation where they could die as a result. It is in the best interest of the child to disregard their parent’s religion.¹⁷⁰ This is a unique situation, and in other less emergency situations, religion should be considered and accepted in decision-making.

Although personal values imply that autonomy is being upheld, it can be common for patients, including parents, to be influenced by societal values that they encounter regularly. The Social Value Theory describes this social influence. It states that an individual can be persuaded to make a decision based on values that society holds, as opposed to ones that specifically pertain to the individual.¹⁷¹ Although these societal values are not restricting, they usually include not harming children, and choosing an option that ensures the best quality of life. In the case of parents making decisions, it is expected from society, that they will choose the option with the most risk aversion, to ensure the safety and health of their child. If a parent chooses or wishes to choose an option that has an increased amount of peril, they may feel pressure that this is the unacceptable choice, because of how they will be viewed within society. The perception of making the right choice can go from being appropriate for an individual family, to being the acceptable choice within society.¹⁷²

This concept of ‘right’ extends to the question of “Am I being a good parent?” A parent may feel that if they choose an option that is not generally accepted within their community or Western society in general, they will be considered a bad parent. Although the definition of a good parent can be both individual and general, it should be emphasized once again that medical decisions should be autonomous and reaffirm a parent’s own opinions about being a good parent.¹⁷³ When a random sample of parents was asked to define their version of a good parent, most of the outcomes included doing well by their child, being there and constantly supporting their sons and daughters, and making informed decisions that are in the best interest of their children. All of these responses are focused on individual families and allow room for all parents to decide for themselves what being a good caregiver entails.¹⁷⁴ There are situations, however, where society heavily influences whether a parent is perceived to be good or bad, such as the

issue of vaccination. If a parent chooses not to vaccinate their child, they may be viewed as a bad parent, who is imposing their own misguided personal values and harming their child.¹⁷⁵ Such negativity can be hurtful for a parent, and cause them to make a decision that is not compatible with their autonomous choice, but corresponds, instead to society's choice.

Societal values can also be imposed on individuals who are immigrants and come from different cultures. How a society accepts cultural choices can hugely influence a parent's choice to use these external factors when making medical decisions for their child. If a Western community emphasizes medical information and standards that correspond to a specific outlook on life, it can be difficult for recent immigrants or individuals from other cultures to feel that their cultural influences are acceptable with regard to medical decision-making. There may be some level of persuasion from the new host society to not depend on cultural communities to make choices, as one has an autonomous right to make their own individual choices, which may not be the case in other countries around the world.¹⁷⁶ Furthermore, there may be pressure from Western society to completely disregard external factors, and rely solely on medical information. If a patient values their own culture, it can be difficult to be expected to make a decision that ignores this and only includes their new society's values. Moreover, if there is a language barrier between a patient and a physician, there could be added pressure to accept what the doctor recommends, simply because a patient is unable to communicate their own wishes.¹⁷⁷

In the event that a parent makes a treatment decision for their child, and a doctor strongly disagrees with them, use of a court can be warranted.¹⁷⁸ The disagreement between a physician and their patient's advocate must have an indication that a medical intervention is not in the best interest of a child, and, therefore, should be overturned, or vice versa. Disagreements can often be avoided through effective communication and trustworthy relationships, as well as

explanations about the treatment choice.¹⁷⁹ However, a court can act as a third party to ensure that an appropriate decision is made.

In an opposite circumstance, a parent may request a specific treatment for their child that was not recommended because of safety or efficacy. In this situation, a physician has the right to conscientiously object to the choice of medical care, and either recommend another course of treatment or refer their patients to another physician. Conscientious objection allows healthcare workers to object to a treatment or procedure if it goes against their own personal beliefs. In some situations this can include religious practices, such as a physician not performing abortions, or it can include a nurse not wanting to participate in care for a brain dead patient whose family refuses to withdraw ventilators.¹⁸⁰ If circumstances arise in which a parent's decision is not in line with a physician's they have the right to object. Furthermore, if a physician believes that the requested intervention is going to harm a child, a court decision may be sought, which would again override a parent's decision-making capability.¹⁸¹ The same is true if a parent denies or prevents a recommended treatment that could save a child's life.

If a case is brought to court, the purpose of the action is to provide a new and neutral assessment. This ensures that a court is able to make their own judgements and decisions without a biased account from one or both parties involved. The role of a court is always to act in the best interest of the child, and it is up to a judge to attain all important facts associated with a patient.¹⁸² This must always include medical information, as well as a doctor's recommendations. It may include a parent's assessment or statement about personal values or an economic situation that influenced the original decision that was denied. Risks and benefits must be weighed in order for an appropriate decision to be made. In some circumstances, a court simply decides who the proper decision-maker is, not what the ultimate decision is, and in other

instances, a final choice is made to which all parties must be adhered. If a court decides on a medical treatment with which a physician disagrees, they have the option to remove themselves from the case and uphold their right to conscientious objection described above.¹⁸³

When a court does have to make a decision, it can be useful to examine past cases that either set a precedent or that demonstrate the possible results of a current situation. Furthermore, these cases also demonstrate and provide information about the hardships that families have endured that may shed light on the negative aspects of a medical intervention. It has also been observed that many cases involving medical decision-making for children have sided with physicians. There may be speculation or even an assumption that healthcare professionals abuse the court system in order to ensure that their recommended course of treatment be implemented, when there is a disagreement with parents.¹⁸⁴ This method is highly unethical, and a court should be able to assure parents that they are making a choice that abides by the law and is not influenced by specific doctors and their agendas.

ii. Socioeconomic Considerations in Decision-Making

In addition to personal and societal values, there are external factors that parents cannot control that impact medical decision-making for their children. Both financial status and access to resources can pose difficulties in receiving adequate medical care for oneself and for one's children.

Financial burdens are difficult to overcome, especially at times when there are more important uses for money than medical care, such as food and shelter. If a family is impoverished, their children may not have suitable access to healthcare, and, therefore, are denied their human right to health. Poverty, however, causes more than just financial problems, and clinicians have attempted to understand and advocate for children who live in poverty and

are unable to afford medical care.¹⁸⁵ When a parent makes a decision, their way of life may differ from a physician's perspective and may result in a disagreement. It is important for healthcare workers to educate themselves about children who live in poverty, and understand that they may be affected by social determinants of health that lead to medical problems. Examples include lack of financial support, as well as a threatening physical environment, and exposure to violence and substance abuse. These difficult situations may put parents in a difficult situation when having to make medical decisions for their children, if they are unable to understand the information or have the ability to care for their children, for example.¹⁸⁶

In order to ensure that all children have access to medical care, the American government has established programs, such as Medicaid, that provides insurance for children, as well as increased access to healthcare services.¹⁸⁷ In numerous countries around the world, where healthcare is available to every citizen for free, this would not cause the same amount of burden as it does in the United States. Parents may feel that their own insurance or lack of insurance is not sufficient for their child, and it would be assumed that parents would embrace services to ensure their child is able to stay healthy.¹⁸⁸ Not only is it important to provide these insurance programs, more health services are trying to raise awareness about childhood poverty in order to create public policy giving children a right to free healthcare. When making medical decisions, a parent who lives in poverty may be more inclined to use resources, knowing that there are programs that exist that will take care of their children and their medical needs. It may lessen the financial burden and allow for a child to gain more medical care.¹⁸⁹

Further financial factors may influence parental decision-making. Paid leave can be difficult to attain for many professionals, and a parent may experience a decrease in income if they have to take care of their child instead of going to work. This is a sacrifice that some parents

would be willing to make, while others would not be able to afford a lower income or time away from their jobs, in order to be with their sick children. There is the possibility that they may lose their insurance if they do not work enough, which would result in added stress when making decisions on behalf of their child. Intense stress of this kind may even cause the parent to become ill, complicating the situation to an even greater degree.¹⁹⁰

The financial status of a family and how it impacts decision-making is dependent on a parent. Parental autonomy is primarily considered in these situations, and some scholars and healthcare professionals feel that it is never permissible to make a decision about a child's medical care based on financial burden.¹⁹¹ It is not the fault of an infant that their family's socioeconomic status may be low, but this status should not impede a child's right to health. Similarly, if a child is born into a family that is well-off, it is also unacceptable to insist on numerous medical treatments to over-treat a child, if it is not in the best interest of the child. The main focus should be just that, what is in the best interest for a child, not their parents. A child is unable to decide for themselves whether a treatment is warranted, and should have the opportunity to be healthy and use medical resources appropriately and effectively.

In addition to financial status influencing parental decisions, sheer access to medical care can heavily influence whether a parent is able to provide proper healthcare for their child. If a family experiences a poor financial situation, it can be questioned whether the government programs that aim to reach out deeply into communities and promote and provide healthcare are effective.¹⁹² For example, government programs may provide necessities, such as vaccines, basic medications for colds, in addition to common antibiotics that are frequently needed within communities. There may not be, however, access to advanced medical technology that could save a child's life.¹⁹³ The American healthcare system leaves little room for all children to have

access to new and effective treatments because of cost. Are there resources for those families who cannot afford it? The answer to this question is difficult to answer, and it is unclear who is to blame if an innocent child dies as a result to not having access to medical technology because of socioeconomic status.

In addition, not having access to communication due to language barriers can cause problems for parents who are unable to understand their children's physicians. This could lead to a parent not exercising their right to autonomy and agreeing with the doctor because they have no other choice.¹⁹⁴ Language barriers also shed light on the difficulties that individuals have when they are unable to use the English services provided to them. For example, information can be distributed to parents whose children have cancer, or mothers who are having pregnancy complications, but if the information is all only in English, a patient who is unable to speak or read in English will not become informed, and, as a consequence, may not receive adequate medical care.¹⁹⁵ Although hospitals and public health services wish to solve this problem, they may run into issues with cost. It can be expensive to translate documents and resources into languages that are prevalent in a particular community.¹⁹⁶ However, if it is possible, by doing this, healthcare becomes truly inclusive and there is greater access for patients who previously felt neglected and unheard because of a language barrier.

To embrace linguistic diversity, healthcare facilities may implement services, such as interpreters or online information, to ensure that all patients are able to have access to adequate medical care.¹⁹⁷ This also relates to the issue of cultural competency within a hospital, which will be further discussed below. The need for staff and an institution as a whole to be culturally proficient and educated about culture and how patients make decisions, as well as aware of the resources that are available, is great. It is also important that the services that are provided use

professionals to ensure that medical information is being relayed accurately. For example, translators and interpreters should be well-versed in medical terminology and treatment information to ensure that a patient is given all of their options, and nothing is omitted. There is a fear that using family members or other individuals as interpreters may negatively affect a patient's right to autonomy if proper information is not given.¹⁹⁸

Culture is another factor that influences decision making from a social perspective. Cultural beliefs and traditions often inform a person's identity and personal values, but are also impacted by the environment where a person lives and who they interact with. Culture can be defined in numerous ways, and how an individual incorporates 'culture' into their lives varies between people. It can include a nationality with which one identifies and whose traditions and norms they uphold, or it can include a greater community, such as a 'Western' culture that encompasses general values, opinions, and opportunities. It can include race, or ethnicity, and should always be considered when making important decisions, because culture directly influences the way choices are made.¹⁹⁹ In American society, culture is accepted among communities as it contributes to personal values and to decision-making, and is generally respected in order to uphold an individual's autonomous rights.²⁰⁰

Culture, as described above, may heavily influence an individual's identity, which can contribute to how they define themselves as a person. The version of identity to which culture contributes is normative identity, which has the ability to be influenced by environment, society, parental values, and culture.²⁰¹ When an individual possesses a sense of identity, it influences how they live their life, and how they make decisions. Medical decisions require autonomy, but in order to make an informed choice, the values which make up a patient's identity have a bearing on their decision.²⁰² Culture, therefore, strongly influences how one may make medical

decisions. Parents must be careful, however, to ensure that their culture is not imposing on life-saving medical care for their child. Although culture can influence how quality of life is predicted, and subsequently which medical intervention is chosen, it is crucial that parents recognize how culture influences decisions, and ensures that they are choosing an option that is in the best interest of their child, who is not yet aware of their future cultural influences.

An example of cultural considerations that can influence a medical decision is a view of disability. Some cultures may feel that disability of any sort, mental or physical, is a result of demons being present, or events from a past life. In addition, attitudes regarding the caring of disabled children can vary among cultures, as some parents will embrace children who need extra support, while others may consider disability a shameful phenomenon, and may not know how or wish to handle the extra care required. They may have to depend on additional family members to help, if they, in turn, wish to help.²⁰³ A cultural perspective on disability can influence whether a parent chooses for their child to undergo a procedure that may cause disability, or that could possibly remove a disability, in the hopes that their child would become ‘normal’ and healthy. It is hoped that parents recognize that disabilities can be dealt with and that children may still have a fairly good expected quality of life, causing them not to use a cultural opinion about disability to influence a medical decision for their child.²⁰⁴ However, if a parent chooses to act on a risk of disability, doctors not only have a duty to respect the wishes of the parents, but also to ensure that children are not being neglected or punished as a result of disability.

Another common cultural influence on medical decision-making is the association between race and trust in medical professionals. Studies have shown that African Americans are less likely to trust doctors, as a result of historic abuse and deception.²⁰⁵ If a parent does not trust

their child's doctors or the medical profession in general, they may be less likely to seek medical care, possibly endangering their child. Furthermore, if in a situation where one has to choose between various treatment options, a parent may choose the option that coincides with their values, but which also leaves the least amount of room for distrust or coercion. In these situations, it is imperative for physicians to present information appropriately, with high levels of respect and understanding for parents making these difficult choices. This demonstrates that a doctor is trying to build a trustworthy relationship with a parent and their child, which would presumably result in the best medical care for a child.²⁰⁶

Cultural factors can greatly influence decisions, and as mentioned above, it is important for hospitals to embrace cultural competency within their institutions. Simply being aware and educated about cultural factors that contribute to decision-making makes a significant difference to patients, including parents. Encouraging cultural competency, which is demonstrated through resources being available and staff being educated about specific cultural practices, as well as communication skills about using culture as a decision-making tool, can be comforting for a patient and their family. It acknowledges that culture is valued and that personal cultural values are accepted.²⁰⁷ When a nurse or a physician asks about cultural components that contribute to how decisions are made, it demonstrates a level of understanding and may make a patient more likely to discuss their options with their physician. This builds trust and ultimately leads to ethical decision-making.²⁰⁸

Society, in general, embraces multiculturalism and accepts medical decisions that have been influenced by these personal values. There may be situations, however, where culture can negatively impact decision-making, and doctors should be aware of these circumstances. For example, some cultures emphasize the role of a male in the family. He is the one who makes all

decisions, and is always respected, regardless of what the choice is. A mother not being able to voice her concerns or opinions, and simply having to submit to her husband may alarm some physicians. Similarly, some cultures value the opinions of elders, who have a final say in medical decisions.²⁰⁹ In these situations, culture should be accepted as a method of decision-making, but a physician also has a duty to ensure their patient is being cared for appropriately. It is important that a medical professional approach these situations with caution, in order to not offend a family. They may politely suggest that they disagree with the methods of decision-making.

iii. Fetal Decision-Making Considerations

More complexity is added when parents are tasked with making decisions for their unborn children. Care ethics and personalism, as reviewed above, can play a significant role in the decision-making process. When an individual decides that they would like to reproduce, there are numerous options available if they are unable to do so naturally, often bringing reproductive issues to the center of bioethical debate. Janssens spends a considerable amount of time discussing artificial insemination from a personalist viewpoint, but care ethics can also be considered. Many acts of artificial insemination, such as procuring a sperm donor or In-Vitro Fertilization (IVF), are considered immoral on religious grounds, as they defy the natural law of procreation. However, a personalist and care ethics approach may allow for these practices if certain conditions are met.²¹⁰ The particular relationship that exists between a parent and their child is precious to adults, and many individuals choose artificial methods of insemination to achieve their goal of having children. To justify this, one may analyze an action in its totality – the act itself, as well as its intention and consequences; both matter. In other words, the intention of bringing life into the world and caring for a child may justify using techniques of assisted reproduction.²¹¹

Similarly, the choice to use new technologies, such as Pre-Implantation Genetic Diagnosis (PGD,) may be justified through the lens of personalism and care ethics. Currently, when a parent uses IVF, they have the option to screen and diagnose possible genetic disorders of embryos before they are implanted into a uterus. Couples may use this technique, for example, to implant an embryo that does not have genetic markers for Huntington's disease, due to the fact that one of their parents is either a carrier or they themselves have the disease.²¹² It can be argued that a parent has the responsibility to provide the best care and make the best decisions possible for their child, which includes preventing them from having a life with a serious genetic disease. Although a disease is only one component of a person, a parent may feel that the rest of their child's 'person' would be affected by this particular aspect of their existence.²¹³ Numerous other ethical issues surround techniques, such as PGD, but if used as an ultimate promotion of care, they can be justified. PGD and other technological advances, such as genetic therapies and genetic editing, and their associated ethical considerations, will be discussed in detail in later chapters.

PGD and other technologies that can be used before the birth of a child demonstrate immense promise in the field of disease prevention and elimination, but deciding to use them may be extremely taxing for a parent. The idea of manipulating an embryo's genome can be daunting, even though it may be beneficial for both the child and the parent. This debate mirrors one that is often seen in mothers deciding about abortions. There may be guilt associated with the act, because the reasoning for the use of the intervention may revolve around a self-need.²¹⁴ For example, a parent may choose to change the genetic makeup of an embryo so that it does not code for Down syndrome. This would be beneficial for the parent, as it would be costly and time-consuming to raise a disabled child. A parent may also argue that it would be beneficial for

the child, since they would not have to deal with the difficulties of living with that disease. In these situations, selfishness is compared with responsibility and it is important that parents think about what is best for them, as well as what would be best for their particular child. Every case will be unique to each specific family, and this fact should be emphasized when making decisions of this nature.²¹⁵

This same decision-making process extends to decisions about pursuing genetic editing techniques during the PGD process. While editing an embryo's genome is currently prohibited in a number of countries across the world, and it was not encouraged to proceed with editing until all of the safety and efficacy concerns were addressed, it is a technique that may be used in the future.²¹⁶ Parents have to think about the implications of their manipulation on their child's future – whether it is worth taking the risk of a new technology in order to potentially improve the child's quality of life. This debate will be described further in later sections of this dissertation, as will the difficult task that parents may have when making a decision about partaking in fetal research. However, in all circumstances, the principles and components described above should be upheld and encouraged when making decisions for unborn children who cannot speak for themselves.

Clinical decision making traditionally focusses on a patient's autonomy, demonstrating that informed consent is the backbone of autonomous decision making. This section has clarified this concept by explaining that the many players involved in a patient's care (patients, substitute decision-makers, and providers,) are all involved in the decision-making process. However, it has also suggested that our current notion of autonomy may need to change in order to include an aspect of relationality through care ethics and personalism. These changes make autonomous decision-making more indicative of a whole person and, therefore, result in the delivery of better

care by healthcare workers. This also extends to the process by which parents use to make decisions on behalf of their children. Numerous internal and external factors contribute to these choices and a well-rounded decision depends on the combination of medical information with socioeconomic, cultural and religious factors. In the final analysis, the decision-making formula is made up of both internal and external factors, the sum of which results in the choice that is in the best interests of a child.

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Chapter 3: Population Health Decisions

Many things divide and differentiate human beings, but two elements unite them – their humanity and their possession of human rights. The right to health and the right to healthcare are immensely valued worldwide. However, there are areas in our worldwide community in which the right to health is not valued or upheld. This is cause for concern. The standards of healthcare, both on a local and global level, will be compared and the possibility of universal health standards will be discussed in this chapter. These ideas will then be applied to situations that impede local access to healthcare in a developing country; primarily medical tourism and its effect on vulnerable populations. Furthermore the right to health will be examined through the lens of public health considerations for disease prevention. Diseases are part of the human condition, and a major goal of public health efforts is to prevent and treat the harm they cause the general population. It is crucial to ensure that all prevention efforts are conducted in an ethical manner both with regard to individuals and the broader community. While genetic therapies may be used as a way to increase the standard of health across the globe, as well as for disease prevention, it is important to return to the basic concepts described in this chapter in order to fully understand where CRISPR-Cas9 and other genetic editing techniques may play a role in the future of health care.

A: The Right to Health Care Across Populations

All humans have rights, simply as a result of having personhood. The right to health and healthcare is seemingly universal, but in practice, that right may not manifest itself in the same way for all humans. Furthermore, if it is internationally agreed that a right to health and healthcare exists, what is the solution if an individual or a country as a whole is unable to uphold this right? Once it has been established that there is a human right to healthcare, the next step is

to examine the quality of the medical care and services that should be available to all human beings. Standards are strongly influenced by a country's local determinants and policies, which may result in unethical practices. Universal standards that would be applicable to every country may be unrealistic, but should be analyzed.

i. Standards of Health Care

When a person is born, they join the world's citizens who, in theory, all share a set of human rights that ensure the wellbeing and fair treatment of individuals on the planet. Since these rights are considered to be universal and essential human rights, each person is entitled to them, and laws are often implemented in a state or country, that guarantee that a person's rights are upheld under any circumstances. Despite legalities that may be in place, there are circumstances in which human rights violations take place, either with or without a government's knowledge. These situations call for some sort of intervention, either locally or globally, to ensure that the world's citizens have their basic human rights considered. This consideration may include the involvement of international organizations, such as the WHO or the United Nations.¹ More generally, all humans possess the duty to uphold, respect, and promote these common interests for the greater good of humanity.²

Once again, human rights that are considered to be universal are the right to health and healthcare. The former implies that all citizens have the right to be healthy, while the latter implies that all humans must have access to healthcare and resources to ensure treatment when they fall ill.³ The right to health requires more resources and other considerations to be addressed in order to try and attain the satisfactory health of all individuals. For example, a country would have to implement public health policies, in addition to providing hospitals and healthcare services and medications. At the same time, the state must ensure that its citizens have access to

adequate sanitation, clean drinking water, and healthy food, as well as some sort of education, possibly, which could contribute to the positive mental health of all of its citizens. The right to healthcare is vastly less complex, as it is just a component of the right to health. Providing medical services to all is a daunting task, but it is more attainable across the globe.⁴

The WHO released its definition of health as the complete physical, mental, and social well-being and not merely the absence of disease and infirmity.⁵ This definition is morally pure and ideal, but may not be totally realistic in all parts of the world, due to factors such as poverty, economic distress, or environmental concerns. Furthermore, while this moral right is essential, based on the definition, the law may not consider it to be a legal obligation of the state to uphold the highest standard of healthcare and health. Furthermore, the right to health can be viewed through two lenses, that of individual needs, and those of the common good, which may involve different initiatives to ensure the health and wellbeing of the general public. Balancing these two components may be difficult for a state, as well as health organizations, such as the WHO, but both should be considered to be a part of the human right to health.⁶

Literature about the human right to health is abundant. Scholars have presented different opinions about the extent of one's right to healthcare, as well as the most appropriate and productive methods that individuals can use to ensure their rights are being considered and upheld. Brudney presents a question of whether there can even be a right to health, as human rights usually entail duty, and it is unclear if there will ever be one entity that can make everyone on Earth healthy. Of course, a solution to this may be modifying the language and assuming that all individuals have a right to healthcare, as opposed to the right to be healthy. Problems arise concerning resources in third world countries, as well as other human rights that directly influence individuals' health and wellbeing, such as access to clean drinking water.⁷ These

concepts will be expanded upon below. In addition, Ruger presents her views on the right to human health in the United States, and presents a new patchwork of legal and ethical rights to ensure that citizens have a medical and social right to healthcare resources and procedures. She argues that all individuals should have a right to healthcare, and their legal system should reflect it.⁸

While the right to healthcare includes hospitals and access to physicians, for example, Conly argues that it should also include forms of preventative medicine, especially in countries that deal with preventable conditions. In the United States obesity is a great concern, since it may be preventable with policy and education, and it is up to an individual to make choices regarding their health and their weight.⁹ However, in the developing world, diseases may be of great concern, but they may not be as a result of bad habits. For example, South Africa benefits from measures preventing HIV and AIDS, if possible, as opposed to having to treat it. While this may be problematic socially with regard to policy programs, it is possible to educate men and women as a preventative measure to attempt to decrease the number of individuals suffering from a deadly disease. The question in this situation is whether preventative measures should be part of a human's right to healthcare, or if they should simply be an add-on to the human right of access to medicine?¹⁰

All of the presented definitions and explanations of a human right to health and healthcare assume that all individuals should have access to health in the place they reside. However, problems have arisen with the healthcare available for migrants who are not legally residing in a country. This topic is especially relevant with the increase of migrants and refugees in countries that have above average health care systems. Many migrants may choose to travel to Europe, for example, with knowledge that healthcare is provided free of charge for all citizens, but they run

into problems because of a lack of documentation. A human right implies that all inhabitants, regardless of their status, should receive medical care in times of malady, but these individuals are being blocked by laws and policies that prevent migrants or undocumented immigrants from receiving medical care. For this reason, there is a large population of individuals who are ill, but unable to see a physician, which violates the basic human right to healthcare.¹¹ While current policies are strict in trying to prevent migrants from ‘taking’ resources from the ‘real’ citizens that pay taxes and have insurance for medical resources, it should be considered that many of these migrants fled from their home country under traumatic and dangerous circumstances, in which the human right to health, among other human rights, could not be upheld.¹²

As mentioned above, a country or state is partially, if not mostly, responsible for the health and wellbeing of its population. The most effective way to respect and ensure that human rights are upheld is through legislation or policy. Law is an effective method of implementation for healthcare, as it ensures that all citizens are legally bound to uphold human rights. Depending on the location and current situation of a particular country, a law will have to be created that is able to work alongside other measures, such as education and sanitation, to guarantee all individuals their right to medical services.¹³ Each country may have to determine what is right for them and what methods are most appropriate for reaching their necessary healthcare goals.¹⁴ For example, Canada may have a different law as a result of more healthcare spending, as opposed to Senegal, which ultimately has less money and fewer resources to provide adequate healthcare for its citizens.¹⁵ While both countries should have a law pertaining to health services, they may differ in order to best benefit the country’s inhabitants.

In addition to legislation, access to resources and technology may alter the methods used in a country to provide medical care for all. A state’s resources will influence how much money

is available to spend on healthcare, as well as how many people are able to be served.¹⁶ In a country that has a significant number of people who all need medical care, but whose total income is low, there is a possibility that its resources simply will not be able to be available to everyone. This may result in a lower standard of healthcare for its citizens; some procedures and basic treatments may be available, but the “highest attainable standard of physical and mental health” that is set forth by the WHO, will not be as high as preferred.¹⁷ Ethically, this is not an ideal situation, as citizens who have a right to healthcare would experience a direct violation of a human right, without a plausible solution for achieving an acceptable standard of healthcare.

For states that face the issue of limited resources, there may be a need to evaluate the importance of who should be served. These situations have options of focusing on helping more people with medical problems individually, or shifting their efforts to helping the general public and highlighting the common good. To justify a shift in focus, a government may argue that a human’s right to healthcare is part of a human’s right to health, which deserves equal emphasis.¹⁸ This would be seen through an attempt to help a greater number of people with general health and prevention methods, as opposed to allocating resources for only individuals. Ideally, there would be a balance between addressing common interests and providing individualized medical care, but when resources are limited, a choice must be made. This situation calls for all of the players mentioned above: the state, large companies acting as charities, and individuals to recognize their duty to contribute to a general right to health, and a common good that can serve more than just one person.¹⁹

If there is a shift in focus from the right to healthcare to the right to health, other social rights must be considered as well, as they contribute to the general right to health. The WHO’s definition includes physical and mental wellbeing in describing this human entitlement. This

implies that other rights, such as a right to sanitation, clean drinking water, education, or safe housing must also be included in the efforts to respect human rights.²⁰ In order to maximize one's right to health these other rights must also be addressed, which may be difficult for developing countries. It may be of value to them to invest in sanitation and clean drinking water, for example, as it would decrease healthcare spending for ailments resulting from a lack of those necessities. However, it is evident that regardless of what the most pressing issue is, little can be done without an appropriate budget.²¹ If a citizen's country does not have enough funding to improve a right to a clean and healthy environment, among other things, the standard of healthcare will automatically be low.

Another factor that influences the standard of healthcare is the amount of staff that is available to provide the medical services.²² While this is not an issue in wealthy and developed countries, smaller nations are seeing their citizens leave to become medical professionals without returning to provide a service. This may be as a result of low wages in their home countries, as well as the quality of training and opportunities for meaningful employment. The general view is that other countries may provide them with a better quality of life as opposed to their own home country, whose healthcare standards are lower. This exodus adds to the cycle of individuals being trained as medical professionals at reputable institutions around the world, but the fact that newly trained medical personnel do not return to their home country only makes the standard of healthcare decline further. If there was an incentive for physicians or nurses to return after training, it would potentially improve a developing country's healthcare system as there would be enough staff to ensure that individuals could receive adequate medical care.²³

It is clear that while humans inherently have a right to health and healthcare, it may be strongly influenced by the economic status of their home country. The cost of providing health

services for an entire population is frequently too high for a local government to be able to provide a high degree of healthcare.²⁴ It is unfortunate that finances dictate how our human rights are put into practice, as they lose their status of being fundamental human rights. Once a person is denied such a right as a result of where they live, although they retain their human status, some may feel that it can no longer be classified as a human right. Instead it becomes a privilege that only those who can afford the acceptable standard of healthcare possess.²⁵

It has been emphasized that an individual's local surroundings influence their right to healthcare, as well as the standard of health services that are available to them. The question arises, however, that if all humans have the same right to healthcare, can there be a universal standard of healthcare to which all global citizens should have access? It is clear that the amount of money available and the number of resources that are at a country's disposal will vary greatly around the world, and the hope of any universal standards of healthcare may be unattainable. The idea that all humans have a right to health, however, may be more attainable, but will require improvements in other areas, similar to the explanations above.

At first glance, universal healthcare standards imply that all individuals around the world, regardless of their income, living situation, or state limitations, would have access to a level of medical services that would allow them to attain the highest standard of physical and mental health.²⁶ This is difficult to realistically visualize, because there is a great variety in available healthcare services between countries, and even within countries. In congruence with an earlier point, if a human right is, in fact, deemed a human right, there should already be a level of universality associated with it, as it applies to every person due to their inherent humanity. Therefore, once a right is unable to be universal, it should lose its designation as a human right, and should be demoted to just a right that is determined by each individual nation depending on

their views of healthcare.²⁷ Although this opinion is plausible, the universality of the human right to healthcare will be further explored.

If a universal healthcare standard was to be implemented in all nations of the world, the issue of money would arise again. To make the standards universal, all countries would have to spend the same or similar amounts in order to provide the same standard of care. While there may be some fluctuation depending on where resources are coming from, identical spending would be necessary.²⁸ This seems like a great burden on smaller countries that do not have enough money to provide the same level of healthcare to their citizens as developed countries do, such as the UK, so a minimum level of spending in order to achieve the minimum acceptable standard of healthcare services would need to be decided upon. This minimum would need to be accepted by all countries, and be realistic in terms of feasibility. However, having a consistent standard, albeit a minimum of healthcare, around the world would ensure that human rights were respected and promoted.

Another issue that arises with the hope of universal standards of healthcare is the quality level that would be expected from every hospital around the globe. Many countries would have to alter their medical centers so that they meet a minimum requirement that adheres to a universal standard of health services. This would be a great feat and cause immense difficulty as a result of existing resources and staffing. It may be more realistic to mandate a minimum to which hospitals should aspire, and to set national universal standards, which allows a nation to consider its own possibilities for healthcare. This already happens in developed countries, such as the United States and Canada, where accreditation is given to hospitals that meet the minimum standard of healthcare services, but also for going above and beyond the necessary requirements.²⁹ Accreditation could be a form of universality around the globe, ensuring

consistent standards and expectations to which institutions would strive to achieve. While every hospital may not be considered to be of the same quality as those in the developed world, some developing nations may start with a few accredited hospitals to ensure that their citizens also have access to quality healthcare.³⁰

While universal healthcare standards would be an ideal solution to the human rights violations occurring in parts of the world where medical services are not available, universality causes a significant amount of difficulty for developing countries. If and when these nations do not meet the universal standard for healthcare, it is unclear if there are any legal implications as a result.³¹ There is no way to ensure that a right is legally binding; a country could choose not to acknowledge health as a human right or acknowledge it as a right, and, consequently, not allocate the necessary funding and resources to make it a reality. While these are human rights violations, they may not be legal breaches requiring intervention. There is no system currently in place to ensure that countries are upholding human rights, aside from the United Nations' responsibilities towards its member states to uphold peace. As a result, if universal health standards are implemented or suggested, a method of insurance would need to be considered, to ensure that all global citizens are, indeed, receiving or have access to the established universal standard of care.³²

ii. Access to and Affordability of Genetic Therapies and Editing Techniques

Although genetic therapies and editing technologies are proving to be effective treatments for a variety of diseases and will continue to do so, it is evident that for most people, they will be unaffordable. This is especially true in countries whose healthcare systems do not provide accessibility to expensive treatments, as well as within communities that are struggling to promote and provide access to basic human health needs. Before specifically analyzing how

accessible and affordable genetic therapies and editing techniques will be, it is crucial that general access and affordability of health care and health resources is examined.

A state of poverty often impedes one's access to healthcare, but is very difficult to eliminate in any country. America sees extreme amounts of poverty, even though it has the healthcare and structural resources to eliminate it.³³ A country has a responsibility to ensure that its citizens are cared for, with adequate housing, healthcare, and economic opportunity. However, the issue of poverty within its own borders should ideally be dealt with at the state or local level.³⁴ This is not always feasible, due to financial constraints as well as a lack of resources.³⁵ States will maintain that it is up to the local government to find solutions to ensure the care of their citizens. However, globalists disagree and feel that organizations, such as the United Nations or WHO, as well as other countries, if able, should offer their support and resources, as they are caring directly for global citizens.³⁶

Both of these solutions require the aid of someone more influential than an individual to solve the problem of poverty, which may improve the access and quality of available healthcare in a developing country. For individuals in a third world country, healthcare may be accessible, but it may not be affordable for those living in poverty. The state definitely has some level of responsibility towards its citizens, namely, to provide them with resources and services that will enable them to live their life to its highest standard.³⁷ Healthcare is a major service, and, as it has been established, should be available to all of the world's citizens, regardless of their ability to afford it.³⁸ A government must be able to allocate some finances and resources to ensure that at least basic medical services of an adequate quality are available.

It may not, however, be realistic for a state to take complete responsibility for the medical care in its country, especially due to the increasing cost of healthcare staff and medication. Large

global companies, such as those that make pharmaceutical drugs, could be deemed to have a moral responsibility to ensure that all citizens of the globe have access to drugs that are necessary for basic care. While some countries may be able to afford drugs at their high prices, it can be suggested that pharmaceutical companies find a way to create a generic drug that is less expensive and easily distributable to nations whose citizens desperately need medicine to survive. It can be suggested that this is a moral responsibility, in which case it is wrong for a company who makes millions from developed countries, to withhold life-saving treatment from those countries who simply cannot afford to pay.³⁹ This act of charity is obviously a burden if it is done on an ongoing or perpetual basis, as countries should contribute to the global market of medications, but it should be recognized that if a company is able to provide resources at a cheaper price, they have a moral obligation to do so in order for the human right to healthcare to be upheld.

In addition to government and organizational solutions for affordable healthcare, there are measures that individuals can take which will enable them to maintain their right to healthcare. For example, avoiding unhealthy habits, such as smoking, drinking, and eating unhealthy foods would potentially lead to fewer health complications requiring medical attention.⁴⁰ Furthermore, recognizing harmful environmental factors, such as toxins in the air or water, or mold in a wall, for example, allows an individual to remove oneself from harm. There are situations where this is not possible, such as if a person can only afford to live in an environment that may have health concerns. In this case, they can take other precautions, such as implementing cleaning measures or wearing a mask, to eliminate the need for seeing a physician who may not be readily available.⁴¹ These solutions, however, are minor, and should not be the primary method that a government uses to promote healthcare. Prevention is always important, no matter the nation or

healthcare system, but these suggestions should only be preventative, and should not deter an individual from seeking care for serious medical ailments. Access to care should be available to them, as it is their human right.

A most obvious solution is to find methods of reducing healthcare costs and spending without affecting the standard of care, so that more impoverished citizens are able to afford basic medical service. Issues arise, however, when allocating procedures according to their cost.⁴² For example, if an individual requires triple bypass heart surgery in order to live, some may see this as part of the right to healthcare, as the procedure is required for sustained life. However, this procedure is extremely expensive, and for countries who cannot afford to perform these surgeries frequently, it may be difficult to provide, what some believe to be 'basic' healthcare to its citizens. A government or policy maker has to decide how to either reduce the cost of procedures while maintaining a high level of quality, or to only allow those individuals who can afford expensive medical care to attain these services.⁴³ Therefore, it may be determined that humans have a right to healthcare, but not a universal right to expensive procedures. The definition of 'healthcare,' therefore, must be reexamined. The issue of monetary spending will be discussed below.

Specific to genetic therapies and editing techniques, cost is a major factor in having access to this type of healthcare. For example, using Pre-implantation genetic diagnosis (PGD) after IVF, can potentially be financially impossible. Using IVF alone can cost a couple approximately \$10 000 per cycle in the U.S. There are additional costs associated if this treatment is followed by PGD.⁴⁴ It can be assumed that in the future, enhancement technology will also cost an extreme amount. This introduces the issue of access. Since costs are very high for any of these techniques, it is assumed that only families who are financially able can undergo

IVF and PGD. This adds to the separation of socioeconomic status and contributes to the fear that more discrimination will result due to only rich parents being able to afford to modify or choose their child's genes.⁴⁵ Furthermore, it causes a global issue as well, in that only developed countries will be able to use this technology regularly, creating more of a gap between the world's elite and those that are suffering in poorer countries. As a result of these reproductive methods being so expensive, it is feared that a genetic aristocracy can be created, where privileged individuals are able to be free of disease and, perhaps, favor a certain gender, and those who cannot afford these methods will be seen as lesser individuals.⁴⁶

There is hope, however, that as IVF and PGD become more common, costs will decrease, making it available to more families. In some parts of the world, where everyone has free and equal access to healthcare, IVF falls under the category of necessary medical treatment, and public healthcare pays for the use of this technology.⁴⁷ It is undetermined whether PGD also falls into this category, as it can be used for social traits, but some proponents of PGD argue that if it is used for genetic disease elimination, it can be justified that not using it would directly cause harm to a child, and is, therefore, necessary. In addition, some individuals view the right to healthcare to be a human right, and feel that parents who have a specific illness or are carriers, have a right to use this technology, regardless of its cost, to ensure that healthy children are born.⁴⁸ The issue of universal healthcare is difficult to discuss in American contexts, because it is not a reality, and it is unlikely that Americans will have free access to IVF and PGD in the near future. As a result, it may be more likely that there will be a class distinction between those who are able to produce healthy children, and those who will be plagued by disease.

This discrepancy could also extend to the cost and accessibility of genetic therapies. If basic health care is inaccessible, novel treatments such as gene editing or replacement therapies

would probably be completely unattainable.⁴⁹ Currently there are a number of genetic therapies that have been approved by the FDA for the United States, and other approval bodies across the globe. All have undergone research studies to determine their safety and efficacy.⁵⁰ However, one common denominator among them is that the cost of these therapies is astronomical. This is due to the fact that the process of creating, researching, and approving these therapies is extremely expensive, resulting in the ultimate cost to consumers having to be extremely high.⁵¹ For example, a gene replacement therapy called ‘Luxturna’ which aims to improve retinal disease, costs about \$425 000 per eye in the US. Another therapy, ‘Zolgensma,’ targeted toward spinal muscular atrophy costs \$2.1 million per patient per dose.⁵² These astronomical prices make the drugs almost impossible to access, causing a further divide between those citizens who can cure a disease for their child, for example, and others who have no way of accessing these life-saving treatments. Further information on the specifics related to these therapies will be provided in a later section, but it is important to also recognize that these types of treatments will have to be evaluated at a national or global level.⁵³ Countries who provide universal health care will have to determine whether they can afford to offer these treatments to patients and countries who rely on insurance plans. They will have to encourage insurance providers to determine whether it is feasible to cover these therapies.⁵⁴

It also becomes clear that only developed countries will have initial access to genetic editing and replacement therapies because of the cost and amount of research funding available. This further emphasizes the divide between the developed and developing world and a lack of universal standards of health care. If a treatment exists that could cure or effectively treat a disease like spinal muscular atrophy, a disease which mostly affects infants, it should be used to save lives.⁵⁵ An ethical concern arises when less-developed countries lose access to a treatment

because of its cost, as it was described above. However, it can also be expected that once genetic therapies become more common, developing countries may be able to offer the treatment at a lower cost (although that cost would still be extremely high to its citizens). This opens the door to medical tourism.

iii. Medical Tourism

It has been established that there is a concern with developing countries and their healthcare services, as they may not be adequate or abundant enough for its citizens to be able to have their human right to health care respected. This section examines one factor that may impede local access to healthcare, and the effects it has on already vulnerable populations. Medical tourism is a growing industry, and although it is beneficial for some, it may be harmful for others.

As healthcare costs rise in developed countries, their citizens are looking abroad to access expensive procedures and treatments at a lower cost. The medical tourism industry is growing rapidly, as more developing countries are taking advantage of the need for medical services by individuals abroad. An American, for example, may choose to leave their own country which has a long waiting list for a specific procedure that is extremely expensive, in order to procure the treatment or medical service in a country that offers it at a lower price and with a shorter wait-time.⁵⁶ Currently, medical tourist agencies exist, which facilitate the entire process of travel, medical procedure, and recovery for citizens around the globe. Facilities that offer this service also portray themselves as being internationally accredited with the highest quality of technology or equipment along with an abundance of caring and qualified staff members.⁵⁷ Examples of the procedures that medical tourists purchase are stem cell therapies, cancer treatments, transplantations, and surgeries. Often these services offer procedures that are experimental or

that have strict regulations attached to them in developed countries, which deter individuals from having them done at home.⁵⁸

As a result of this booming business, many entrepreneurs are beginning to build medical centers in developing countries solely for the purpose of attracting medical tourists. These private facilities would be tailored for a specific procedure or surgery so that the staff becomes efficient at the service, and can provide an appropriate level of care to its visitors. This is often regarded as an economic benefit for countries such as the Bahamas, as it would boost its economy and bring in funding for the state.⁵⁹ However, if new centers are built solely for the purpose of serving medical tourists, it suggests that these facilities would not be available to the local population, which may also be in need of certain procedures. Furthermore, these centers would require a significant number of staff members, and may insist on current medical professionals in the country to participate and be trained in a particular treatment that the center is offering. This would take these individuals away from their current place of work, and would ultimately result in local citizens losing a medical professional, which affects the standard of care for the people of the country.⁶⁰ While medical tourism has benefits, there is a great concern regarding how the human right to healthcare for the local populace could be affected negatively.

Since there is no universal standard of healthcare, medical tourism also poses risks to the individuals who are choosing to utilize these services. If an American travels to a country that does not have adequate healthcare services or has a lower standard of care, their wellbeing may be compromised by factors not associated with their requested treatment. For example, if a country does not have clean drinking water, a medical tourist would need to ensure that they are staying in an area that does, or to take necessary precautions in order to avoid infection.⁶¹ Visitors would need to be sure that the facilities in which they seek medical care, as well as the

location of their stay, are safe, or they may be affected by the lower standard of care.⁶² Universal standards would be beneficial in these situations, to ensure that all citizens, whether they are travelling for medical tourism, or for other reasons, would have access to safe medical services.

A main concern regarding medical tourism is the effect it has on a local population. It has been alluded to that this business can bring in significant amounts of money for a country, which would improve its economic status.⁶³ This implies that there could be more money to spend on resources and medical care for the local citizens, therefore, medical tourism is ultimately a positive endeavor. However, while these businesses do improve the economic stability of these nations, there is concern that the local population is not benefiting from this increase in funding. Money may go to the physicians that have invested in the medical centers, who are often not locals themselves, but, rather, to big business owners from abroad. Nevertheless, some states feel that medical tourism will be beneficial for their economy and for their citizens and choose this as one solution to the disparity in healthcare standards between the world's nations.⁶⁴ They choose to place less importance on human rights and conditions, and more importance on the benefit of other global citizens.

Governments who approve these practices also take advantage of their country's shortcomings, as having less strict medical regulations than other countries becomes an appealing aspect to tourists, in that procedures that are highly regulated and not available in their own countries due to possible risk or high cost, are accessible in countries with lower medical standards. Stem cell therapies are an example of such a procedure. Medical tourists are willing to overlook lower medical standards and seek countries that do not place as much value on safety or efficacy established through research trials in order to receive experimental, and potentially life-saving therapies.⁶⁵ While the absence of regulation is beneficial for tourists who are only in the

country for a short amount of time, and can go back to their own country for other medical care, it raises concerns for the local population that would be exposed to other medical treatments that lack regulation and could cause harm. Experimental treatments may lack regulation due to minimal research, but other more basic medical services, such as surgery, are known to need particular safeguards to ensure the safety and wellbeing of individuals. If regulation does not exist for some treatments, there is a fear that it may not exist for others, which directly affects the local citizens, and therefore, leads to a decreased standard of medical care.

The fear described above applies to the population of a country that is at risk of a lower standard of care than that to which they have the right, making them a vulnerable population. It is difficult to assign only one meaning to the term ‘vulnerable,’ since the word can be interpreted in various ways according to a specific context. When a population or group is labelled as being vulnerable, it implies that they collectively may have a diminished autonomy.⁶⁶ Some scholars disagree with this definition, as they believe that all humans are inherently vulnerable; we can succumb to disease or tragedy, regardless of where we come from or what we do.⁶⁷ However, for scholars who do feel that vulnerable populations exist as part of general humanity, there are varying categories into which vulnerability can be divided. For example, an individual or group may be ‘vulnerable’ either intrinsically or extrinsically: intrinsic vulnerability results from a human condition, such as gender, race, or age, while extrinsic vulnerability is due to circumstances, such as being impoverished, or living in a developing country. Other scholars use different terms to denote similar distinctions, such as ontological and special vulnerability.⁶⁸ These categories, regardless of how they are labelled, indicate that individuals can be vulnerable in different ways, and that extra care should be taken to ensure that they are treated

appropriately. The next chapter will further explore vulnerability within health care in more detail.

The UNESCO Universal Declaration of Bioethics and Human Rights indicates that all humans have a right to dignity. This means that the interest of an individual should be of greater importance than the interest of science (in the case of research) or society in general. Dignity is applied to life through practices such as informed consent and physical integrity.⁶⁹ When an individual who is considered to be vulnerable consents to a high-risk project or activity for the purpose of increasing their income with the hope of being able to afford healthcare, extra caution should be applied to ensure that their dignity is being considered. For example, economically disadvantaged populations, such as Indian women agreeing to commercial surrogacy, may be perceived as only possessors of wombs, and not as real human beings who have human rights. This causes a problem, since clinics that facilitate commercial surrogacy may not encourage these women to think of themselves as humans, but simply as service providers. This essentially takes away their dignity and minimizes their integrity.⁷⁰

The example above explained how an individual who lives in a country where medical tourism is a main source of government funding, may resort to participating in the medical tourism industry in some way, in order to improve their quality of life, and hope for the opportunity to be able to improve their standard of healthcare by being more financially able to afford medical services. A method of doing so may involve participation in research or in services such as commercial surrogacy, which is a form of medical tourism.⁷¹ There is a concern that women who participate in this practice are being exploited due to their vulnerability, and their desire to fulfill their individual responsibility in upholding their right to healthcare.

However, in the pursuit to improve access to healthcare, these women may have other human rights that are violated, such as informed consent in participating in these transactions.⁷²

Like many vulnerable individuals, there is a risk of exploitation due to the fact that they may live in poverty. Their economic status strongly influences their decision to participate in commercial surrogacy, for example, or to work in a facility that offers procedures to medical tourists. These individuals may also be recruited to help build new medical centers so that they can be finished quickly and inexpensively. This may create an opportunity for these citizens to receive a significant amount of money, possibly in a short amount of time, which would help both them as well as their families, and increase their chances of being able to afford medical services for themselves.⁷³ However, when framed in this manner, it is clear that there may be exploitation of these individuals by foreign companies or local governments that would rather put effort into attracting tourists with the hope of acquiring their service and payment, as opposed to respecting the human rights of their own citizens, who also deserve access to healthcare, simply due to their status as human beings. Ideally, these governments should also focus on eliminating levels of poverty in their nations, but this solution would require serious efforts and money from either government organizations or charitable groups that would be aiming to eliminate the amount of poverty.⁷⁴ Medical tourism may be the answer, but it should not be the sole solution to solving healthcare accessibility problems.

B: Disease Prevention Across Populations

Diseases are part of the human condition, and a major goal of public health efforts is to prevent and treat the harm they cause to the general population, in order to uphold the human right to health. It is crucial to ensure that all prevention efforts are conducted in an ethical manner both with regard to individuals and the broader community. Examining how the

implications of disease prevention affect the overall health and well-being of the public is highly beneficial. Moreover, the debate between paternalist or libertarian efforts should delineate which theories are best to apply to disease prevention, in order to ensure that the promotion of public health efforts achieves its goal in aiding a large group of people within a community. In the first section of this chapter, the principles and basics of standards of health care and population-based decisions relating to health were examined. Public health measures must be explored in the same way, before applying them to the future uses of genetic therapies and editing techniques as public health models of disease prevention.

i. Public Health Models of Prevention

Disease prevention is commonly compared to curing illness, and there is often debate about whether prevention is more effective than cure. Many scholars differ in their opinions, as factors, such as cost, access, and technology, can impact which method is the best for eliminating disease. Public health aims to help communities avoid serious medical conditions, making prevention the best choice for public health efforts to maintain a healthy society.⁷⁵ Many diseases, in today's scientific age, are preventable, with minimal effort. For example, deadly illnesses such as polio and rubella can be avoided through vaccination, or an individual's risk for cancer can decrease through frequent screening. Although the curing of disease should be considered an equally important investment of government funds and effort, one would assume that prevention would avoid many cases needing cure in the future, and that would benefit individuals physically, and society economically. Both prevention and cure can be applied to the clinical setting, as doctors are able to provide education about preventative actions that individuals can implement in their everyday lives.⁷⁶ Furthermore, the comparison between prevention and cure can be compared to the concern within public health of whether an

individual or a community is more important to protect. The answer is, of course, that both are equally as important in differing ways, and there must be a balance that allows individuals to have a choice to participate in public health efforts to prevent disease within a larger society.

Population concerns are prevalent in any area of public health, as the entire field aims to improve health within a community. When trying to prevent disease within a certain population, considerations must be taken to ensure that resources are properly allocated and appropriate priorities are determined. For example, if a specific disease is more prevalent within a subset of a community, it may be beneficial to allocate more resources or funding to provide help for that set of people, as opposed to equally dividing among a greater community.⁷⁷ By adopting a population approach to disease prevention, it can be assumed that there will be a decrease in a specific disease due to the implementation of non-medical interventions. For example, hypertension can be treated with pharmaceutical drugs once a person is diagnosed with this condition. Preventative efforts, however, can include lowering sodium content in processed foods, which would benefit more than just the one person with hypertension; it would benefit the larger society and prevent others from succumbing to the disease. Population efforts for disease prevention such as these, are not focused on a medical cure, but aim to provide other methods to improve one's health before having to turn to medicine.⁷⁸

While implementing these efforts, it is crucial that social justice is also considered, in order to ensure that all individuals within a society have access to public health initiatives and are able to benefit from them. Similarly, vulnerable populations should be treated fairly to avoid discrimination. It is unacceptable that only 'productive' individuals have access to both preventative measures and curative healthcare, and are given a higher priority than the elderly, the uneducated, the disabled or other people who may not benefit as much from public health

initiatives.⁷⁹ Within population-based efforts, all citizens are of equal value and should be regarded to have equal social standing. However, it can be questioned whether those living in poverty should yield more attention from public health authorities, because they may be in more need of medical help. It may be ethically justified to prioritize impoverished groups within the United States so that they receive more education or more facilitated encouragement to participate in prevention efforts. This would also ensure that all members of the population have access and utilize the resources provided to them. In this situation, it is likely that a government would assume that individuals within the middle or higher class would be able to approach their physician for preventative strategies or embrace public health efforts for disease prevention without an added influence from a higher body.

In order for public health efforts to be deemed successful in preventing disease, epidemiological research must be done to evaluate how effective the methods employed were within a society. Epidemiology can be very beneficial, in that it is able to provide data demonstrating how a population has dealt with a disease, or if a particular disorder was prevalent in a given time period. There are, however, precautions that must be taken to ensure that the data were not influenced by other factors. For example, a disease may be examined in contrasting frameworks, and, therefore, provide differing results. Socio-economics can vary from scientific or medical expectations for disease prevention, and the best solution would be to combine all frameworks to ensure a comprehensive review of disease prevention efforts.⁸⁰ Furthermore, it should be confirmed that this combination is accurate. For example, epidemiology can be used to provide scientific facts about a disease's prevalence or how it can spread. Public health, however, needs epidemiology to provide suggestions with regard to future community efforts that can be effective in preventing or eliminating certain conditions. They rely on this research to

evaluate whether prior public health efforts were effective. This combination of multiple disciplines should be encouraged to render a report comprehensive and accurate.⁸¹

Currently, there are many models of disease prevention that have been implemented within society. Two major efforts, immunization and genetic screening, will be discussed below. Other initiatives have also proven successful, such as the Cost-Effectiveness Analysis (CEA) model. This method of analysis is quantitative, and allows priorities to be set in any prevention program being implemented. It compares the cost of public health interventions to their effectiveness or benefits. It is extremely difficult to measure benefits, however, since one cannot put a value on a life. This is countered somewhat with a quality of life assessment, or more specifically a Quality Adjusted Life Year (QALY), to measure how a person's lifespan was affected by the disease prevention program.⁸² Issues do arise, however, concerning the method of collecting data from individuals within a population. Personal values of the researcher may influence the results they provide, and lead to inequity among a group of people. For example, even though a person who has a disability claims that their life is fairly normal and enjoyable, a researcher may feel that they have a diminished quality of life, and subsequently assign them a lower QALY score.⁸³

Another example is provided by Community-based Prevention Educators (CPE) who “encourage and facilitate preventive health care across a whole community.”⁸⁴ They are professionals who coordinate disease prevention efforts to reduce risk factors or progression of chronic diseases in a population, such as cancer.⁸⁵ CPEs are an example of individuals who promote disease prevention within the actual community, either for a whole geographic area, or, perhaps, an ethnic subset, within the population.⁸⁶ The role of a CPE can include a variety of activities, such as exercise promotion in schools, healthy eating campaigns, and policy development. It can also be a supportive role, illustrated through celebration events for

community efforts, or recognizing individuals for their health accomplishments. The advantage of using CPEs is that they are already a part of the community and understand how it functions, and are, therefore, able to implement effective disease prevention strategies.

Preventative care is being further improved by technology. For example, physicians' offices and hospitals have begun to use electronic registry systems that provide quick access to all of a patient's data and medical information. Having everything in one place facilitates the keeping of records of individuals who are at risk for specific conditions, or who already have a particular disease which must be monitored. Furthermore, this system allows for automatic reminders for certain procedures, such as vaccinations, to ensure that individuals are taking the steps to prevent disease. There are both pros and cons to this method. For example, it may be argued that it is very tedious to enter every patient's information into the computer, and then have to keep updating it to ensure that the information is correct. This takes time and effort away from staff.⁸⁷ In contrast, some feel that there is too much data about a given patient to go into a paper chart, and it creates a greater job for healthcare professionals to remind patients or monitor the progress of a disease for an individual. A computer is able to do these tasks without causing great burden for healthcare professionals, making the process of disease prevention more effective.⁸⁸

A government may implement laws with regard to disease prevention to ensure that a population is taking measures to improve their health. This method, because laws are involved, is very paternalistic and may cause some concern. However, by looking at examples, it is evident that such laws are, in actuality, beneficial for society.⁸⁹ Taxes are a common measure taken by a government. For example, higher taxes can be implemented on cigarettes, alcohol, or firearms, in the hopes that fewer people will engage in risky behaviors. This can be seen as purposely

creating a disadvantage for the poor and creating an inequity, since only rich people will be able to afford these commodities. Other initiatives include governments requiring food companies to label their products with certain nutritional information. This is a less paternalistic method of implementing methods of disease prevention, and is generally more accepted by individuals within a community. A last example is imposing building requirements to ensure the safety of the structure and materials used, in order to prevent future diseases, such as cancer from mold.⁹⁰

Historically, diseases were more dangerous and prevalent, and immunization was a means of elimination and cure, which eventually led to vaccination being used for prevention. An understanding of historic efforts to cure and eradicate diseases, such as polio and rubella, are useful for today's prevention precautions and overall safety of society. It is important to look back through the history of vaccination in order to analyze what methods were effective, and which ones could not boast the best outcomes. This can prove advantageous for implementing a preventative immunization program in the future, and also shed light on the effectiveness of a mass prevention program, which can be evidence for a future prevention tactic using genetic editing technologies.

In the past, diseases that vaccines were designed to target were considered to be pervasive and dangerous.⁹¹ For example, outbreaks of polio and smallpox caused great concern for the public, but also for state and federal governments.⁹² Epidemics of these diseases, as well as others, emphasized how important and life-saving vaccines could be. As a result of numerous children dying of polio, as well as former president Roosevelt's diagnosis, the polio vaccine was heartily welcomed and rarely questioned. Most people considered immunization to be an easy cure for a terrible condition, and supported the efforts of government to eradicate polio completely through vaccination.⁹³ Furthermore, vaccines caused a dramatic decrease in the

percentage of the population dying from polio and other diseases, such as smallpox and diphtheria, which added more positive evidence that supported mass immunization.⁹⁴

Concern did exist, however, when vaccines became available for diseases such as measles and mumps. These two conditions were previously considered to be a common part of childhood, and as such, did not warrant proactive interference. They were treatable, and usually did not lead to anything more than a fever or malaise.⁹⁵ In order for governments to promote these vaccines, however, they had to re-structure how the public viewed these illnesses. They reported them to be deadly if spread, and advertised the more serious side effects that could happen if a child caught the measles or mumps. Death was often cited, and the growing number of individuals dying from these preventable diseases convinced the public to support and participate in further vaccination.⁹⁶

As the previous examples have illustrated, immunization became an encouraged practice within American society in order to prevent and eliminate certain diseases. Governments and public health authorities introduced mass immunization programs to undertake, or at least attempt the vaccination of every American against the above mentioned conditions.⁹⁷ They promoted the principles of beneficence and non-maleficence through data showing a decrease in deaths as well as outbreaks, demonstrating a vaccine benefiting individuals and avoiding harm to larger groups within a community.⁹⁸ Furthermore, they tackled the issue of justice, making vaccines available to all Americans, regardless of income or social status. It did prove difficult to make vaccines available to poorer communities, where some argue vaccines were most needed. These neighborhoods were considered to have the most outbreaks, due to lack of immunization, but also as a result of more difficult living conditions.⁹⁹ As a result, campaigns to improve public

health clinics and encourage mothers to immunize their children through door-to-door education programs were organized and undertaken.¹⁰⁰

These efforts promoted all but one of the four principles, namely autonomy. There was little opportunity for individual citizens to question vaccines or suggest that they are more harmful to the human body than helpful.¹⁰¹ When mass immunization policies were enacted, numerous states created policies insisting that all children be vaccinated in order to attend school, and provided minimal opportunities to opt-out for personal or religious beliefs.¹⁰² In the past, this policy was more supported, as more dangerous diseases were spreading within schools, and the idea was that immunizing children would also protect adults from exposure.¹⁰³ A lack of autonomy, however, contradicts the human right we have to make our own medical decisions. Although harm to others may have occurred, one should have been able to freely decline a vaccine for their own reasons.

Even though vaccines have proven useful to prevent disease, every individual has an autonomous right to decline to be vaccinated. When a vaccine is refused, it indicates a fear or mistrust on the side of the individual or parent. This may stem from the reported adverse effects that arise after immunization. For example, in the past there is evidence that some vaccines, such as polio shots, actually resulted in people contracting polio.¹⁰⁴ This risk has been determined to be quite low, but to a parent whose child was one of the few who did experience these side-effects, it ultimately causes a distrust in vaccination.¹⁰⁵ Moreover, in today's society, there is a focus on the side-effects caused by vaccines that are not the disease itself, but rather other issues, such as mental disabilities, paralysis, and behavioral changes.¹⁰⁶ A link between the vaccine for measles, mumps, and rubella (MMR) has been made to autism by many parents and some scholars, which is supported by the increasing rate of children with autism today.¹⁰⁷ Scientists

were quick to disprove this theory, but it may influence how a parent makes a decision about their children's health.¹⁰⁸

Aside from those individuals who feel that vaccines are ineffective or unsafe, most of society supports childhood immunization for diseases that are difficult on the human body, or can be spread within a community. However, vaccines are starting to emerge for conditions that are not easily spread among groups of people, such as Hepatitis B and the Human Papilloma Virus (HPV). Both of these diseases are not spread through the air or by simple physical contact, making some parents and members of society question their need or their campaigns within schools for young children.¹⁰⁹ Some parents feel that the HPV vaccine, which aims to prevent a solely sexually-transmitted virus, should not be encouraged within schools for young girls, as it only encourages them to engage in sexual behavior.¹¹⁰ It is up to an individual or a parent to decide whether they feel these vaccines are necessary or a positive investment in the future health of themselves or their children, but in today's western society, there must always be that choice.

Society often judges those individuals who decline to be vaccinated to be uneducated about the scientific benefits of immunization, or believes that they are causing harm to the community.¹¹¹ If more and more children do not have proper immunizations, and they all go to school together, there is a fear that a resurgence of these conditions is possible. They believe that an outbreak would use up resources, but could also result in death.¹¹² The benefits of vaccination are recognized in that they avoid outbreaks of preventable diseases, which saves money and time in the future when hospitals are not treating these conditions.¹¹³ Scholars and doctors both feel that vaccines maintain public health safety and that those that forgo vaccination are putting others around them in jeopardy.

On the other hand, some members of society are concerned that the unvaccinated population is simply free-riding on others' immunity. Free-riding enables those who oppose vaccines to reap the benefits of those around them, who have supported immunization and have protected themselves against disease.¹¹⁴ In this situation, utilitarian mass immunization campaigns that encourage people to vaccinate themselves to protect against deadly diseases are benefiting not only themselves, but also all of the 'free-riders,' who subsequently become safe from contagious infections. There is a fear, however, that if more and more people decline immunization, free-riding will not be possible, since there is an increasing amount of the population who are not vaccinated, and, therefore, are not able to provide immunity for those around them. This would lead to further outbreaks of disease and the resurgence of preventable conditions.¹¹⁵

Autonomy must be maintained in today's world of medicine, and matters related to vaccination are no exception. Every individual has a right to determine for themselves or their child, whether to be vaccinated. Before any medical procedure, informed consent is necessary, and it relies on the individual to assess information and make a suitable decision. Information, however, may be difficult to find. A doctor is expected to outline the risks and benefits of a vaccine, but it is not expected that they go into detail about every possible risk that exists.¹¹⁶ There are common side-effects, such as pain and fever, but the possibility of disease or death are very low, and that might be all that is said. Some people scour the internet for more information, which can be dangerous, as much of it will not be scientific data released as a result of research studies. There may be a one in 100 000 chance that a severe adverse effect will occur, but to a parent, that risk may be one too many to take.¹¹⁷ Conversation with healthcare providers seems to be the most effective way to receive useful and accurate information regarding vaccination.

Once informed, it is up to each individual or parent to assess the risks and benefits, and analyze the amount of harm that could occur. Some parents may be adamant about their stance on vaccines and decline any immunization on the basis of that it will harm their child. Other parents may whole-heartedly trust vaccines and opt for any and all possible vaccinations to prevent against disease. Either way, it is important to educate oneself, and not jump to conclusions, or rely on faulty facts to influence the decision. This leads to the right to opt-out for any individual or parent. For example, a female may feel that the HPV vaccine is not necessary for herself and may choose not to participate in vaccination.¹¹⁸ Moreover, a parent with a child who has an allergy to eggs may decide not to pursue traditional vaccination, and try to find vaccines that do not contain animal products.¹¹⁹ The ability to opt-out allows for the adherence of autonomous rights.

Although a government may be criticized for interfering in public health, there are multiple responsibilities that a governing body has to maintain and promote health within a community. One important role that the government plays in the field of public health is to ensure that accurate information is being distributed to both doctors and healthcare facilities, but also to individuals. This can be through the funding of scientific research for vaccines, that are free of bias from pharmaceutical companies, and that use samples large enough to yield an accurate result.¹²⁰ This information is essential so that individuals can make an informed decision about immunization. They may accept immunization as a safe practice or refuse to participate in any immunization program. Furthermore, this information should try and be impartial. It is known that governments encourage vaccination for a variety of reasons, such as political gain or resource allocation, but information about risks and benefits should reflect the truth. There should be equal amounts of information regarding possible side-effects, as there are promoting

the benefits of vaccination. This allows individuals to be certain that they are well-informed and do not feel the need to seek possibly inaccurate information elsewhere.

All of the discourse presented on vaccination has been at the forefront of the COVID-19 pandemic. A number of vaccines became available in 2020 and immunization campaigns have been implemented across the world to try and prevent more deaths as a result of the virus.¹²¹ COVID-19 has claimed millions of lives and will continue to do so unless public health measures are increased, and vaccination rates rise.¹²² While there are hurdles to overcome in procuring vaccines, many obstacles are around public acceptance of them, and of other public health measures in general. It is harmful to society and the greater public when a deadly disease is not taken seriously, and individuals decide that they do not wish to protect those around them in addition to themselves.¹²³ For example, people who refuse to wear masks, a simple and cost-effective public health measure, put not only themselves at risk, but everyone around them.¹²⁴ The COVID-19 pandemic has demonstrated both the benefits of government involvement, as well as the drawbacks, especially in the US where the government, arguably, did not implement public health measures soon enough.¹²⁵ With regard to vaccination specifically, it is crucial that accurate information based in scientific evidence be distributed so that the pandemic can be mitigated, both in the US and across the world. It may be beneficial for government agencies as well as the general public to reflect on the historic vaccination efforts and their success rates to better support the current efforts to control and eradicate the virus.

Public health measures may also one day include the use of genetic therapies or editing technologies as a form of disease prevention. Using genetic screening techniques, such as CRISPR and Preimplantation Genetic Diagnosis (PGD), focusses on individual concerns and actions, rather than community efforts. Influencing which embryos are selected for implantation,

solely because of their genome's features may be legally acceptable, but it may be difficult to determine whether this method of disease prevention is ethical. For example, some parents may be choosing to eliminate genes, such as those that affect Huntington's Disease or Down's Syndrome. If the use of IVF becomes more affordable and accessible, more parents may use PGD techniques or eventually CRISPR editing to eliminate certain diseases from their embryo's genomes. This may lead to a decrease in the prevalence of a certain condition.¹²⁶ However, it can also be argued that the elimination of genetic-based disabilities, such as dwarfism, would not be beneficial for the diversity within a society.¹²⁷ Further information about the uses of PGD to eliminate disabilities and conditions will be examined in a later chapter.

ii. Decision Making for Communities

Public health, by definition, revolves around a community or the 'public' as a whole, which precludes any individual component, and only takes into account how to improve the health of a large population of people. Public health efforts can be executed in a paternalistic way, heavily influenced by consequentialism, or utilitarianism, that factors in the greater good for the most amounts of people, instead of focusing on individuals' health.¹²⁸ In reality, these efforts can be extreme, but sometimes necessary as in the case of infectious disease, explained below. By analyzing consequentialism, and how it affects public health, we will be able to determine whether it is the best method for dealing with public health initiatives. Utilitarianism is a version of consequentialism which states that the right action is the one that brings about the best consequences and, therefore, the most benefits for a group of people. Furthermore, utilitarianism does not take individuals into account, and ensures that everyone, regardless of race or class is treated or considered equally.¹²⁹ In theory, public health aims to do just this, especially with regard to preventing disease within a community.

The clearest indication of paternalism in today's society is seen in the area of infectious diseases. Infectious diseases, though not very prevalent in western society, can pose great danger to individuals and communities alike. Although diseases such as tuberculosis (TB) and malaria are not often seen in the developed world, there is still a risk to others if an individual with TB, for example, comes into contact with a healthy community member.¹³⁰ As a result of these diseases being potentially detrimental, it can be justifiable for utilitarian measures to be taken to ensure that an outbreak of an infectious illness does not occur. As it has been seen during the COVID-19 pandemic, this could include insisting on quarantine for infected individuals, isolation, or travel advisories, depending on the severity of disease transmission.¹³¹ These methods are acceptable for conditions that are highly contagious, as they protect not only the individual at risk, but also the entire population. This prevents or decreases any chance of a mass outbreak of disease, and also eliminates the need for future, more stringent interventions aimed at a larger group of people, as opposed to just one infected patient.¹³² Even in isolation, for example, the diseased patient would still receive treatment, which is an autonomous right, but if the individual were to refuse isolation or treatment, a problem would arise concerning the safety of the public. These prevention methods do infringe on personal liberties, but are justified to avoid detrimental consequences and to ensure the health of the community around them.¹³³

Another paternalistic measure that governments take is surveillance of disease. This method of screening can be classified as utilitarian, because the purpose of these methods is to ensure the safety of the population.¹³⁴ An example of surveillance is testing anonymous blood samples for HIV. This completely bypasses the autonomy of individuals since no informed consent is obtained for each individual blood sample. However, this can be deemed permissible, because epidemiologists can use the data, which is anonymized, to produce statistics. This may increase

awareness of a particular community's incidence of HIV, and cause more people to choose to be tested.¹³⁵ Furthermore, individuals who are HIV positive have an obligation to inform any sexual partners of their condition, for their partner's safety. Governments have the ability to arrest individuals who do not obey this statute, on the basis that they are directly putting other lives at risk.¹³⁶

Paternalistic efforts that can be defended through utilitarianism are not always realistic and may be considered to be not fully paternal actions. For example, a government may need to focus on initiatives that aim to reduce harm, which ultimately results in disease prevention and benefits a large group of people. This can be an alternative to enforcing laws, while still maintaining a level of utilitarian influence. Harm reduction must be an important priority for a governing body in the attempt to prevent or reduce the levels of disease.¹³⁷ For example, in the case of HIV transmission through intravenous needle sharing, public health authorities may witness more success in providing safe injection sites, as opposed to completely banning the practice. This would, potentially, result in a decrease in the number of cases of HIV that are contracted from sharing needles, or would help drug users learn about possible treatment options.¹³⁸ Furthermore, harm reduction must be tailored to the specific issue that needs to be solved. Not all public health concerns can be dealt with using such strategies, and there should be some analysis to predict that the harm reduction initiative will be beneficial in preventing disease.

Another method of influential disease prevention is the promotion of health through behavior modification. This is on the border between individual and community responsibility, but a government has the responsibility to encourage healthy lifestyles and provide the means for individuals to change the way they approach health and wellness. There are ethical concerns, however, when a government attempts to alter an individual's entire lifestyle, as opposed to just

point out and modify their unhealthy choices or actions. Paternalism may be associated with behavior modification if this method of health promotion is presented in such a way as to change a person entirely.¹³⁹ Furthermore, there may be concern that targeting an individual's behavior is blaming them for their unhealthy nature. They are portrayed as the victim and it is their fault that the health promotion is necessary, when in fact environment and social influence play greater roles in how a person behaves with regard to their health.¹⁴⁰ Common health promotion campaigns that suggest behavior modification include targeting smoking cessation and obesity, both of which can lead to a variety of diseases, and an overall unhealthy lifestyle.

In contrast, libertarian paternalism is a theory that values the autonomous rights of an individual to make their own decisions, but also includes a small level of state influence that takes into account the overall best interests of a community. This is executed through a paternalistic 'nudge' when influencing individual decisions.¹⁴¹ For example, in the case of trying to improve healthy eating, a buffet could position healthier options in more visible places. Consumers still have options as to what they eat, but they may be more likely to see the healthy options and choose those. This example illustrates the theory: a larger body can manipulate the choices that are available to the public, but the public still feels as though they make their own decisions. This may seem deceptive, but obesity is an example of a serious issue that must be addressed. This theory allows the government to take responsibility for the products or programs available to the public, and obese individuals can choose any option they prefer. The issue of obesity will be discussed further, to illustrate how this theory allows individuals to maintain autonomy while still participating in public health efforts from a higher governing body.

Although this theory maintains balance between individual autonomy and government influence, obesity will not be easy to resolve. Changes can be implemented, such as better access

to exercise facilities or more pressure on food and drink companies to improve the health of their products. This demonstrates the prioritizing of health as opposed to the promotion of financial gain for businesses. Behavior modification through education will be one of the most crucial habit-changing factors.¹⁴² This same concept will be illustrated later with regard to the issue of smoking. With obesity, many individuals are simply not aware of how they are negatively changing their bodies. They may not have nutritional facts about sugar and fat intake, or how to properly portion meals. In addition, education about diseases that stem from obesity, such as heart disease or type II diabetes, should be improved.¹⁴³ If an obese individual is made aware of the possible risks associated with their lifestyle choices, they may be more likely to make changes to avoid a shorter life expectancy or later health complications.

When deciding how to try and reduce the incidence of obesity, it is also important to examine who is affected. Although obesity impacts populations or even countries as a whole, people do not directly harm each other or transmit obesity. Solutions to this problem must stem from an individual being willing to reduce the harm they are doing to themselves, but they also require external support.¹⁴⁴ It is important for there to be a balance of effort from a government program and effort at the level of the individual. Governments do have a responsibility to make it easier for an obese person to modify their lifestyle and values, but not to push them into feeling uncomfortable. This balance is difficult to maintain. It can be easy to offend an over-weight person by telling them they must change and that the way they look is not normal, therefore, it is crucial that health information is presented in a non-threatening way that will benefit numerous individuals within a population.¹⁴⁵ For this reason, complete utilitarianism is not effective – a government cannot force an obese individual to change their lifestyle in a way that will

guarantee weight loss. Libertarian paternalism, therefore, is a better suited theory to deal with obesity.

Libertarianism, where individuals make most of their own decisions with regard to public health, such as the case of obesity, is only applicable to a small number of public health related issues to lower the incidence and eventually prevent disease. The issue of smoking cessation will be expanded on to demonstrate how a habit, such as smoking, which can lead to a deadly disease (cancer or lung disease), illustrates the possibility of a happy medium between libertarianism and paternalism, as it affects both individuals, and the community at large.

Similar to obesity, giving up smoking depends on the individual smoker making changes to their behavior in order to quit. The government has an interest in reducing the prevalence of smoking and may implement programs to nudge the smoker to make healthier choices. For example, putting a “sin tax” on cigarettes may prevent a smoker from being able to afford buying cigarettes, therefore, causing them to quit.¹⁴⁶ This paternalistic action seems negative, but any individual still has the option to buy the cigarettes, making it an example of libertarian paternalism. Although in some ways the government is interfering with the liberties of individuals by curtailing their ability to afford this unhealthy habit, they are still leaving room for personal decision-making. Furthermore, health education should have as its primary goal to try and minimize the number of smokers. It is common for cigarette packages to have images of diseased lungs or highlight damaging effects of smoking, as methods of education about the negative side effects of smoking. As important as education is, it is more crucial that the information being distributed is accurate. A common example is the link between smoking and lung cancer. Numerous scientific studies have demonstrated this correlation, but some members of the general public may not be aware of this work. It is not guaranteed that every smoker will

at some point get lung cancer, nor is it true that if a smoker quits, they completely eliminate their cancer risk. These misconceptions should be clarified to ensure that individuals are properly educated about their health, and will hopefully be influenced to break their habit in order to live a longer and healthier life.¹⁴⁷

Unlike obesity, being in direct contact with someone who is smoking can cause direct harm to the non-smoking individual. This is often a non-voluntary encounter, and it is up to the government or community to implement changes to avoid second-hand harm.¹⁴⁸ Since smoking is not illegal, it is difficult to insist that people completely stop smoking around others, but it can be strongly encouraged, through policy such as not being able to smoke indoors or in public restaurants.¹⁴⁹ These methods do not allow for personal liberty regarding where one is allowed to smoke, making them examples of utilitarian actions. Furthermore, second-hand smoke can be just as dangerous as actual smoking and could also lead to lung cancer, for example. It may be acceptable that governing bodies take action to try and prevent this problem for individuals who are unable to do so individually. These methods are justified and may set a precedent for how governments deal with similar smoking problems, such as smoking around children. Although this would be extremely difficult to implement, it could be justified to make smoking around children illegal to promote their health and safety when they are unable to make their own decisions about their environments.¹⁵⁰ Similar to the role a government can play in reducing obesity, a governing body can prioritize the health of its citizens over the promotion of a tobacco business.

Diseases can be critical and life-threatening if not treated in a timely and organized manner, but, in many cases, they can be avoided almost entirely through disease prevention strategies described in this chapter. An analysis of the concept and theories of disease prevention allows

public health authorities to effectively introduce methods that will inhibit the onset and spread of disease in ways that will most benefit a community. By doing so, the human right to health and the right to health care is being ensured, which promotes and maintains the health and welfare of all citizens. While universal standards of health care may not exist, it is clear that there are methods of reducing disparities between populations, and there is evidence that compels that higher powers, such as governments and global organizations take action to improve the wellbeing of global communities.

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- ¹ Tasioulas and Vayena, “The place of human rights,” 367.
- ² Tasioulas and Vayena, “The Place of Human Rights,” 368-369.
- ³ Liao, “Health (care) and human rights,” 259-267.
- ⁴ Liao, “Health (care) and human rights,” 267-272.
- ⁵ Tasioulas and Vayena, “The Place of Human Rights,” 370.
- ⁶ Tasioulas and Vayena, “The Place of Human Rights,” 375-380.
- ⁷ Daniel Brudney, “Is health care a human right?” *Theoretical medicine and bioethics*. 37, no.4 (August 2016):249-250, doi: 10.1007/s11017-016-9376-6.
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- ¹⁵ Sreenivasan, “Health care and human rights,” 356,
- ¹⁶ Tasioulas and Vayena, “The Place of Human Rights,” 375.
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Chapter 4: Vulnerability in Health Decisions

The concept of vulnerability extends beyond public health, and there are many groups of people who are considered to be vulnerable within the context of healthcare. This chapter specifically looks at vulnerability in the context of research, where many of these populations have previously been ignored or exploited. By following appropriate research protocols, groups, such as children, pregnant women, and impoverished individuals, can be appropriately included in medical research. This directly extends to the safeguards that must be in place when conducting clinical trials for CRISPR/Cas9 technologies and genetic therapies. Beyond research, these groups often face vulnerability at the beginning and end of life. Religious beliefs may create vulnerability factors for individuals who are making decisions that contradict their belief system, requiring analysis of the faiths of Islam and Catholicism for comparison. Religious principles and values will also affect opinions regarding the use of genetic editing techniques to potentially avoid the specific concerns related to abortion and Physician-Assisted Death. Both Catholicism and Islam strongly contest these procedures. By examining vulnerability through the lens of these topics, a brighter light is shed on the importance of genetic therapies and editing technologies along with their role in the medical field which is intended to serve everyone, regardless of aspects of vulnerability.

A: Vulnerability in Research Subjects

Medical research relies on clinical trials for accurate results and evolution in the field of medicine.¹ Clinical studies can be therapeutic when they are directly targeted towards a population of individuals with a particular disease, in an effort to provide a new treatment or procedure for relief. Non-therapeutic trials also advance medicine, but use research participants who volunteer their time to partake in studies that do not directly affect them individually, but

benefit society. Medical research is crucial in order to advance medicine and provide options for disease prevention and treatment that previously did not exist. In order for a researcher to accept a participant into their trial, informed consent must be given by a competent research subject or a substitute decision-maker acting on a participant's behalf.² This simple requirement poses challenges when research is conducted with vulnerable populations, however. This is especially apparent when conducting research on genetic therapies and editing techniques, due to the novelty of the treatments and the unknown risks associated with new technologies.

A vulnerable patient or population is one which is incapable of protecting themselves against possible harm caused by research. Extra safeguards must be developed to ensure that human rights are upheld and that any medical research is ethical.³ These individuals or groups of people can have varying levels of capacity, and must be considered differently than others in the same category. For example, an individual may have a high level of capacity, but as part of a vulnerable population, is viewed to be in some sort of danger when participating in research, such as those within an impoverished population. A single individual is also able to have changing levels of capacity, and demonstrate varying levels of competency throughout the time of a research trial, such as patients with dementia.⁴ This encourages the use of a substitute decision-maker to ensure that all consent is informed and autonomous, similar to their role described in an earlier chapter for consent to treatment.⁵ It is crucial, however, that research is done with vulnerable patients and populations to ensure that everyone has the opportunity for medical relief and proper information can be obtained for safe and effective treatments. CRISPR-Cas9 technologies may specifically benefit vulnerable populations, and require additional efforts to include often-excluded groups in research projects.

Numerous safeguards are in place within most countries to ensure ethical research is conducted, due to historic blunders that have violated individual human rights. Research oversight is required for this reason and in the context of genetic research, it is mandatory.⁶ It has been mentioned in the literature that one scientist in China, Dr. He, did not follow appropriate research standards when using the CRISPR-Cas9 technique to manipulate the genomes of embryos, leading to the birth of the first genetically-modified twins.⁷ His example will be expanded upon below, in order to demonstrate the vulnerability in medical research.

i. Informed Consent and Relationships between Researchers and Participants

All medical interventions, whether they are research trials or individual treatments, require the informed consent of the participant. This is true of any type of research participant, including one who belongs to a vulnerable population. The subject must be made aware of all of the potential risks and benefits associated with their participation in the study.⁸ If a clinical trial is being conducted, a doctor must also describe how an experimental treatment could potentially affect the patient's body and health, both positively and negatively.⁹ Informed consent makes evident that a respondent has made an autonomous decision to participate in research, based on all the required information having been provided. This is the beginning of the subject-researcher relationship.¹⁰

In order for consent to be accepted from a research participant, an individual must be deemed to have adequate decision-making capacity with which to provide their informed consent. Details regarding how to assess the capacity of an individual were given in the second chapter of this dissertation. A capable individual is able to understand simple medical facts about the trial or treatment to which they are consenting, and to appreciate the effect that the medical intervention will have on their body and on their life.¹¹ By providing their consent, a research respondent

indicates that they fully understand any possible harm that could occur and that they are able to appreciate the purpose of the research and its limits, as well as the possible impact of their contribution.¹²

In order for informed consent to be considered valid, the “Common Rule” must be followed, which dictates that a researcher must attain a participant’s informed consent before they begin their clinical trial. This includes the patient indicating, usually on a consent form, that their decision to participate is voluntary (free of coercion), and informed.¹³ When providing information about a trial, an experimenter must take into account an individual’s specific background. For example, a vulnerable participant who comes from an impoverished community and who has little formal education will probably not be able to understand difficult medical terminology which will lead to an informed decision regarding their involvement in a study.¹⁴ Unlike patients providing consent for treatment who must prove they understand and appreciate their situation by paraphrasing their diagnosis, prognosis, and treatment options, a research participant must only sign a consent form indicating that they understand and appreciate the study and its implications.¹⁵

When considering the autonomous choices of a patient in any kind of medical intervention, it is important to acknowledge that coercion can seriously impact a capable individual’s ability to make a decision that is reflective of their own wishes. If a patient is coerced, their consent is not considered autonomous. As a result, it becomes invalid, since an outside party has influenced their decision. Coercion nullifies an individual’s freedom to make their own choices. In its most serious form, it involves direct threats towards a patient, such as a family member threatening to stop caregiving services if the patient does not participate in the trial.¹⁶ It is crucial that informed consent is free of external pressure and that doctors are aware of

any ways coercion can be present in the decision-making process, as well as in the process of a participant wishing to withdraw from a study.

Coercion commonly arises if a participant is unsure about the trial facts or if there are multiple people involved in the decision-making process.¹⁷ A patient may be coerced by an outside influence to make a decision to participate or not participate in research, a choice with which they may not agree. Patients from vulnerable populations may be particularly susceptible to pressure from those they respect or consider to be authority figures, whether they are medical professionals or members of their family. Coercion can appear in the form of a doctor making the patient feel guilty if they do not participate, or a paternalistic family member forcing their loved one to make the decision to go ahead.¹⁸ This practice must be avoided to ensure that the informed choice of the patient is an autonomous one. If a participant believes that they have made their decision themselves, free of outside influence, they are more likely to cooperate and provide honest and accurate data, because they trust their researcher, and feel in control.

When an individual does not have the suitable decision-making capacity to provide their own informed consent, such as a patient suffering from advanced dementia, a surrogate or proxy decision-maker is able to consent on their behalf. A patient must be deemed incapable, but the level of incompetency can differ; a patient can be completely incapable (i.e., unconscious) or partially incapable (i.e. mentally disabled patients or children). Although there are subtle differences between the roles of a proxy depending on the level of incompetency, the basic need for informed consent is the same. The way that a surrogate decision-maker is chosen can vary, depending on whether the patient chooses an individual or whether one is appointed after the patient loses capacity. For example, a patient has the right to appoint a durable power of attorney for health care to make any decisions on behalf of the patient.¹⁹ Without the selection of a

specific individual, the surrogate automatically becomes a family member or close friend, or is appointed by the court. Chapter 2 of this dissertation goes into further detail the appointment of a substitute decision maker and their role in the consent process.²⁰

While examining an incompetent patient's capacity, it is crucial for an investigator to establish what their respondent's current capacity level is, and to respect it. In studies conducted with dementia patients, it was found that although few of them were able to provide informed consent for research trials involving high-risk neurology treatments, they did possess enough capacity to appoint a surrogate decision-maker to make choices for them. It was evident that these patients recognized their loved ones and felt comfortable enough to pass along the rights to decision-making.²¹ Better results were observed for patients suffering from schizophrenia. Fisher's study proved that although these patients are considered to be part of a vulnerable population, very few posed any risk or demonstrated a level of incapacity for consenting to research. If these patients were clinically stable and receiving standard treatment for schizophrenia, they had no issue understanding and appreciating the risks and benefits associated with research studies.²²

As mentioned, an important component to a participant agreeing to join a research trial is the nature of the relationship with their researcher. A way to strengthen this relationship is through education. Education consists of both the investigator and the respondent being aware of their roles and responsibilities within the parameters of the research project. If both parties have all the necessary information, and understand each other's roles, trust develops automatically regarding the intent of the research as well as the eventual use of the collected data. For a relationship to be successful there must exist a collective trust between all the individuals involved, especially when conducting research with vulnerable populations. A researcher, who

can outline how they intend to protect their subjects' information and honestly explain the intent of their work, creates a level of assurance among their subjects.²³

An investigator has the duty to weigh the risks and benefits of the research and of possible results. A trial or research idea may seem beneficial to the scientist conducting the experiment, but it may only help a small number of people. It could also potentially present significant and troubling risks for participants. Risk/benefit analysis is essential to ensure safe and ethical research and contributes in a major way to the preparation a researcher must undergo before seeking out respondents for their work.²⁴ If the benefits significantly outweigh the risks, the project is assumed to be very safe. If the risks begin to increase and surpass the amount of benefit, care must be taken to decide whether it is worth conducting the study.²⁵ High risk experiments, that may provide little or unknown benefit, must be analyzed to determine how they would affect society, and if there is merit in going through with them. If a trial involves treating an incurable disease with minimal available treatment, for example, the experiment could be seen as beneficial enough to be worth the risk.²⁶ This necessary analysis is vital for a researcher to engage in and leads to an improved relationship with the participants taking part in the experiment. Extra care must be taken with vulnerable populations to ensure that the relationship between the researcher and respondent acknowledges the protections needed for a high-risk population. If all risks and potential benefits are outlined in sufficient detail, a participant will be more likely to trust the investigator going forward.

In order to effectively educate a participant about information related to a particular study, an experimenter must decide what information to include when having this discussion. A participant may not feel that all medical facts or drug chemistry will be relevant to their decision making process, and only significant and potential risks and benefits, as well as a simplified

version of the science, are necessary. If a patient has mental disabilities, or if there is a language barrier, adjustments must be made to accommodate these vulnerability factors. A researcher may choose from one of three disclosure standards to present the proper information in order to obtain genuine informed consent. The “professional practice standard” involves a researcher outlining all information that a fellow professional would also feel is necessary; the “reasonable person standard” entails an investigator explaining what a reasonable person would find the most useful; and the “subjective standard” requires the experimenter to discuss information they feel is relevant to a specific individual respondent. The best standard is one that combines the latter two, which ensure that the proper facts are provided at a level that the participant can understand and which reflect their own lifestyle, and therefore allow them to make an informed decision.²⁷

Clarifying the intent of research is also crucial for forging an effective relationship between a researcher and their participant, as well as creating a safe and trustworthy trial. When a researcher is deciding upon the details of their inquiry, as well as explaining it to others and choosing participants, there is a need to defend why and how the research is fair and just.²⁸ Exploiting a vulnerable economically challenged community whose members rely on research participation to survive, or doing research on a drug where it will never be made available can certainly be considered unjust. It is important that the subjects know that they are not being exploited and that their time and contributions are valued.²⁹ A participant should never feel as though they are being ill-used or utilized solely because of their quality of life. A researcher has the responsibility to ensure that the project is not taking advantage of anyone, and that emphasis is placed on this during discussions with all respondents.

When a participant gives their informed consent to partake in a research study, they also have a right to know where and how their personal information and eventual results will be used.

The very serious issues of privacy and confidentiality are crucial when handling data, and if maintained, a mutual trust between the researcher and the individual will grow. A participant has the autonomous right to their own information being kept confidential, during and after research. Oftentimes, this is the law, which generally decrees that although data can be shared, a specific identity cannot be, without proper permission.³⁰ Every subject is also promised a suitable level of privacy, and has complete power over how much access others have to their data. These concepts comprise autonomy, and it is crucial that the respondent is aware of their right to privacy and options regarding release of information. If these policies are outlined during initial phases of research, a participant will gain more respect and trust for the investigator, which will have a positive impact on their working relationship.

All of the described components of an effective discussion between participant and researchers must be taught to and recognized by the research community. It is also important for investigators to consider the nature of their participant pool. For example, a study was conducted by Desine et.al. to examine how information is given in the context of genetic editing and Sickle Cell Disease (SCD).³¹ SCD will be further explained below, but this community was engaged in a conversation about how they previously received information on available genetic therapy options for SCD, and what improvements can be made. The most significant finding was that physicians underestimated the knowledge that patients and families of those with SCD had, as well as their ability and desire to understand new information. Often physicians verbally used or included on consent forms, vague and overstated language, without going into details about experimental information.³² Patients and families felt that if those conversations included more detail about the risks and benefits, side-effects, study mechanics, eligibility criteria, and impact

on patient quality of life, more trust would be gained and more interest in the research would be seen.³³

In addition to having a beneficial and robust discussion with their physician and/or investigator, understanding the research approval process may increase a patient's trust in the research process, and the research team. In the United States, before any research participants are chosen for a study, the research study must be approved by an Institutional Research Board (IRB). IRBs exist to evaluate and approve experiments. It is the job of these review panels to determine whether each trial is ethically acceptable and what risk level is associated with it.³⁴ If the risk is minimal, and considered to present a hazard which can occur in everyday life or during regular physical or psychological exams, then it is permissible for individuals to participate. Specifically relating to children, if there is a minor increase over minimal risk, then it is permissible for children to participate with their own assent and the consent of parents. If there is more than a minor increase over minimal risk, there must be a direct benefit to the individual for the research to be permissible, and the review boards must approve the study to be beneficial and worth the risk.³⁵ This overview process is a necessary safeguard to ensure that all individuals, especially those that are categorized as being part of a vulnerable population are protected from harm.³⁶

ii. Vulnerable Research Participants and Safety Measures

Often in research, a study will protect vulnerable patients' rights by simply excluding them from a trial. This is unjust and unproductive, since it makes no distinction within vulnerable groups and bars the possibility of beneficial research results. Vulnerable populations do not always have to include incompetent individuals, as some 'vulnerable subjects' are vulnerable

because of their current status in life.³⁷ The examples of pregnant women, disadvantaged populations, mentally incapable individuals, children, and embryos will be examined.

The classification of pregnant women to be ‘vulnerable subjects’ has caused controversy, as some authors believe that the women themselves do not need extra protection and are capable of making their own medical decisions. Conducting research with pregnant women does bring about some concerns, however, because there are risks involved.³⁸ The main issue deals with the fact that there are multiple lives in question, and the fetus inside its mother should be protected from unnecessary harm. It can be difficult to allow a woman the right to put her fetus in danger, by participating in a study for a new medication previously untested, for example. Furthermore, some believe that pregnant women are in such an emotional state, that they do not, in fact, have the appropriate capacity to make any medical decisions, and require numerous safeguards for ethical research.³⁹

Although considered vulnerable, pregnant women make up a population that is in need of research, especially of studies that directly benefit expectant mothers. Research studies, whether they are medical trials or involve social observation, can be of value to pregnant women and provide knowledge about their condition and experiences. Furthermore, women are more likely to trust the healthcare system if they are provided with accurate data, and if they are asked for their own opinion, such as participating in a social study about past pregnancies. A trusting relationship with the whole system leads to improved care.⁴⁰ Another direct benefit of increased trials with pregnant women is that they would provide greater information about safe drug doses for expectant mothers. Currently, most drug labels do not indicate any known risks for pregnant women or children, simply because no research exists that provides these answers.⁴¹ An increase in research with children in drug dosage trials is beginning to be seen, and the same should begin

to be done with pregnant women. This would benefit a significant number of individuals, as well as result in a reduced level of risk when taking medication while pregnant.⁴² Growing numbers of research trials which include pregnant women may lead to an increased number of studies being conducted on vulnerable groups within the larger group of pregnant women, such as female sex workers, women with HIV/AIDS, and expectant mothers using drugs. More research directed towards these groups of pregnant women would lead to a higher standard of care.⁴³

Research on the human fetus is an area of great concern, both for researchers and for mothers who are providing consent. This type of research significantly affects legislation and drives policy-makers who implement laws and protocols that are meant to uphold the rights of a fetus. Fetal research is permitted as long as it poses minimal risk to the fetus, and either directly benefits that particular fetus, or would help develop biological knowledge that is unable to be obtained using other methods. Unlike research with children, it is not permissible to conduct research on a fetus if there is more than a minimal risk associated with the study.⁴⁴ Moreover, there is no law that distinguishes research with ex-utero fetuses, such as those that have been aborted, from in-utero fetuses. As long as the research only poses a minimal risk, research with these fetus is permitted.⁴⁵

If there is a concern with pregnant women participating in research, some wonder if equal apprehension should apply to women who could potentially become pregnant. There is no legislation that prevents a female research participant from partaking in a study, but some argue that researchers have a duty to disclose any risks associated with their trial that could potentially affect a future fetus or future fertility. For example, a woman may not feel comfortable taking contraceptive agents due to personal or religious values, but would like to participate in a study for Thalidomide, a drug known to cause deformities in children whose mothers took the drug

while pregnant. It would make sense that contraceptive agents be mandatory, to ensure that any future fetuses would not be affected by this drug, but, ultimately, it is up to the female research subject to judge the risks and potential benefits before giving her informed consent to research. It is crucial, however, that a researcher explains the risks of a teratogenic drug to all female participants.⁴⁶

Minority groups can also be counted among vulnerable populations, especially if they have experienced abuse in historic research trials. It can be difficult to conduct studies with minorities and ensure that the research remains ethical. Usually, minority populations experience a lower quality of care, poorer healthcare outcomes, and have less access to health care than normalized populations, making it the mission of research to learn why these inequities occur. Research can also shed light on reasons for economic and social disparities. A common example of minority research is done with African-Americans. There are certain diseases that have a higher prevalence among African-American individuals, which leads to research studies, such as investigating the efficacy of ACE Inhibitors and Beta-blockers being conducted among that sector of the population.⁴⁷

In the context of research for genetic editing technologies, such as CRISPR-Cas9, it would be beneficial to conduct studies specifically aimed at improving diseases that minorities, such as African Americans or Hispanics, experience in high prevalence. Sickle Cell Disease, which was mentioned above, is the most common inherited blood disorder in the United States among African Americans and Hispanics, and reduces the lifespan by 25-30 years compared to a Caucasian American.⁴⁸ There is an argument to be made for including SCD in genetic research so that this disease can be mitigated, both in the US and around the world where it is also prevalent. A significant hurdle that researchers will have to overcome, however, will be in

creating and maintaining trusting relationships with these populations, who have previously experienced human rights violations in research studies. By promoting and pioneering studies that use this technology to affect SCD, the disease prevalence can decrease, but the scientific community can address historical and sociopolitical injustices, further fostering trust with vulnerable populations.⁴⁹

Although the research itself is important, it is crucial that minority research projects consider possible complicating external and internal factors. Confidentiality and stigmatization can occur in small communities, where study participants may experience a great deal of distress due to the improbability of anonymity. Psychosocial problems could also arise, as well as group harm, such as in Native American communities, when a researcher undermines traditional beliefs and values. Similarly, a researcher must consider cultural norms in these small communities and modify their research to remain respectful of beliefs and cultural practices. Some individuals could find the concept of autonomy and individual consent abnormal, and prefer to consult with a group elder or other community members. Although legally one is allowed to make their own decisions, some cultures may function differently, and an investigatory body should maintain the respect of persons by accepting and encouraging this type of behavior.⁵⁰

Individuals who have lower education levels, experience language barriers, are economically disadvantaged, are considered poor because of income rates or being uninsured, are all considered to be vulnerable populations. Not allowing these groups of people to participate in trials in which they could be included, is a discriminatory practice. It may be assumed that ‘poor’ or uninsured participants choose to partake in research trials because free medical care is the incentive, but there is actually a low representation of disadvantaged respondents in research, and individuals in less advantaged socioeconomic groups seem to be

less likely to participate. Improvements that could be made in order to encourage economically disadvantaged populations to take part in research include simple modifications to a research study to ensure that all participants feel comfortable. This can include plain language explaining the scientific methods and facts, or translating the information into other languages. Furthermore, it is crucial that all participants understand the trial and any known risks that are associated with it. If an individual is unable to fully grasp what the research is about, it is recommended that they participate in a trial that is of minimal risk. If an individual is able to provide autonomous consent, there is no reason to prevent them from partaking in any research studies.⁵¹

A concern arises with economically disadvantaged populations in other countries, as well. Research trials are often conducted internationally, because of lower costs and a higher number of willing participants. However, this convenience is sometimes abused and pharmaceutical companies use this method to conduct unethical research trials. For example, a drug company conducting clinical trials in developing countries to test for possible treatments that will be exclusively available in developed countries, demonstrates how research can be perceived as unjust. On the surface, it is not fair that an individual or community is being exploited like this when they are receiving very little benefit in the long run. If a company, however, can provide the community with some compensation, through health programs, or the drug itself, the research is considered ethical.⁵² A common example is HIV/AIDS trials conducted in Africa that mostly benefit Americans living with the disease.⁵³

There are certain vulnerable populations, such as patients with dementia, schizophrenia or depression that have varying levels of capacity depending on the progression or severity of their disease. Capacity, in general, lies on a continuum and can change depending on the circumstances. An individual, for example, may possess the capacity to assign a substitute

decision-maker, but not be able to understand and appreciate information associated with clinical trials. When an individual is not able to consent to research, but is considered a valuable candidate, a proxy decision maker can do so on the patient's behalf.⁵⁴

In order for a vulnerable patient, such as one with dementia, to have the capacity to participate in a clinical trial, there are three elements that must be considered. One is that the patient must be able to understand the differences between clinical care and clinical research, as the former is considered directly beneficial, whereas the latter is still research and never guarantees a positive outcome. A substitute decision-maker for an incapable patient must also be able to make this distinction. Additionally, a patient should be able to recognize the appropriate levels of risk associated with a clinical trial as opposed to a medical treatment, and be able to assess whether those risks are worth the participation in the trial. Finally, there should be a planned evaluation of a subject's capacity, to ensure that the previous stipulations are accounted for, and that the patient or surrogate is truly competent.⁵⁵ A common sign of incompetency or misunderstandings is therapeutic misconception, where a patient does not understand the purpose of the research study, and believes it will be beneficial for their condition.⁵⁶ It should also be emphasized that a diagnosis does not result in an automatic status of capacity. Patients should not be judged on the basis of their disease, but should be assessed individually to determine their specific competency to make decisions.⁵⁷

Current legislation only allows vulnerable and incapable patients to participate in research trials that may be of direct benefit to them. "The Necessary Clause" proposed by Wendler is sometimes followed, which stipulates that research is only done when it is necessary for the patient.⁵⁸ However, more often than not, an acceptable study is one that must only pose minimal risks, if any, and any increase in risk that is more than minimal can be justified only if

the research is for the direct benefit of the patient. The same rules apply in the case of pediatric research and the assessment of risks of participation.⁵⁹ These safeguards exist as a direct result of exploitation that has taken place in the past. Appalling historic events, such as the Tuskegee syphilis trial and Nazi experiments, have led to explicit policy regarding vulnerable and incompetent population research, to ensure the safety of these populations and to uphold their human right of autonomy.⁶⁰

To ensure that research trials with incapable patients are ethically conducted, there are various improvements and safety measures that an investigator can undertake. Within facilities such as nursing homes, education can be improved to ensure that nurses become aware of the risks and benefits of research, and that patients come to realize that research trials are available in which they may be able to participate. For the research to be effective, it is crucial that caregivers are informed and instructed, and that they agree to aid investigators. Oftentimes, a caregiver or nurse is the one conducting a study, in feeding method trials for dementia patients for example, as a mentally incapable patient would feel more comfortable with a familiar face. By ensuring that a nurse agrees and cooperates with the research being done, a study may be more effective and yield more accurate results.⁶¹ Education of the research participants themselves should also be improved. Even though they may have a limited capacity, an investigator should have the ability to modify the process of informing a patient of all the necessary information about risks and benefits associated with a trial. Although each patient varies, a researcher should strive to improve this education so that the reasoning of these patients subsequently improves as well.⁶²

Another large vulnerable population is children. Studies involving pediatric patients can help researchers better understand how a child reacts to social and medical interventions. Ethical

issues can arise, however, because of their various vulnerabilities. Children differ from the previously described individuals, in that they do not typically possess their own capacity and often rely on a surrogate in the form of a parent. Safety measures for the protection of children, the autonomy of both the child and their parent when providing informed consent, and payment for participants are important ethical concerns associated with pediatric research.

When a child enrolls in a clinical trial, whether it is a medical or social trial, they must be aware of their individual rights.⁶³ They are able to autonomously withdraw from an experiment at any time if they feel uncomfortable, and they are not required to provide a specific reason.⁶⁴ This autonomy can be forgotten or disregarded, however, if a child believes that there may be personal repercussions for ceasing to participate in a study. For example, if they think their parents will punish them or that they will be treated poorly, they may stay in the clinical trial, despite reservations or discomfort.⁶⁵ In order for autonomy to be at the forefront of a researcher's concerns, it is essential that a child is aware of their rights and that a researcher explain to the best of their ability to both a child and their parent that a subject can withdraw from the study at any time without penalty or repercussion of any kind.

A reason for withdrawing from research might be because of too much risk or harm associated with the experiment. Although review boards evaluate the level of risk that a research study contains and may determine that the trial is safe, it is up to a child and their parent(s) to decide if they wish to partake in the study despite a certain level of potential harm.⁶⁶ If a medical trial is classified as being therapeutic, most patients believe that even the smallest possibility of benefit is worth an elevated level of risk. If the trial is non-therapeutic, there is no intended direct benefit for an individual participant. Its purpose is to provide general data about trends or to test toxicity levels. The risks associated with non-therapeutic studies may not be worth participation

in the trial, as it could directly harm a healthy child. It is recommended that children who do not have a specific disease or condition associated with the research should not be exposed to any increases over minimal risks, and, therefore, should not partake in such studies. However, it is ultimately up to a child and their parent to decide whether they choose to enroll in a study, and conduct their own risk-benefit analysis in order to make this decision.⁶⁷ These stipulations apply to all vulnerable populations, but are especially monitored and enforced with trials involving children.

Within medical research, children who already have a disease or condition being studied are more sought after, and additional concerns must be considered. In many instances, there can be cases of therapeutic misconception associated with non-therapeutic studies. For example, if an oncology trial is phase-1 and testing drug toxicity levels, a parent or child might believe that there is a possibility for therapeutic relief or a cure. In fact, the purpose of these studies is not therapeutic at all, and it must be explained to the subjects that it is not intended to act as a treatment.⁶⁸ Furthermore, children with the studied disease may be perceived to be able to tolerate a higher level of risk. For instance, it may be assumed that a child who has already experienced a lumbar puncture will view another procedure as a minimal risk and non-invasive, while a healthy child may feel more uncomfortable. The literature suggests that this assumption is not valid, and all children, regardless of their prior experiences, should be considered equal when it comes to the amount of risk that is considered minimal and tolerable in research.⁶⁹

This concept also raises the question of approving certain treatments for compassionate use. In the US, there is a “Right to Try” law now in effect, which allows for patients to access unapproved treatments outside of a clinical trial, often meaning that there is not established safety or efficacy data to support use. However, when a child with a specific disease either

cannot access a clinical trial (due to ineligibility or geographic location, for example), or there is no current clinical trial for that treatment available, a physician can seek permission to provide the treatment out of compassionate use. Typically this is considered when no other treatment is available for a particular disease.⁷⁰ While this may seem like a beneficial system, it also raises concern about the future integrity of scientific research, especially with children. Since there are already few research trials that include children, it is feared that the increase in compassionate use will deter parents from enrolling their children into a randomized trial, where there is a possibility that their child will not receive the studied treatment. This would result in only anecdotal evidence being available about a medication, for example, and not the gold standard of clinical trial results.⁷¹

When scientists are planning pediatric research experiments, they may be able to adapt methods from trials conducted with adults in order to make them more suitable for children. A survey, often used in adult social research, may be difficult for a small child to understand, and may need to be converted into a very basic conversation. Furthermore, if research is being done on toddlers who are unable to read or write, and whose vocabulary is not fully developed, a researcher may have to enlist the help of other professionals to properly communicate with these subjects.⁷² Additionally, visual aids could be used to gather data, since children may feel more comfortable interacting and communicating in this way.⁷³ This is important to ensure that a child is comfortable and that information accumulated is accurate. Although a researcher may have to invest extra time and effort to add these modifications, it is crucial that they do so in order to improve the quality of their research procedures and results.

It can be difficult to assess a child's capacity and to determine that they are sufficiently competent to make their own medical decisions. It is often assumed that a child cannot

understand and appreciate the implications and workings of a research study, which invalidates their consent for participation.⁷⁴ As a result, their parent must provide supplementary consent. Within research studies with children, if the participant is old enough, usually over the age of seven, a child must have parental consent as well as provide their own assent to take part in an experiment.⁷⁵ A child's assent means that they have agreed to partake in the research, but legally, the parental consent makes it valid. A child can also dissent when they do not feel comfortable participating in the experiment.⁷⁶ Currently in the US, only 'mature minors,' usually teens between the ages of 14 and 17, can provide their own informed consent without the additional consent of their parents.⁷⁷ Assent and dissent is very important as it still allows a child to voice their own opinion and feel as though their autonomy is being considered.

As indicated, a parent has an important role in research with children, as they must provide informed consent on behalf of their child. An earlier chapter described the challenges that parents face when making decisions for their children, but frequently it is assumed that parents act in the best interest of their children and in the context of their beliefs and values.⁷⁸ A parent also has the ability to override a child's assent or dissent within a study. This is only permitted if the research will directly benefit the child, such as the case of a subject with an existing disease or condition who does not wish to try a new therapy or contribute to ongoing research, but their parents believe it would be of benefit (in the case of overriding dissent). Similarly, a parent may feel the experiment is not safe or beneficial for their child (in the case of overriding assent).⁷⁹

When conducting research, an experimenter may hope that a participant is motivated to partake in the research, because they share the common goals of the study. This, however, is not always the case, and some sort of compensation may be provided as an expression of thanks for

participation. For trials that are non-therapeutic or provide no direct benefit to a subject, a compensatory payment can render participating in the research more worthwhile for the child and their parents. Providing payment for these types of studies may also act as incentive for more people to get involved and volunteer to take part.⁸⁰ A researcher can also put forth the option of paying for any travel or medical fees associated with the study, as opposed to a general compensatory payment that goes directly to the child or their parents as a form of reward.

A strong objection to any sort of payment for research is that a reward of this type may negatively influence the motivation for participating in a study. This is true for all vulnerable populations, but there is a fear that a child may be coerced into the study if there is compensation provided to the parents, or if a child feels the need to provide for their low-income family with the monetary remuneration that the experiment provides.⁸¹ Another concern that researchers have with regard to compensation for children is how it will affect the validity of the collected data. It may be perceived that payment could cause a family to lie about their personal information or history to ensure that they are accepted into a trial, because they are in need of financial aid. This calls for better screening processes to ensure honesty, which would prevent invalid scientific data.⁸² A researcher would hope that a child and their parents could understand the goals of a study and that their decision to participate would be a sign of willingly donating their time for the common good. Perhaps the child and their parent might feel that the benefits outweigh any possible risks, so they would consent to joining the study, without payment. Some may even view partaking in research as a type of community service, and feel that a fee is unnecessary.⁸³

A final issue regarding compensation is whether the parents of child participants should be paid separately, aside from any travel or medical expenses. It can be argued that a parent may have to take time away from their job to bring the child in for research sessions, thereby

impacting a family's income. They may, therefore, call for extra payment. This argument should not stand, however, because a parent is not the one participating and providing data. If parents received monetary incentive, children could be enrolled in research solely for the benefit of their parents. It is acceptable for a study to cover transportation costs, but all rewards should go to the child. Children receiving some financial reward can be compared to a child having a part-time job or, in the case of younger children, doing chores and receiving an allowance. These arguments would allow research studies to provide participants with some sort of financial compensation at the end of a study.⁸⁴

A last vulnerable group to consider is embryos. An embryo is typically defined as “a human organism during the first 56 days of its development following fertilization or creation.”⁸⁵ Under this definition, embryos are not considered to be ‘humans’ and, therefore, would not be subject to the ‘Common Rule,’ or the rules for approving and overseeing human research in place in the US.⁸⁶ Some countries, such as Canada and the UK, have established laws and regulations about doing research with embryos and fetuses, often stating that embryos cannot be manipulated past the 14th day of development.⁸⁷ However, in the United States, no such distinction exists, although many researchers follow this unofficial international guideline. Vulnerability to embryos can be looked at in two ways: one where embryos should be protected from any research or creation outside of natural conception because of the inevitable destruction that happens in embryonic research, and the opposite view, where embryos are too protected and more inclusive oversight should be sought to further embryonic research. Religious considerations at the beginning of life, which correspond to the first stipulation will be explored below. The opposing view is informed by the current American law prohibiting any federal funds from being used for embryonic research or equipment used for it. It can be argued that

federal recognition of the need for embryonic research, particularly with stem cells, would provide benefit to the medical community and ensure appropriate involvement and oversight in clinical trials.⁸⁸

This is specifically important in the context of CRISPR-Cas9 technologies used in embryonic research. While currently there is a worldwide consensus that is not safe to use the editing tool in embryos and then implant them into a womb, it is possible.⁸⁹ If specific guidelines do not exist, some scientists may attempt to edit an embryo's genome and allow an edited child to be born. However, it is interesting to consider that even when regulations exist, some researchers may choose to ignore them. Dr. J. He in China violated Chinese research guidelines including properly obtained informed consent. This section outlined the importance of informed consent in research, especially with vulnerable populations, such as individuals with HIV, which the participant in Dr. He's research had. In his report, the consent form did not adequately explain the risks and used inappropriately complicated language. Furthermore, it is evident that he did not appropriately weigh the risks and benefits of the treatment, and there is suspicion of coercion of the parents.⁹⁰ Dr. He's process of scientific research clearly did not comply with the outlined perspectives explained here with regard to doing studies with vulnerable populations, and further illustrates the need for regulation in research.

B: Vulnerability at the Beginning and End of Life

The previous section explored how clinical research affects vulnerable patients. This part will specifically explore how vulnerability of fetuses at the beginning of life, and vulnerability at the end of life for children and adults, affect medical care that could reduce vulnerability factors through the use of the CRISPR/Cas9 technology or genetic therapies. Patients who are unable to speak for themselves, or who fall into easily-manipulated populations, are at risk for a lesser

quality of medical care, especially at the beginning and end of life. When a patient loses their capacity to provide informed consent or never even has the opportunity to do so, a substitute decision-maker is tasked with making decisions on the patient's behalf, complicating already difficult circumstances at the beginning or end of life. For example, new parents who are considering a termination of pregnancy, can only use their own values to guide decision-making, making their unborn child more vulnerable, who cannot express their own wishes. Conversely, an individual may have to make choices about end-of-life care for their parent during a time of heightened emotion or grief, which could impair decision-making, once again causing the dying patient to become more vulnerable. It is crucial to maintain as much autonomy as possible for the patient, whether at the beginning or end of life, and to implement safeguards to ensure the safety for those who are deemed vulnerable.

- i. Established religious beliefs about the beginning and end of life

Decision-making can be a difficult task for patients and substitute decision-makers (SDM) alike. When making decisions for children or neonates, parents, for example, must consider not only their own wishes, but those of their child as well. Two polarizing practices often cause a significant amount of stress for patients and SDMs: abortion and physician-assisted death (PAD). Decisions regarding either of these procedures would be considered more challenging than a common choice, such as whether to consent to surgery, and require both practical thought and moral consideration. Aside from medical facts, someone may turn to their religious beliefs for guidance when contemplating either of these courses of action. Two of the most-practiced religions, Islam and Catholicism, will be focused on, as they share similarities, but also exhibit significant differences. Before focusing on the specified topics, it is important to examine the main tenets of a religion regarding decision-making. Islam and Catholicism vary, but both

present important teachings and guidance that allow its followers to make choices in their ordinary lives

God influences all decision-making within the Islamic faith. His teachings through the Quran, as well as those of the Prophet Mohammad, through Hadith, indicate that all choices, actions, and decisions should be based on the criteria for what is good, and should not promote or cause evil. Since all decisions must, in theory, please God or abide by His teachings, it is clear that autonomy has a small role to play in the lives of Muslims. Although this may seem as though they lack the right to make decisions regarding their own body or their own lives, they have chosen to live a life that is dedicated to God and that will eventually lead to Him. Because God is almighty and good, an individual should also strive to live their life that way, which includes choosing options that are best for their family and their lives.⁹¹ This may differ depending on the school of Islam to which the individual belongs, as the Shia group allows for more autonomous thinking than the Sunni group does. There is some level of autonomy, but not in the same degree as Western society believes in and emphasizes. More detail will be given below.

The Sunni branch of Islam is more conservative than its counterparts. Sunnis rely on holy literature, such as the Quran, the Hadith, and other writings of the Prophet Mohammad when deciding whether an action or thought is good or bad.⁹² God indicates in the Quran to always do what is good, and the Sunnis have applied their insight from the literature to create laws that dictate what should and should not be done. Their reasoning for these distinctions is based solely upon the historic writings, and since there may not be direct answers to today's questions among them, it can be difficult to find solutions for contemporary problems. This leaves little room, for individual human reasoning, nor collective reasoning among the general public. Only those who

are theologically educated or physicians can provide some insight on bioethical inquiries.⁹³ It can be assumed that decision-making is practiced among scholars by discussing past events that may be similar, or examining scripture from the Quran that can be interpreted in a way that indicates what should be done.⁹⁴ Once the outcome is decided, the ‘no questions asked’ approach applies. While they believe they are doing what God is asking them to, the conclusion is based more upon the law, as opposed to ethics.⁹⁵

While the Shia group also value the Quran and the Hadith, they are more objective when it comes to ethical reasoning.⁹⁶ The Quran instructs the followers of Islam to always do good and avoid evil, but it never mentions specifically what good and evil consist of. It assumes that individual Muslims are able to distinguish between the two, and make the proper decision at the appropriate time. It relies on its followers to be educated and moral to ensure that they always follow the right path.⁹⁷ Human reasoning, in this case, is necessary for Shia Muslims to make decisions, especially ones pertaining to bioethics. Although there seems to be a greater degree of autonomy, in that individuals are making their own decisions, there is actually less of an emphasis on autonomous decision-making, as opposed to decisions that are ultimately influenced and reflective of God. The Quran says that humans do not have rights, but, rather, duties toward God.⁹⁸ As a result, an individual does not solely think about what choice is most beneficial for them, but focusses on what God will perceive to be the best choice in accordance to His teachings. Individuals have a larger role in coming to a conclusion about this, but they do ultimately use the same end reasoning as Sunnis do – what God has relayed through his teachings is what must be followed and sought.

It is clear that bioethical decisions within Islam require the approval of more than just one individual. Personal relationships, such as those with a spouse or a family, are important to

consider when making medical choices. For example, a husband and wife will have to make decisions and think about the impact on themselves, individually, and as members of a family.⁹⁹ Family is strongly valued within Islam, and it is considered to be a priority among Muslims to create a large family whose members are loving towards each other and dependent on each other, as well as united through their spiritual relationship to God. This is the only other relationship that an individual has apart with God, that ensures that their actions correspond to the good that God requires.

Furthermore, decisions are made with the community in mind. A patient or individual often has to consider what will be of benefit to the greater good, i.e., the Muslim community. Will a decision agree with one that a group of believers would make? Having a place within the Muslim community holds great importance, and being able to live among a faith-based community can be very rewarding and encouraging.¹⁰⁰ However, it can also be intimidating. If an individual feels that a medical decision they must make is personal, having to consider a community's opinion in addition to an autonomous one can be overwhelming. In theory, an individual's opinion should correspond to what God would have believed to be right, and, in turn, the collective should also share the same viewpoint about specific issues, as well as more general topics. This, obviously, can vary among individuals or religious sects, but the opinion and reaction of one's community, which can judge as well as praise, definitely weighs on individuals while making decisions.¹⁰¹

Unlike Islam, which references the Quran, the Hadith, and other teachings to make decisions and determine positions within the Muslim faith, Catholicism only refers to one Holy Scripture: the Bible. This text has influenced all of Christianity, but the Catholic Church recognizes it as the ultimate teaching of God's values.¹⁰² The Bible, unlike the Quran or Hadith,

however, is not often taken literally. It acts as a collection of stories that allow a reader to interpret them in order to gain guidance about an issue or a question. Bible stories can be compared to fables that teach you a lesson, rather than instruction guides that provide steps for the ‘right’ thing to do.¹⁰³ As a result, interpretations vary among both scholars and practicing Catholics. With regard to the topic of abortion, for example, the Bible does not directly explain that the termination of a pregnancy is wrong, but implies that it should be avoided.¹⁰⁴ In contrast, Islamic teaching does mention the prohibition of abortion, as well as the reasons that one should not choose termination, such as poverty or sex preference.¹⁰⁵

A significant difference between Islam and Catholicism as general religions is the system of leadership which is in place. Muslims do not have one authoritative figure to esteem, as there are various branches of Islam who follow different leaders.¹⁰⁶ Catholics all have one Pope, who represents their ultimate connection to God. He is responsible for sharing wisdom and knowledge about all topics related to faith.¹⁰⁷ Moreover, there is a further hierarchy of cardinals, bishops, priests, and clergy who are available to smaller groups of individual Catholics around the world, in order to provide them with a figure who is able to relay the teachings and messages from the Pope, and from God. All of these religious leaders are considered to have extensive knowledge of the Catholic faith, and of every position that the church takes regarding topics, such as abortion.¹⁰⁸

As a result of this system, whose ‘powerbase’ stems from just one person, the Catholic religion is able to draw universal conclusions about all topics related to the Bible and to the Catholic faith. There can be an official statement or position by which the entire Church is expected to abide, in order to ensure that all Catholics practice the same values.¹⁰⁹ The benefit of having one official position is that it unites the entirety of the Catholic following, and provides

little opportunity for debate that can lead to conflict, and potential harm. Although a position may be controversial, it is the duty of all official individuals within the Catholic Church to accept it and to pass it along to congregations.¹¹⁰ Furthermore, a universal conclusion is easier to implement within institutions, such as Catholic hospitals or schools. Streamlined Catholic teachings make this process simpler and, therefore, possible, which ensures that Catholic values are upheld in such environments.

Although having one universal position is beneficial, there must always be room for debate and progress among Church officials, as well as the general public. As science and technology evolve, ancient policies may have to be re-examined and adjusted in order to address new findings. For example, ancient scholars once believed that all sperm contained a human life, and its encounter with an egg was irrelevant. An ovum was simply an egg that fed the sperm to become a human fetus. After the microscope was developed, it was discovered that this was not, in fact, true, and genetic discoveries demonstrated that the egg did, indeed, serve a purpose in contributing to the DNA of the fetus, and it was not just a method of nutrition.¹¹¹ Abortion is also a controversial topic, and often divides groups of people into pro-life supporters, and others who are pro-choice. The Church is firmly pro-life, but there has been debate among bishops to consider some extraneous exceptions that would allow an abortion to be regarded as moral and, therefore, permissible, such as in the case of rape or incest. There is less debate surrounding physician-assisted death, as Catholicism strictly prohibits any version of PAD.

With respect to abortion in particular, the Bible does not directly mention it nor does it discuss the termination of a pregnancy. It does, however, discuss the beginning of human life, as well as the responsibilities of Catholics with regard to killing and murder of innocent lives.¹¹² One can use citations dealing with these topics, as well as other verses to determine that a fetus is

an innocent life, and that ending its life would be a sin. It is clear that the Bible bestows rights upon the fetus, and hopes that the followers of God and Christ are able to interpret the stories in a way that leads to the conclusion that killing is prohibited, and, therefore, the killing of a fetus (which is how abortion is perceived) is a sin. This also supports the prohibition of physician-assisted death, since it is seen as a form of killing. All of the conclusions about the topic of abortion, however, require thought and analysis to ensure that a decision reflects the values and the teachings of God. This process of reasoning, while it can be done by a lay Catholic, is often left to religious leaders, who can influence not only an entire congregation, but the entire religion.

It is clear in both Islam and Catholicism that physician-assisted death is prohibited. The concept of physician-assisted death and its forms will be explored below, but it is considered to be either a form of suicide or a form of killing, making it unacceptable from a religious perspective. Death in the Islamic faith signifies leaving this life and moving onto another, in which you come to be judged by God and go to heaven. Scholars outline four stages of life: inside the mother's womb, the life we live as humans, limbo, and the afterlife.¹¹³ With this in mind, dying is not seen as a negative occurrence, but one that will bring a Muslim closer to God. God also determines when a person is born, the duration of their life on Earth, and when they will die.¹¹⁴ By intervening in this process through suicide, for example, one is deemed to have sinned. If suicide is unacceptable, many also believe that physician-assisted death is not permissible, as it interferes with God's ultimate plan for each human being.¹¹⁵ Even if an individual is suffering, it is unacceptable to hasten death in the manner of providing lethal medication. A case can be made for withdrawing or withholding treatment, since these actions are not hastening death, but simply allowing death to occur naturally.¹¹⁶

From a Catholic perspective, most theologians believe these procedures can never be acceptable, but there are some who feel PAD may be permissible in certain circumstances. A common theme in these discussions is martyrdom. A martyr would rather feel pain and preserve their integrity and faith, than give up and ask to die or kill themselves, because they could not handle the suffering that God intended them to experience.¹¹⁷ In addition, some believe that if an individual is already dying, the process cannot be reversed and PAD should be permissible in order to relieve them of any suffering.¹¹⁸ Those who believe that physician-assisted death is morally right agree on the need for safeguards and well-defined policy for practice in real life. There are numerous ways that these procedures could be used for evil purposes, but with proper control, PAD could also be beneficial.¹¹⁹

However, overall forms of physician-assisted death are strongly condemned. PAD through a physician providing a lethal injection is regarded as killing, even if a patient asks for it, and is, therefore, never morally permissible. Suicide is also considered a form of and choosing to kill oneself violates God's plan for humans, and disrespects the idea that God is the only one who should decide when an individual dies. The concept also goes against the belief that human life is eternally sacred and has immense value.¹²⁰ Catholic believers typically prefer to focus to improved pain management or palliative care in order to relieve a patient of their suffering.¹²¹ Suffering, however, is also thought to be an integral part of the human life.¹²²

These are clear religion-based positions, but one aspect that is frequently debated is whether involvement in forms of physician-assisted death is in any way permitted. For example, in Canada, specifically in Ontario, PAD (known as Medical Assistance in Dying or MAID) requires physicians, nurse practitioners, pharmacists, and any other health care providers who are approached about MAID to make an effective referral to another provider if they choose to

conscientiously object to being involved, as directed by their professional colleges.¹²³ This ensures that patients seeking MAID, who are typically quite vulnerable due to their conditions, are not abandoned or prohibited from accessing legal health care services. Among Catholic physicians, there is a concern that even making that referral is tantamount to being involved in the process of MAID, and, therefore, an immoral act.¹²⁴ It could also be argued that the autonomy of Catholic (or other religious-oriented) health care providers is at risk because they are feeling pressured to participate in acts that they deem to be against their personal values. These moral dilemmas could result in significant harm to vulnerable patients who are at the end of life, by preventing them from accessing a service that could greatly relieve their suffering, which is how the Ontario court system has approached the issue.¹²⁵ In a country, such as Canada, in which public health care is funded by the government, it should be required for physicians to make an effective referral to ensure that patients are treated fairly and not judged for their own choices.

The debate around abortion is more robust and controversial, especially in the context of religion. An embryo or a fetus is considered to be at the beginning of its life, if it is considered to be a person, and abortion could bring it to the end of its life according to that thought process. It is clear that within both Islam and Catholicism, personhood and ensoulment are the deciding factor for when life begins. These concepts are applied by these religions to determine the permissibility of abortion. Another factor may also play a role; the law in the country in which an individual is living, which affects the health care services that are available and safe. While a woman or couple will turn to their faith to make a choice, they may also be influenced by legal information to determine an ultimate plan.

Muslims believe that God has given them a pre-determined path to follow, which will eventually lead to paradise in the afterlife if they pursue a good life. It is the duty of the followers of Islam not to interfere with this plan by actively trying to control the time they die, such as with the use of PAD explained above, or the time a baby is born.¹²⁶ With this in mind, Islam has designated certain regulations about end-of-life actions such as suicide or withdrawing end of life support, as both of these choices hasten the time of death for an individual, thereby tampering with God's plan.¹²⁷ If both of these are prohibited, where does abortion fit when determining its permissibility? The termination of a pregnancy after one is determined to have personhood is considered to be directly interfering with God's blueprint in ending a life that has a determined path. Therefore, one would assume that abortion is prohibited, just as suicide would be. By aborting a fetus, one is actively choosing its time of death, which is a right that no Muslim or individual is considered to have.

The justification that a human being may not be killed needs additional clarification about what it truly means to be a human being, from a Catholic perspective. The Church agrees that a human being must have a soul and a body, and the two working together constitute a whole person.¹²⁸ Similar to the Muslim belief that God has a pre-determined plan for all individuals, Catholics believe that each person has a pre-destination that ultimately leads to salvation. Within this time period, each human has the freedom and capacity for transcendence so denying this fact or interfering with it through murder or, more specifically, abortion, constitutes doing harm. Moreover, the sanctity of life is integral to keep in mind when discussing termination of pregnancy, because the concept places value on each individual human life, and upholds a person's dignity, destiny, and integrity.¹²⁹ These determinations hold true for every

being that is considered a person, and since fetuses are considered to be human beings, they also have a right to live the pre-determined life that God has gifted to them.

It is clear that in both Catholicism and Islam, life is believed to begin at ensoulment, which happens while inside the womb. Islamic faith teaches that personhood is granted to a fetus at a time when an angel breathes a spirit or soul into their body, making them eligible to be resurrected into the afterlife.¹³⁰ Moreover, the fetus is considered to be a human being entitled to human rights. God's plan for an individual begins at ensoulment, and, as previously mentioned, has a pre-determined path, as well as a planned death in the future. By this definition, after ensoulment takes place, it is prohibited to end the life of a fetus, just as it is to murder of a living human. Although there are circumstances where abortion of a fetus after ensoulment can be justified, it is commonly agreed upon that after a fetus gains the status of a human being, intentional termination of that pregnancy is prohibited.¹³¹ Even though most scholars agree that after ensoulment a baby cannot be aborted, there is significant disagreement about the actual time of ensoulment. A verse in the Quran implies that there are three stages of development, each lasting forty days: a formation of a drop, which next becomes a blood clot and finally a lump of flesh.¹³² This has led some scholars to believe that ensoulment occurs after these developmental stages, at 120 days.¹³³ Therefore, an abortion that occurs before 120 days after conception is permitted since the fetus is not considered a human before that time. However, there are other scholars who believe that ensoulment actually happens at 40 days, and so abortion would only be permissible between conception and the projected time of ensoulment.¹³⁴

In contrast, Catholics do not have the luxury of ancient texts explaining when ensoulment takes place, and it has become difficult to use the argument of pre-ensoulment abortion as a justification of the act. Thomas Aquinas was an early proponent in the discussion about

ensoulment, as he argued that a human being did not have a human soul nor was considered a person until they had a functioning human body. This means that a fetus has to go through other soul stages before gaining a human soul.¹³⁵ However, his theory did not withstand time, and the Catholic Church has decided that there is no way of truly knowing when a fetus gains a soul. As a result of uncertainty and great disagreement, they chose to believe that an easier and more universal agreement was that ensoulment happens at conception, and the destruction of an embryo or fetus after this time was a harmful act on a human being.¹³⁶

Islam also outlines an additional protection of personhood when a parent wishes to terminate a pregnancy for ‘selfish’ reasons, such as economic hardships or the preference of a particular sex. These examples demonstrate how the value of a soul must take precedence over the wishes of the parents. The Muslim teachings firmly explain through verses in the Quran that these fetuses have souls and a pre-determined path, and, therefore, are not permitted to be aborted. In the example about poverty, the Quran states: “Slay not your children for fear of poverty; we will provide for you and them. Surely the slaying of them is a grievous sin.” (Quran 81:8) This directly implies that aborting a child due to the fear of not being able to economically support it is prohibited.¹³⁷ Another reason why abortions may be considered by parents or guardians, both within Islam and other cultures, is because of dissatisfaction with the sex of the unborn baby. Sons are typically valued more than daughters, and there have been accounts of the practice of burying female infants alive. The Quran also states that neither these extreme practices nor abortions are permitted because daughters and sons should be welcomed equally.¹³⁸

While a woman or couple may deem an abortion permissible for a specific reason, they may be impeded by a pre-determined law of their country of residence. Some countries have a state religion, which influences all legislation and policy. For example, Iran is governed by *Shia*

law and is the only Muslim country that follows the Shia school of Islam.¹³⁹ Their abortion laws, along with all other legislation, is directly associated with the Islamic belief system. In Iran, the heads of state all must be religiously educated to ensure that Islam is represented in government. As a result of these qualifications, they, as well as the Supreme Leader of Iran, are able to issue advice, or *fatawa*, that act as a type of law guided by faith, that can deem a practice, such as abortion, permissible.¹⁴⁰ Iran's laws currently allow abortion before the time of ensoulment, 120 days after conception, for reasons associated with the mother's health or the fetus' health. This includes physical malformations such as Osteogenesis Imperfecta or anencephaly, as well as genetic disorders such as Trisomy 16 or 18. However, all abortions must be approved by a specific number of physicians to ensure that the health of either the mother or fetus is the reason for the termination.¹⁴¹ Any abortions that take place after the time of ensoulment and before viability of the infant must be as a result of direct harm to the mother; otherwise they are prohibited and punishable by law.¹⁴² In Iran, even if an abortion is requested by an individual who deems it permissible for themselves, they are locked into a belief system that is governed by Islamic teachings.

This differs, however, in countries that do not have an official state religion, but that have a large population of individuals who are of a certain faith. Turkey, for example, is a secular country, but 99.8% of its citizens are Muslims.¹⁴³ This indicates that while the law is not supposed to be associated with a particular religion, the citizens of the country who practice a specific faith will follow the law or take advantage of its neutrality only if it coincides with their beliefs. Abortion in Turkey, while not generally encouraged, is more readily available and safer to attain than in other predominantly Muslim countries. Legally, women in Turkey are able to terminate their pregnancy under any circumstances in the first trimester, and can opt to have an

abortion at a later time in the case of a maternal-fetal conflict.¹⁴⁴ This governmental position may influence an Islamic woman to make a decision for herself about whether she wishes to terminate her pregnancy. While her faith may not allow it (for a selfish reason, for example), she has the means to attain an abortion and her individual viewpoint may be influenced by the secular law.

Catholic law varies from Islam, as the strict Catholic position on abortion is that no fetal life should ever directly be terminated. Since the Catholic view is that life begins at conception, there is no room for an abortion to happen before ensoulment, which is the case in Islamic belief. Costa Rica, for example, recognizes the state religion as Roman Catholic, but has laws that allow an abortion to take place in the event of a serious threat to a mother's life.¹⁴⁵ It is assumed that a country, whose official state religion is Catholicism, provides their citizens with adequate medical care, but direct abortion is not permitted under any circumstances within the country.

Similarly to Turkey, which is a secular country with a predominantly Muslim population, other Latin American countries have a predominantly Catholic population, but their laws are not indicative of the religion. Historically, countries, such as Mexico and Colombia, implemented laws that prohibited abortions.¹⁴⁶ In more recent years, these laws have changed, and abortions under certain circumstances have been legalized. However, even though termination of pregnancy may be legal, there is still concern among the citizens of the country who are practicing Catholics, and their opinion diverges from the state law. In 2014, a survey in Mexico was completed which gathered information about the opinions of Catholics on the stigma associated with abortion.¹⁴⁷ While a woman may have legal access to the procedure, she may feel shamed by her community for doing something that is deemed intrinsically evil, bringing about a level of vulnerability that may be harmful. Although some individuals felt that a woman who had previously had an abortion could still be a 'Good Catholic,' others believed that she should not

have sought the termination in the first place.¹⁴⁸ This stigma may directly influence a woman's decision to have an abortion, and is an example of how the laws may influence a community, as well as an individual.

In a secular country, such as the United States, which has numerous religions being practiced within its borders, there is an importance placed on the separation between church and state. All US citizens have an equal right to attain adequate healthcare, as well as the right to practice their own religion. There is little Islamic influence on American healthcare, as there are not entire systems, like Catholic ones, that control hospitals and healthcare facilities. Furthermore, Muslim women may not be as influenced by their community when deciding if they wish to terminate a pregnancy, since the population of the US is not predominantly Muslim, unlike a country like Turkey.¹⁴⁹ A woman may feel more comfortable pursuing her own wishes and would not be influenced by the people around her, even though it may contrast with her faith.

Despite the separation of church and state in the United States, Catholicism plays a dominant role in American healthcare, as more than 600 hospitals and 1400 long-term care facilities function under a Catholic identity.¹⁵⁰ In these institutions, Catholic doctrine is followed strictly and there is little room for digression, especially when discussing a topic like abortion.¹⁵¹ Debate, however, does arise in emergency situations and when a case is presented that could have multiple interpretations. A case in Phoenix, AZ caused controversy, because a direct abortion was performed in a Catholic hospital in order to save a mother's life. The hospital was stripped of its Catholic standing, because the Bishop of their area believed that the abortion was not warranted. Other bishops, however, disagreed and felt that the course of action was justifiable.¹⁵² In situations such as these, the Catholic faith is directly influencing the lives of

patients, and there may be situations in which an abortion is not permitted causing a woman to die as a result.¹⁵³ Although Catholic hospitals will remain a part of the American healthcare system, it is worth acknowledging that some patients who are not Catholic could be harmed by their care, as all patients treated within the institution must abide by Catholic teaching. Patients who are not Catholic, but who receive care at a Catholic facility should be aware of their possible vulnerability and the potential that their autonomous wishes will not be followed.

Although abortion is generally discouraged within Islam and Catholicism, there are some situations that allow a pregnancy to be terminated. Maternal-fetal conflicts are the most common, as it is important to try and save the life of the mother in the case of direct harm from her fetus. Furthermore, fetal physical abnormalities or genetic diseases may strongly impact the quality of life for a child, and an argument could be made to terminate the pregnancy. Lastly, rape and incest have provided a legitimate reason for abortion.

Within Islam, abortion is permitted if it is necessary to save the life of the mother carrying the baby. Abortion is allowed, in this circumstance, at any time, both before and after ensoulment. There must be an urgent threat to a mother's life to terminate a pregnancy; only when the pregnancy itself is causing serious harm to a mother can it be aborted.¹⁵⁴ Usually, if there is some kind of maternal-fetal conflict, both lives will try to be saved, but a mother can instruct doctors that if only one life can be saved, it can be her own. In addition, if a baby is viable and a mother is in distress, the goal may be to deliver the baby instead of aborting it, which could potentially save both lives. The justification for allowing a termination of pregnancy in this case is that a mother's life is more valuable than the potential life of the fetus, and so her rights to life are more important than a fetus' rights, thereby making her more of a priority.¹⁵⁵ Furthermore, if a mother is not being seriously harmed in emergency situations, there are

circumstances that are acceptable for having an abortion before the time of ensoulment, as a preventative measure. This reason is legally acceptable in Iran, and is one of the only methods in which an abortion is permissible in the Muslim country. For example, if a woman has known cardiac problems, neurodegenerative diseases, such as Multiple Sclerosis, or types of cancers.¹⁵⁶

Catholicism never allows the direct and intended termination of a pregnancy, even to save a mother. However, a procedure may be permitted if its main purpose is to help a mother, and an abortion happens indirectly. The Principle of Double Effect (PDE) is applied to these situations. A common example that involves PDE is the case of an abortion during an ectopic pregnancy. A woman may become pregnant and carry a fetus in her fallopian tubes, which is problematic. It is permissible, however, to remove the fallopian tube that contains a fetus only because not doing so would seriously harm the mother. This is an indirect abortion, and is permitted, because the intended effect is to protect the mother's health, and not to kill the fetus.¹⁵⁷ The intention has nothing to do with the fetus, and is only concerned with saving the life of a living human being. The Principle of Double Effect is used in most cases of maternal-fetal conflict in Catholic teaching, but does not appear to be a guiding principle for Islamic physicians or patients. There is no explicit concept, such as PDE, that is used as a justification for acts that may seem immoral. Within Islam, there is less room for interpretation of depicted morals from spiritual teachings, while there is more debate about what is considered right and wrong.¹⁵⁸

This same idea extends to the justification of an abortion for the mental sake of a woman. A female may feel that psychologically, a pregnancy could be detrimental, and would prefer to terminate the pregnancy. While this may be legal in the United States, depending on the gestation of the pregnancy, it is not permissible in the eyes of the Catholic Church. Catholicism teaches that no direct abortions are permissible, and a mother does not take precedence over a

fetus, as it has the same rights. Therefore, a mother, even if she is mentally incapable of dealing with a pregnancy, or is in mental distress, must find a way to have courage and compassion and realize the importance of carrying a baby to term.¹⁵⁹ While adoption is an option for mothers who do not wish to keep their baby, it is impermissible to terminate a pregnancy just because a woman does not think she can handle the stress of pregnancy.¹⁶⁰

A situation in which abortion may be accepted within Islam is in cases of rape or incest. One important factor to consider is the emphasis Islam puts on lineage and on the maintenance of a particular genealogy. Historically, as in many other cultures and religions, a family was considered blessed to have a son who would continue their family's lineage and ensure their family legacy.¹⁶¹ If a mother is raped, her child may not ever know their biological father, and, therefore, never be able to recognize their proper lineage, leading to a lack of inheritance.¹⁶² This may cause the child emotional and psychological distress as a result of being ostracized by a community and, consequently, abused and shunned.¹⁶³ Furthermore, the psychological distress to a mother caused by an incestuous pregnancy is considered to be enough justification for an abortion.¹⁶⁴

Within Catholicism, direct abortion is starting to be considered acceptable in cases of rape or incest as well. There are a growing number of proponents of this idea, in that they believe that women who suffer from pregnancies as a result of rape or incest should not be subjected to the distress of carrying a pregnancy to term and be reminded of a tragic event.¹⁶⁵ For example, in Brazil, a bishop condemned another bishop for prohibiting a 9-year old girl from receiving an abortion for twins that were a result of rape. The child was raped from the age of 6, and was clearly in distress. The Bishop who prevented the abortion stated that the twins were fine and could be carried to term, and then put up for adoption. He did not believe that the severity of the

situation called for going against Catholic morals. Other bishops disagreed in this situation, as they believed the girl did not deserve to suffer further, and that a girl of that age should not have to be pregnant, let alone as a result of rape.¹⁶⁶ The increase of extreme cases like this may result in a re-evaluation of the abortion policy, but there is a general fear that more exceptions will lead to a slippery slope that will eventually result in all abortions being permissible.

In addition to cases of rape, some Islamic countries allow an abortion as a result of genetic diseases associated with consanguineous marriages and procreation. More than 50% of marriages are consanguineous in Saudi Arabia, for example, which has caused its government to issue a policy or *fatwa* allowing couples to consider abortion for a genetic condition. Often it is unknown that this policy exists, allowing couples to seek an abortion for this specific reason, and education is encouraged before marriage to ensure that couples are aware of their risks and options.¹⁶⁷

While it is important to consider the mother when discussing abortion, it is equally as critical to consider a fetus' wellbeing as a reason to terminate a pregnancy. An individual or couple may discover that their unborn child has a physical deformity or genetic disease that could seriously impact their quality of life and abortion is one option that may be available to them.¹⁶⁸ Depending on the severity of the discovered condition, a parent may decide that terminating the pregnancy would be more beneficial, as it would eliminate the suffering of the infant in-utero or after birth. Furthermore, some parents may feel that coping with the death of their malformed child shortly after birth would be more difficult than having an abortion. Islam is more accepting of an abortion (before 120 days of pregnancy) as a result of a physical abnormality or genetic condition that is incompatible with life.¹⁶⁹ Catholicism, however, does not believe that abortion is permitted under any circumstances having to do with the fetus' health.¹⁷⁰

Within Islam, a couple is commonly able to terminate their pregnancy for medical reasons, such as a severe genetic disorder, by fulfilling three conditions: three experts (physicians, geneticists, etc.) in that field must confirm a diagnosis, the diagnosis and termination must be done before the 120th day of pregnancy, and the request for termination must come from both parents. These conditions may vary depending on the laws that are enacted in individual countries. An example of a disease that can be detected before the 120th day of pregnancy is Spinal Muscular Atrophy (SMA). There are two types of SMA, one that is compatible with life, and one that causes infants to die within two years of life. Parents may feel that aborting a child who is known to have SMA would be a better option for them, and a better option for the fetus. Genetic testing must be administered which can determine whether the lethal type of SMA is present in the fetus.¹⁷¹ Nevertheless, this practice has been difficult for Muslim scholars, because Islam teaches that God has a specific plan for each individual and it must be accepted, no matter how great the hardships may be. Therefore, aborting a baby because it may have a difficult life directly interferes with the challenges that God intended for the child to have.¹⁷² However, Muslim scholars have accepted certain genetic diseases to be sufficient grounds to terminate a pregnancy, such as Down syndrome or Tay-Sachs disease.¹⁷³

While abortion is not permitted under the Catholic doctrine for the reason of genetic disorders of physical deformities, laws may be enacted in predominantly Catholic countries that allow the termination of certain fetuses. For example, Brazil legalized abortion in cases of anencephaly, where a baby's cerebral hemispheres fail to develop, causing the brain stem to be exposed. Some cases of anencephaly are not compatible with life, and infants only live a very short time after birth. If approached in this manner, an anencephalic fetus is not, in fact, a potential life, as they would not live more than a few hours.¹⁷⁴ The argument that a mother

should not have to see her child suffer after birth was another justification that the Brazilian courts used when enacting this law.¹⁷⁵ However, the Catholic church does not condone this practice, as they feel that every fetus, regardless of deformities or physical problems, deserves the right to live and its life should not be terminated. Each life has an equal right to dignity, and it is considered to be morally wrong to end an innocent life.

ii. Uses of genetic therapies and editing techniques to maintain autonomy

Religion clearly dictates many decisions with regard to the beginning and end of life, which may put various parties at risk of becoming vulnerable. The uses of abortion or physician-assisted death frequently aim to alleviate some type of suffering, but are prohibited in this context. Religion is not the only factor that makes people vulnerable when considering PAD or abortion, and the use of CRISPR/Cas9 or other genetic therapies may be able to provide benefit to these vulnerable patients who would rather not explore these options for their own personal reasons. It is important to think about both reproduction and PAD from a general point of view, in order to understand how genetic therapies and editing techniques can be useful.

It was established in a previous chapter that humans have the right to healthcare, but it should also be assumed that humans have the right to reproduce. These two rights are directly related as one relies on the other for success. It is necessary for women to have access to appropriate healthcare for a safe pregnancy, as well as other services such as abortion clinics. Reproductive rights are equally as important, and women and men should be able to access reproductive resources within a healthcare setting.

The United Nations, as well as the Universal Declaration of Human Rights affirms that humans have the right to reproduce.¹⁷⁶ They have a right to start a family and have children.¹⁷⁷ These statements give all individuals the autonomy to make a choice that is in accordance to

their wishes to procreate at their own leisure. All subsequent resources, including healthcare services, are expected to be provided. It should be noted that the right to have children is not synonymous with the right to reproductive health services, which focus primarily on abortion or contraception, for example, but include the required services for a safe pregnancy.¹⁷⁸ While there is a right to have children, there is also a right to choose not to have children; there is a basic right to decide what option is best for oneself. As a human right, procreation can be considered a potential part of life for all, which implies that infertility is a disability and deserves to be addressed and alleviated.¹⁷⁹ By this definition, any measure that makes it possible for an individual to start a family should be acceptable. However, while the WHO recognizes that although it is a human right to bear children, it is not a human right to have unlimited access to a treatment, such as In Vitro Fertilization (IVF), as it is only a method to circumvent infertility, and not a definite cure.¹⁸⁰ Nevertheless, IVF may be the only suitable treatment that is available for infertile individuals who wish to fulfill their right to start or expand a family.

It is evident that legal restrictions can influence an individual's choice to have a child, or multiple children, but another influence can come from one's religion. Two of the world's most prominent faiths are Catholicism and Islam, and these two belief systems both place immense importance on procreating and having a family. In Islam, a large family is strongly valued, and its members are seen to be united not only by birth, but also through their spiritual relationship to God. This religious relationship is the only other relationship that an individual has, to ensure that their actions correspond to what God has willed.¹⁸¹ Similarly, Catholics believe that God promotes having children and procreating fruitfully. It should always be a goal of a married couple to bring children into the world, and any type of procedure that would prohibit this, including abortion and sterilization, is not allowed.¹⁸²

That being said, both religions may have influence over the laws of a country. For example, countries whose laws are directly associated with Islamic law, such as Saudi Arabia, have forbidden all contraceptive means to its citizens. Saudi Arabia promotes reproduction, and feels that providing resources and information about contraception would decrease the number of Muslims living in the country, which would be harmful to their society.¹⁸³ This ban on a healthcare service would directly affect a couple's decision to have children. They would see no other option, but to procreate.

Since a human being has a right to reproduce, it is assumed and often repeated that a complimentary entitlement is the universal right to reproductive services. This includes information and resources pertaining to contraception, abortion, and family planning, in addition to support during a pregnancy.¹⁸⁴ All of these services are considered to be a part of basic healthcare, and should be included in a human's universal right to healthcare. These services ensure that the human right to procreate is upheld, but also that a woman's right to choose is respected and supported through medical necessities. Reproductive services can also include technologies and treatments that aid with infertility, as well as complications associated with unsafe abortions or diseases that hinder reproduction, such as sexually transmitted infections (STIs) or reproductive tract infections (RTIs).¹⁸⁵ The ability for an individual to access these services, as well as a state's ability to provide them is affected by resources and funding, exactly like other healthcare services, but may be influenced by religious or moral opinions of society or government. For example, if abortion is considered immoral, it may not be readily available for all women in a strongly pro-life country, as was described above.

It is hoped that countries enact legislation that guarantees reproductive services to women and men and recognizes such access to be a human right. While this may be more common in

developed countries, such as Canada or the UK, it may not be possible in developing countries. Africa, however, has enacted a charter for women's rights, which details the services to which all women should have access in order to respect and promote their right to healthcare.¹⁸⁶ At a first glance, the legislation is a significant step in the right direction, especially since the rate of STIs and RTIs is extremely high in some African countries. However, when researched to see if countries are following and promoting this legislation, it becomes evident that laws are not implemented to their full capacity. For example, some African countries acknowledge that this law exists, which gives women access to contraception, treatment for infections, and safe abortion methods, but these services and treatments are not actually made available to women. Some states may require multiple signatures and committee approval before a woman is permitted to have an abortion. This was noted by the committee that enacted the charter, and states are required to remove any restrictions that are in place for reproductive services.¹⁸⁷ Examples such as the charter in Africa should motivate other countries with limited resources to recognize that women and men have the right to reproductive health, and while it may not be the most ideal solution, enacting laws that attempt to regulate and provide these services would be beneficial.

In addition to providing reproductive services that focus on the health of the woman and man, the issue of infertility merits being addressed. Infertility is a common problem globally, and many women in developing countries suffer from either primary infertility (not being able to reproduce at all), or secondary infertility (not being able to get pregnant again after one prior pregnancy).¹⁸⁸ Humans have the right to reproduce, and there are healthcare measures, such as assisted reproduction technologies, that would allow infertile couples to have children. For this reason, it may be useful for countries to consider an option, such as IVF to combat high rates of

infertility in their nation. In Vitro Fertilization was created for the purpose of aiding women whose fallopian tubes were damaged resulting in the inability to become pregnant naturally. This implies that it was created to help those whose human right to reproduce was impeded. The main issue standing in the way of more exposure and access to IVF is the cost of facilities, the procedure itself, and trained staff.¹⁸⁹ For this reason, many developing countries do not have many IVF clinics, resulting in low access for infertile women around the globe.

Access to IVF would need to be considered, especially in the countries who have strict opinions about abortion. IVF may actually help to reduce the number of abortions that occur. Assisted reproduction, such as genetic screening of embryos (PGD), as well as genetic enhancement may eliminate genetic diseases which may be the reason that some individuals seek to terminate a pregnancy. These may be solutions that compensate for the reasons that an individual may seek an abortion, and, particularly in the case of religions that prohibit termination. It may be of value to reconsider both assisted reproductive technologies so that abortion rates decrease.

One way to combat fatal genetic diseases in infancy is to use In-Vitro Fertilization, and subsequently, Pre-Implantation Genetic Diagnosis, to ensure that an embryo's genetic makeup does not include a genetic anomaly that is incompatible with life.¹⁹⁰ Pre-implantation genetic diagnosis is a technique used to examine an embryo's genome - to identify if an embryo carries a gene for a particular disease.¹⁹¹ Often parents who have an autosomal recessive or X-linked disorder or a familial history of one, may want to ensure that their future child is not faced with the same disease. Mothers over the age of 35 have the same concerns, and also want to make sure that a healthy child is born.¹⁹² After fertilization outside of the body, there are methods to extract one or a few cells and examine the genetic make-up of the embryo. If an embryo is

shown not to contain a gene that codes for a specific illness, it will be implanted into the mother, with the certainty that the child will not have the disease.¹⁹³ In the future, the use of CRISPR/Cas9 could also be used to manipulate and edit the genome of an embryo, further eliminating a specific disease.

In order to determine the permissibility and opinions of PGD from the viewpoints of Islam and Catholicism, the procedure of IVF itself must be examined, as it causes some controversy among religious scholars. Part of the process of IVF is the creation of embryos in vitro, and the subsequent freezing of extra embryos. There has been a debate within Islam about whether destroying frozen embryos is considered abortion. Some scholars believe that those embryos, since they were created outside of the womb, never reached the point of ensoulment, and cannot, therefore, be considered equal to a human life. They are simply potential human lives and it is permitted for them to be destroyed or donated to scientific research.¹⁹⁴ Other scholars feel that those embryos have human status and they should only ever be implanted into their mother's womb, and cannot be destroyed, because it would carry the same weight as killing an established soul.¹⁹⁵

The Catholic Church considers the process of In-Vitro Fertilization completely unacceptable, as it defies natural law and eliminates the traditional act of a man and a woman procreating. Furthermore, it creates the possibility of having to destroy an embryo.¹⁹⁶ Even though an embryo would be created in the same method, albeit artificially, Catholic teachings place emphasis on the sacred act of intercourse between husband and wife; the physical integrity of the act is the most important in this situation, making IVF irrelevant.¹⁹⁷ As a result of condemning IVF, the Catholic Church automatically must refuse to condone PGD, as embryos are necessary for the procedure. Furthermore, based on the Catholic teaching that life begins at

conception, the idea of destroying or disposing of embryos after PGD, which is often done, is unacceptable. Destroying an embryo would be equivalent to killing a life that has equal value to that of an adult, making it an immoral and impermissible act.¹⁹⁸

As mentioned above, the Catholic position on IVF reflects the negative stance that the Church would have on Pre-Implantation Genetic Diagnosis, simply because it requires manipulating embryos outside of the womb. Although there is evidence that the Catholic Church supports gene therapies that may modify a genome to resist cancer, for example, there is little proof that this support extends to reproductive genetic therapies.¹⁹⁹

In Islam, IVF can be accepted, and is encouraged for couples who experience problems with fertility. Issues arise, however, when discussing the manipulation of an embryo's genome. Aborting a fetus due to a pre-disposed anomaly that may not be life-threatening is not permitted, as it defies God's intended plan for each human soul. It would interfere with that plan if the fetus was aborted.²⁰⁰ Therefore, using a technique such as Pre-Implantation Genetic Diagnosis, which eliminates the possibility of a debilitating disease, may be permitted.²⁰¹ Islam teaches that physicians and the medical community were given their expertise by God and that Muslims have a responsibility to improve their health if possible. Any improvements to the quality of life of a Muslim is not only encouraged, but required, which may be an argument for genetic research with regard to disease.²⁰² There is some belief, however, that using PGD interferes with God's plans, as it gives parents the power to determine the type of life their child may live.²⁰³ Anxieties do arise when predictions are made for the future of genetic enhancement, where scientists may be able to create an embryo's genome and include modifications that are not medically relevant, such as height, athletic ability, or intelligence. This enhancement would be directly prohibited, as

it changes that which God has created. This, however, is not a typical reason for an individual to choose to abort a child.²⁰⁴

Conversely, when thinking about people at the end of life, many can be considered vulnerable, especially those with debilitating diseases. In Western society, the attitude towards death and dying is changing.²⁰⁵ Some American states as well as European countries are recognizing that individuals wish to choose how and when they die, so euthanasia and physician-assisted suicide, or collectively known as physician-assisted death, are becoming accepted legalized practices.²⁰⁶ For the most part, capable adults are being given this option, but vulnerable populations, such as children and those with dementia are being neglected. Although it is often safer to exclude these groups from legislation, they should still be considered with respect to assistance in dying.

Currently, eleven countries allow for forms of physician-assisted death. All but four allow a physician to administer a lethal dose of medication directly to the patient, or patients can choose to administer the medications on their own. In the US, nine states have physician-assisted suicide laws allowing that specific practice to take place.²⁰⁷ It is unclear why the United States have opted to discuss only PAS, as opposed to also considering euthanasia, since many scholars and societies argue that the two practices, while not identical, have the same implications. Perhaps America will follow the example of its neighbor, Canada, which has legalized both practices federally, and consider adding euthanasia in some states, or possibly nationally in the future.²⁰⁸ Currently, many of the countries and all of the states in the US require that a patient have a terminal or debilitating illness in order to be eligible for PAD. Often these patients are suffering from diseases, such as cancer or ALS, making them vulnerable to the health care system as treatments are either non-existent or debilitating themselves.

It should also be recognized that a physician has a duty to ensure that their patient is capable and informed about all of their options, including palliative care.²⁰⁹ Some scholars tend to argue that if PAD is legalized in a country or state, the quality and accessibility of palliative care will decrease, making dying the preferred option of patients.²¹⁰ Furthermore, it is thought that patients may opt for PAD because they do not understand the goals and abilities of palliative care and its benefits, as well as any other treatments that are currently available. Genetic therapies aimed at curing some types of cancer may be available in the future, and all physicians who are treating patients with a terminal illness who are requesting PAD should be well-versed in both available palliative care options and their purposes, and genetic therapies that have been approved. They should also be able to determine which practice may be better suited to meet the patient's goals and values. If a doctor is unable to accurately describe palliative care, there is a possibility that a patient is not making a truly informed decision regarding end of life care.²¹¹ However, a physician should be careful not to pressure a patient to choose palliative care over PAD. They have a duty to outline all available options and their expected harms and benefits, and to aid the patient in making an autonomous choice free of any pressure or coercion. This also extends to the future when genetic therapies will be an option for such patients. While their disease may be cured, it may be too difficult or expensive to attain these therapies or they may not be available where a patient lives, and patients should still have all of their options, including PAD, explained to them so that they can make an informed and autonomous choice.

Since most legislation pertaining to PAD insists that individuals must be 18 years of age to request the service, children below the age of 18 are ineligible and not considered. The only countries which allow children to have access to euthanasia or physician-assisted suicide are Belgium, in which no age requirement exists, and the Netherlands, which stipulates that children

must be over the age of 12.²¹² However, the Netherlands also follow the Groningen protocol, which allows neonates to be euthanized if they have a terminal disease and are suffering unbearably.²¹³ Belgium specifically acknowledges that children also suffer, and not having full capacity or adult status should not exclude them from having appropriate options at the end of life. In Belgium, there are safeguards that include parents also providing consent, to ensure that children do actually understand and appreciate the implications of their actions.²¹⁴ More information on children and PAD will be discussed below.

Incapable patients with dementia would not be eligible for PAD in the United States, especially in later stages of the disease, since they would not be capable enough to request the process. Patients who are given lethal medications to take on their own must be capable enough to understand their request and be able to make it multiple times.²¹⁵ This may be difficult for patients with Alzheimer Disease, for example, if they are unable to remember actions from the day before. Furthermore, advance directives instructing a physician to assist in suicide would not be considered valid, since the patient would not be competent at the time of the request. Dementia patients who are in the early stages of their disease are also ineligible for these services, since their disease would presumably take more than six months to manifest into a state which is considered negative, or not a worthwhile life. These patients would be able to create an advance directive indicating whether they wish to have extraordinary treatment administered at the time of death, or if they would prefer palliative sedation at times of great pain.²¹⁶ Since these options may hasten death, but not have it as their goal, they would be deemed acceptable to include during advance care planning, and may be a compromise for individuals wishing to maintain some control over their lives in the future, when they are unable to make autonomous choices.

In the United States, the driving factor that has allowed PAD to become legal is autonomy and the notion of dying a dignified death. This implies that a patient who is suffering from a terminal illness has the ability to decide for themselves that they would like to die, instead of having to live through a life in which their control and their dignity may disappear.²¹⁷ Oregon was the first state to implement a law pertaining to PAD, which was called the “Death with Dignity Act,” indicating that the maintenance of dignity was the central justification of this law.²¹⁸ The Death with Dignity National Center believes that individuals should be allowed access to methods with which to die in a “peaceful, humane, and dignified way.”

As it has been mentioned, children are currently not eligible for PAD in very many locations, due to their perceived incapability to make their own decisions. This dissertation has already mentioned children and their decision-making capabilities in other contexts, and the same can be extended to PAD. Euthanasia for children who possess some capacity to express autonomous wishes is often debated. In Belgium, the law now allows children regardless of age, to request to be euthanized. Some argue that children should not be able to request to terminate their lives, since it is believed they do not have the capacity of discernment and the ability to make meaningful choices. Both of these theories have been disproven, and it has been demonstrated that some children, especially those who deal with debilitating diseases, are, in fact, able to make meaningful decisions about life and death and understand the implications of their actions.²¹⁹ Those children should not be ignored due to their age, and should be considered when discussing treatment options. These studies have also shown that some minors are able to recognize the importance of decisions, especially regarding PAD, and are capable of weighing the harms and benefits of their choices.²²⁰ Physicians, parents, and society should acknowledge that some children do have the capacity to make autonomous choices, and should allow them the

opportunity to do so. There should be safeguards in place to avoid manipulation or coercion, but these individuals should not be neglected.²²¹

One important safeguard that must be in place is a method of monitoring a child's specific decisions. Evidence has demonstrated that children who deal with stressful situations, such as having a terminal illness, are aware of how the people around them are suffering. For example, a minor may feel that their parents are not coping well with the illness and are having a difficult time. A child may feel that requesting euthanasia would be benefiting their parents, since they would no longer have to watch their child suffer or be in pain. This reasoning may be considerate, but it should not drive requests for aid in dying. Furthermore, parents may pressure their child to make a request for medical assistance in dying to end their child's suffering, or perhaps, because they cannot afford treatment. External pressure should be investigated, as no coercion should influence the autonomous choice of a child.²²² These pressures may exist, but it is up to medical staff to detect them and try and explain that they should not have any influence on a decision. Having multiple physicians and nurses talk to the child may be beneficial to ensure that their motives are sound.

Similar to children, patients who have advancing dementia may have partial capacity at earlier stages of their disease, but it may disappear progressively as they near the end of their life. The autonomy of these individuals must be upheld until their death. It is essential to discuss the topic of euthanasia with regard to patients with dementia, as it may be another option for death and for maintaining control over their life.

A capable patient is granted the autonomy to make their own healthcare decisions if they understand and appreciate their medical situation. As we age, our capacity may begin to fade, either as a result of expected memory loss and confusion, or because of disease, such as

Alzheimer's.²²³ The ability to think clearly diminishes and disappears, effectively eliminating autonomous decision-making.²²⁴ Individuals with Alzheimer Disease, for example, lose their ability to learn new information, as well as remember past knowledge, in addition to experiencing problems with language, motor functioning, object and human recognition, organization and planning, and personality changes.²²⁵ This deterioration happens over time, and it can be difficult to recognize the early signs of AD, as simple memory loss is associated with aging. Preparation in cases of late diagnosis is often not possible, but the future need for care from others is guaranteed.²²⁶ These individuals rely on substitute decision-makers who would ideally provide a substituted judgement or make a choice in the patient's best interest.²²⁷

While an incapable patient has to rely on their relatives, friends, substitute decision-makers, and medical team to make their decisions for them, a capable patient who is experiencing aging may feel that even though they are still considered 'capable,' their autonomy is being 'stolen' by their lack of options for care. When an individual has their autonomy taken away from them, either for medical reasons or solely as a result of aging, it can be detrimental to their dignity and outlook. The right to make their own decisions and live as they please disappears when control is transferred to an institution or another caregiver.²²⁸ Age should not limit a person to the choices they are able to make. They have lived their life fully capable of determining their healthcare, and they should not have to relinquish their dignity for safety. Safety is the main concern for the elderly, as living alone and in an unsafe environment could harm them physically, which could lead to a detrimental disability.²²⁹ It should be a priority of society to try and find methods to uphold the autonomy and dignity of the elderly.

There is an importance in maintaining autonomy, since, as it was mentioned above, it is considered a human right and promotes human dignity. When a patient with AD does progress

into the late stages of the disease, they are still a human being who deserves to be respected. While they may not be able to make their own decisions, their autonomy should be considered.²³⁰ Although it may be difficult, respecting the autonomy of patients with Alzheimer disease is essential. It is important to recognize that although they may be unable to make significant medical choices with regard to treatment, these individuals still may be able to communicate about treatment, such as indicating when they are in pain, and about daily activities.²³¹ Allowing some liberties for these patients indicates to them that they are still being valued and that they are still leading meaningful lives. This also strengthens the relationship between a patient and their caregiver, and leads to better care. While there may be some level of risk involved if a patient is allowed to walk around a nursing home alone, for example, it may be worth a possible minor physical injury if a patient can recognize that they are being cared for as a person, and not as a patient in an institution.²³² PAD would be considered a significant medical decision, and it would be difficult for dementia patients to truly understand and appreciate the choice they would be making. If there was an indication that the patient wanted to die, their substitute decision maker in addition to their physicians, may consider the option of PAD if it is legal.

When dealing with situations that involve patients with limited capacities, but who are aware of their condition and surroundings, such as mentally disabled patients, it is best if a surrogate works with the patient to make medical decisions. Even if the incompetent patient is unable to rationalize or process their condition and their options, they are often able to understand the words and facts that are provided.²³³ The dual decision-making model is most effective, because the largely incompetent patient feels included and respected, most likely because their autonomy is being acknowledged. By using a substitute decision-maker, it is

ensured that a proper decision will be made that is in the best interest of the patient. If both of these individuals agree, proper consent can be provided for effective medical care.²³⁴

Ideally in these situations, a surrogate or a capable patient would partake in shared decision-making with their healthcare team. This method, where doctors and surrogates collaborate to make medical decisions, is effective, because it combines the scientific knowledge and recommendations of a physician, with the personal values and preferences of the patient (by means of their SDM).²³⁵ By using a shared decision-making model, surrogates are able to use the support of physicians or nurses or other healthcare workers to guide them into making a suitable proxy decision.

Having conversations about death can be difficult and daunting, but ultimately, they are crucial if an individual's autonomy at the end of life is to be upheld. These conversations should be approached with care, and should focus on what an individual feels is most valuable for a meaningful life.²³⁶ While some people may feel that the ability to communicate with their peers and relatives is the most important, others may be happy with the ability to watch a football game on television.²³⁷ These discussions should happen between a physician and their patient when a terminal or unfavorable diagnosis is presented, and between family members, such as spouses, parents, and their children, to ensure that in the event that an individual's capacity disappears, their surrogates will know what the patient's autonomous wishes are for their death, and how much treatment is desired at the end of life. It is important to discuss what sacrifices the patient is willing to make, and ultimately, what they feel is the best outcome of their situation.²³⁸ An individual can dread these conversations, but they are important preparations in the event of death.

An individual who has AD may also want to create an Advance Directive directly related to their preferences for end of life. Such documents respect a patient's autonomy when they are unable to speak for themselves.²³⁹ Advance directives also allow all members of a medical team, as well as family members, to know exactly what a patient's autonomous choices are. For example, a patient with terminal cancer may indicate that they do not wish to live on a ventilator if there is no hope of survival or cure, or may indicate that if a cure did become approved, such as a genetic therapy, they would be willing to try it if there is minimal discomfort. The patient's autonomy is fully upheld and their final wishes will be recognized.²⁴⁰ It is currently in doubt whether patients who indicate in an advance directive that they would like to choose PAD and specifically euthanasia provided by a practitioner at the end of life, under certain conditions, would have their wishes respected. If there are specific conditions that the patient has expressed under which they would prefer to die, as opposed to live and suffer, it may be acceptable to administer euthanasia to an incapable patient. Further analysis would be necessary.

Planning ahead can be immensely valuable as it would comfort both an individual and their family in knowing that their autonomous choices would be upheld. However, it is very difficult to predict the future, and to know what the future 'self' will value and need. The choice that a capable individual might make may not be the same choice that the incapable but communicative individual might make.²⁴¹ For example, a patient could specify in their advance directive that if they were diagnosed with cancer at the end of life, they would not want treatment and would simply like to be kept comfortable. They would not have considered that available treatments, such as genetic therapies, might be available, and a patient's SDM proceeding with using that therapy would be going against their loved ones' wishes according to the advance directive. It is important to understand that the planning that is done in the present will allow for

some flexibility in the future. That version of the individual should still have an influence on the care being provided or discontinued at the later stages of the disease. For this reason, having a power of attorney may be more beneficial, as they would not only be able to consider previous values, but also take into account the present situation.

Advance directives will be created more frequently as practices such as euthanasia come to be more accepted. There must be a discussion as to whether a patient has the ability to create an advance directive as well as indicate that they would like a physician to aid them in dying. By doing this, a patient with early dementia, for example, will be able to maintain a level of control over their future, and ensure that their current values are known and documented.²⁴² They are able to share what a meaningful life means and what quality of life they would wish to lead in the future. Many scholars and individuals argue that if a patient has the option to create an advance directive indicating situations in which they would prefer that treatment be withheld or withdrawn which would presumably lead to their death, specifying that euthanasia is preferred should also be allowed and respected.²⁴³ A patient still has the right to have their autonomy upheld, which may include purposely ending their life. Some authors feel that this option should be available, because the future implications of dementia are well-known, and it is understood that an individual's critical interests would not change. Critical interests can include particular ways an estate should be handled and what may happen after death, but it can also include the intrinsic values that a patient holds.²⁴⁴ Respecting the wishes of a patient who feels that they will prefer euthanasia in the future may soon become a more routine practice in countries which have legalized this practice.

There are opposing arguments with regard to allowing individuals to create advance directives indicating euthanasia. Numerous scholars have presented the fact that while a patient

may become incompetent, they would still have values, and may still be able to lead a meaningful life, which is the opposite of what the patient predicted. A patient in the early stages of their dementia may feel that if they are unable to communicate clearly or recognize their family, they would not be leading a worthwhile life. However, in the future, this patient may not be able to perform those actions, but may be able to find joy in daily activities and social interactions. While they may not be able to remember their past or plan for their future, they may feel content living in the present.²⁴⁵ This is not always the case for dementia patients, but there must be a method to ensure that advance directives leave room for adaptation, since, as was mentioned above, the future cannot be predicted.²⁴⁶ In these situations, a family member or physician would need to decide that the quality of life for their patient is satisfactory enough for them to keep living.

Dementia can be extremely complex, and it affects all individuals differently. For this reason, advance directives instructing a physician to administer euthanasia at a specific point in time would need to be evaluated on a case by case basis. This creates difficulty for physicians, as well as families, and may even cause stress to the patient at the time of document creation.²⁴⁷ If there is no guarantee that a lethal injection will be administered, some patients may feel frustrated in knowing that their wishes may not be respected. Since it can be extremely difficult to interpret these documents, the patient must be adequately informed about events that may occur due to their future condition, and it may be more beneficial to instruct a physician more generally (i.e. if the patient is experiencing intolerable physical and mental suffering) than to pick a specific moment at which the medication should be administered (such as the moment they cannot recognize their family). This would allow a physician more space for deliberation to ensure that they are making an appropriate decision.²⁴⁸

Genetic therapies may be able to alleviate some of these concerns, particularly in the case of abortion, but also with regard to Physician-Assisted Death. Certain diseases will have a cure, and fewer patients will seek PAD due to suffering and lack of effective treatment options. However, it is also important to set limitations on the expectations of gene therapies and editing capabilities. Considering the cost and length of clinical trials related to gene therapies, it will take a long time to normalize the use of these treatments across the United States and the rest of the world. Although they will be beneficial in the future, current practices in abortion and PAD should be considered and implemented in order to ensure that patient autonomy is upheld to the highest degree.

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Chapter 5: The Integration of Clinical and Organizational Issues in Genetics

While it is crucial to examine general concepts that apply to the implementation of new genetic therapies and editing techniques, it can also be helpful to consider how similar medical advancements have been implemented in the health care system. It has been made clear that any new technology or treatment contains both clinical and organizational components that should be looked at together. This chapter presents two specific examples which demonstrate how CRISPR/Cas9 may, one day, be introduced within health care. From a clinical perspective, Pre-Implantation Genetic Diagnosis (PGD) can provide a template for a specific gene-related procedure at the beginning of life involving embryos, which directly addresses the most-feared aspects of the CRISPR/Cas9 technique. When evaluating organizational systems, the introduction of new technologies and gene therapies is directly to how gene editing technologies could be incorporated into the current health care landscape.

A: Clinical Issue: Pre-Implantation Genetic Diagnosis (PGD)

In the last few decades, the notion of assisted reproduction has increased in popularity and improved in techniques to effectively allow parents to influence the characteristics of their unborn child. These ideas are exciting, but they can also bring about numerous ethical concerns. The technique of Pre-Implantation Genetic Diagnosis (PGD) is a method which, in one way or another, makes it possible for parents to decide what kind of child they wish to have. The current uses of Pre-implantation Genetic Diagnosis can be considered ethical, but ongoing, related scientific research could lead to a slippery slope of unethical practices through the use of CRISPR/Cas9.

i. Ethical Principles associated with Parental Decisions to use PGD

It has already been mentioned that Pre-implantation genetic diagnosis is a technique used to examine an embryo's genome - to identify if an embryo carries a gene for a particular disease.¹ Often, parents who have an autosomal recessive or X-linked disorder or a familial history of one, may want to ensure that their future child is not faced with the same disease.² PGD is carried out with the use of In-vitro Fertilization (IVF).³ After fertilization outside of the body, there are methods to extract one or a few cells and examine the genetic make-up of the embryo. In most circumstances, a specific disorder is being targeted, and if an embryo is shown not to contain a gene that codes for that illness, it will be implanted into the mother, with the certainty that the child will not have the disease.⁴ Similar to PGD, Pre-implantation Genetic Screening (PGS) consists of examining an embryo for aneuploidy, and subsequently transferring an embryo with the correct number of chromosomes. Both PGD and PGS make up the general term of Pre-Implantation Genetic Testing (PGT).⁵

The process of PGD can be done in one of three ways. A polar body biopsy is performed before fertilization, and consists of analyzing the first or second polar body from an oocyte. This method does not interfere with an embryo by removing any of its cells, often making it a suitable option for parents who do not support embryonic research. This method is carried out mostly for the detection of aneuploidy, as 95% of aneuploidy cases occur in maternal meiosis. The disadvantage to this technique is that paternal traits cannot be examined.⁶ A blastomere biopsy can be done after 3 days of fertilization and requires that one or two cells be removed from the embryo (which has six to eight cells at this stage). The third technique involves the biopsy of the trophoctoderm after five to six days of embryo development. At this stage, the embryo has about 120 cells which allows for more to be removed for analysis. This technique is beneficial as it

provides time for the embryo to self-correct or eliminate any abnormal cells, but embryos must be implanted after six days, which gives very little time for analysis with this type of biopsy.⁷ After a biopsy, various laboratory techniques are carried out, depending on the disease being examined.⁸

Although PGD is considered to be a benefit to couples, there are scientific concerns as well as safety issues that must be addressed and disclosed. A common concern is the time it takes to analyze an embryo's genome. Some laboratories can perform tests immediately, for example, making techniques like trophectoderm biopsy possible, but other tests require more time for results and analysis. This can limit the number of procedures that are offered for the testing of embryos.⁹ Furthermore, if a couple chooses a polar body biopsy, there may be errors as the analysis is happening very early in the fertilization process. Defects or errors in meiosis can still occur after this biopsy, so results have the chance of being inaccurate. In these situations, prenatal testing should be administered during the pregnancy to monitor the fetus and its chromosomes.¹⁰ As with any medical test, there is always room for error, and results may be inconclusive. For example, if a chromosome microarray is used to test for aneuploidy, it can be difficult to interpret which chromosomal imbalances are significant and cause birth defects.¹¹ Similarly, if testing for a specific gene, an unexpected allele may arise and cause a misdiagnosis.¹² A final concern, which many couples may express, is possible damage to an embryo during the biopsy itself. There is always this risk of damage, and some individuals may choose to forgo a biopsy for this reason, if there are a limited number of embryos to choose from.¹³

Although risks exist, the benefits that PGD provides are monumental for some parents. Being able to ensure a child will not have to suffer a terrible disease is comforting for all. There are

fears, however, that if we can identify and avoid the birth of babies with specific diseases, there may be a possibility that this technology will begin to be used for ensuring non-medical traits. Examples include sex selection, which will be discussed below, and manipulating athletic ability or height, which will be discussed in the next chapter.¹⁴ This is becoming a reality through the development of the CRISPR-Cas9 system of altering a genome.

CRISPR, or Clustered Regularly Interspaced Short Palindromic Repeats, is able to alter the DNA of mammalian cells. CRISPR was discovered as an immune system in archaea and bacteria to fight viruses, and was modified to act in human or mammalian cells.¹⁵ It consists of repeating DNA sequences and associated genes that can make proteins. These proteins, known as Cas, are able to cut DNA at a specific location, which allows scientists to modify that targeted sequence, or insert new DNA that can alter the gene. This can lead to the elimination of specific diseases associated with a gene, such as Cystic Fibrosis. The CRISPR-Cas system is also beneficial because it allows for multiple genes to be targeted at once, and as many diseases have been discovered to affect more than one genetic sequence.¹⁶ Currently this has been done in only a few human cell trials, but success with other animals demonstrates the future possibilities of this method of genome editing.

Pre-implantation genetic diagnosis is a scientific breakthrough, but it has numerous ethical concerns that are associated with the technique. It is important to examine how this testing method affects various principles in order to decide whether it is ethical. The major players in PGD scenarios are parents and their future unborn children, and the autonomy of both should be considered. An embryo's autonomy is negligible since it is unable to provide informed consent, and there is debate about whether an embryo has moral status, which brings into question whether it has any autonomy at all.¹⁷ Parental autonomy, on the other hand, is what is most

prevalent in this situation.¹⁸ Parents use PGD to seemingly ensure that their future child is healthy, and free of a specific disease.¹⁹ Some critics of PGD claim that this is selfish. Individuals have the right to reproduce, but when parents interfere with nature, they are simply doing it for their own interests.²⁰ Parents do, however, have an autonomous right to use this technology if they feel it will improve their child's life and prevent suffering. Especially in the ways PGD is able to be used today, some individuals will want to avoid their child inheriting disease, potentially one their parent has already experienced.²¹

When PGD is used for HLA matching, there is a concern that parents are using the technique for self-regarding reasons because they are disregarding the autonomy of an unborn child. If parents already have a child who has a serious, life-threatening illness, such as leukemia or Fanconi anemia, and traditional treatment methods have proven ineffective, parents may choose to undergo PGD in order to have another child with a Human Leukocyte Antigen (HLA) that matches that of their sick sibling.²² By ensuring that a matching embryo is implanted and born, a new possibility for tissue donation from a newborn child to their sibling becomes another treatment intervention. In this situation, a new child is used as a means to an end, but many parents argue that the benefits of HLA matching are instead two-fold: they are able to have another child (which they had always hoped for) with the guarantee that they will be free of disease, and their existing child is able to get better. This demonstrates that the PGD child is not, in fact, solely a means to an end. There is a fear, however, that the child created through PGD will be expected to help their sibling through future tissue donation. Using embryonic stem cells or umbilical cord blood does not really affect the newborn child, but a kidney or bone marrow donation in the future would pose significant risks to the donor child, and autonomy would have to be re-evaluated to ensure that parents are considering all of their children's autonomies.²³ One

solution is to use a neutral substitute decision-maker for the child undergoing donation to ensure that their rights and autonomy are considered when making decisions.²⁴

Other principles to consider are beneficence and non-maleficence. Those who are in favor of PGD feel that both beneficence and non-maleficence are upheld through this technique. A child benefits when its parents choose to eliminate the risk of a possible detrimental disease and avoid future suffering. Questions do arise, however, that ask whether a child will in fact benefit from future implications of this technology in which parents choose non-medical diseases for their children. Non-maleficence is also maintained in that harm is avoided through this reproductive method of screening. If parents are effectively ensuring that their child will not be harmed by a preventable illness, they are acting in the best interest of the child.²⁵ Moreover, some scholars postulate that by not using PGD to avoid known genetic diseases, parents are actually causing their children harm.²⁶ Similarly, non-maleficence is supported through the present uses of PGD, but future uses for genetic enhancement may alter this viewpoint.

Proponents of PGD also argue that the technique is a very valuable tool for preventing disability. However, there are both positive and negative connotations associated with this viewpoint. Disability is usually viewed as a disadvantage to a normal life, but many individuals who are disabled disagree, and merely describe disabilities as differences. Degrazia goes into detail about whether it is acceptable to label disabilities as simple differences, since the change in terminology indicates a more positive outlook. He argues that disabilities are not just differences, as they do impact the way an individual lives their life.²⁷ There are, of course, unavoidable disabilities that may arise due to accidents or illness, but genetic disabilities, such as dwarfism or spina bifida, are able to be avoided. Parents who opt to use this screening method may feel that having a disability is a burden, or in the case of illness such as Lesch-Nyhan Syndrome,

disabilities cause a life to simply not be worth living. Supporters of PGD feel that if a disability can be avoided, it should be, which allows a child to have a healthy and less burdensome life.²⁸

Conversely, some parents choose to undergo PGD to positively select for a disability, such as deafness or dwarfism. Parents who themselves have one of these disabilities feel that in order for their child to be accepted into their community, they must also have these disabilities, or in their opinions, differences.²⁹ Individuals who are deaf, for example, do not see it as a burden, and have adapted their lives in order to be a 'normal' part of society. The small burdens associated with lack of hearing can be overcome to live a happy life. A parent's autonomy is driving this decision, and these arguments can pose dilemmas for physicians or genetic counsellors who are guiding parents through the process of PGD. If a doctor feels that dwarfism is a disability, they may feel uncomfortable allowing a couple to positively select embryos that have the mutations, as it goes against their duty to prevent harm to a patient.³⁰ How disabilities are perceived is also partly a result of society's opinions and reactions. It is difficult to create policy that will please everyone about this issue. Parents do have the liberty to use this reproductive technique, as they do not feel disabled, and would prefer that their child was just like them, while those who do not have the disadvantage may feel that imposing this disability on a child is morally wrong.

The idea of 'designer babies' rears to the future possibility of parents being able to edit the genome of a specific embryo to include desired social traits, such as height or athletic ability, in addition to the embryo being free of genetic markers for disease. There is a fear that using PGD and CRISPR to modify embryos will change our perception of what it means to be a person, and will forever change our identities. Before delving into the outcome of using this future technology, we must examine how we are defined as human beings, as well as the possible reasoning behind a parent's desire to determine particular traits for their future children.

There is much debate about when we become a ‘person’ and attain moral status. This is important, as ‘people’ with moral status are entitled to human rights. Religious doctrine maintains that life starts before birth, as described in the last chapter, and embryos are considered people throughout a pregnancy. Others feel that life begins at birth, which gives no moral status to embryos or a fetus. David DeGrazia gives another viewpoint, namely that life begins after the possibility of twinning is no longer possible. There is a period of time between initial conception and the moment of time when the embryo begins to form, during which it is possible for the embryo to split, making twins. He postulates that if this is possible, the numerical identity of that embryo could still change, making them not yet an individual person.³¹ Each individual has an autonomous right to decide for themselves whether they feel embryos or gametes have moral status and require the protection of human rights, but creating policy has proven increasingly difficult. If a couple uses PGD, they most likely feel that conception outside of the womb is permissible, and that embryos do not have moral status if they plan to discard or donate leftover embryos to research. Other couples may choose to cryopreserve the extra embryos for a future use, or simply because they feel that destroying them would be morally wrong.³²

When defining personhood, the concept of identity must be examined. Many people believe that our identity makes us who we are, when in fact there must be a distinction between two types of identity: numerical and narrative. Numerical identity denotes that we are one being that does not change in number and, therefore, our numerical identity stays the same for our entire life. It is not affected by genes or personality or disability.³³ Narrative identity is more commonly used when individuals describe themselves. A person’s narrative identity consists of their physical features, their personality, and their abilities that may strongly influence the way they live their life. When PGD is undergone, a couple is influencing an embryo’s future narrative

identity, and not tampering with its numerical identity, although splitting is still possible within the womb.³⁴ In terms of future uses of PGD, such as choosing non-medical traits, a parent is still only choosing to modify the narrative identity of their future child. This general distinction is important, because it is often argued that enhancement of any kind to an embryo entails changing their identity, and while the act of choosing social traits for a child is modifying a narrative identity, that child's numerical identity remains the same, as the intention to have that child is constant.³⁵ This is a common argument that stipulates that PGD use along with CRISPR modifications is acceptable.

A question is often asked about whether genes define a person. By having genes, we are biologically human, which is our numerical identity, but what those genes influence is our narrative identity. Our physical traits, predisposition to some diseases, and some of our natural abilities come from the genome. It is also commonly observed, however, that human beings can change over the course of a lifetime. Our identity changes and we may define ourselves differently at the age of 20 compared to at the age of 40, for example. These differences solely affect a narrative identity, as we are still the same being that we were at birth.³⁶ The change, however, is important to notice, because humans evolve with time. Even in the future if gene modification becomes possible postnatally, a numerical identity would not change, but a narrative one could. DeGrazia defines a "robustness thesis," which maintains that even with genetic modifications, which we can manipulate for ourselves or our children, we are still living the same life, just with different specifications.³⁷

In addition to genes, narrative identity is strongly influenced by environment. Parental decisions about raising their children directly impact the kinds of people their offspring grow up to be. A child may be born with natural musical abilities, and their parents may involve them in

playing musical instruments, but unless the child enjoys practicing and performing, they may not choose to devote their lives to music. Parenting styles heavily influence a child's upbringing, but other factors such as socioeconomic status and parental income affect an individual's narrative identity as well.³⁸ Furthermore, this also affects narrative identity for adults. A person may have had a luxurious upbringing, but if they are not able to support themselves, they may start defining themselves in different ways. Some individuals choose to define themselves by character traits, such as being humble or kind, while others define themselves according to their occupation, or their family. Regardless of how a person chooses to define themselves, it is always based on a narrative outlook on their life. The environment, both for children and adults, is crucial in impacting values and opinions. By putting a strong emphasis on environmental factors that shape our lives, many scholars wonder about the use of PGD for selecting social traits, as environment may be more influential than genes alone.³⁹

Similarly, society as a whole influences how an individual may define themselves or what they consider an acceptable identity to be. In the Western world, which is largely more accepting of other cultures and viewpoints, an individual believes that they have the right to autonomously make their own decisions and do as they please, as long as they do not break the law. In a less developed country, an individual may have different values that focus more on family or survival. These differences influence how we define ourselves in terms of narrative identity. For example, in the developed world, a woman may define herself by her job, her gender, or her personality traits, whereas in a society where women do not have rights or are expected to suppress their own values and beliefs, the source of her sense of identity may be vastly different, and any independent sense of self may be completely negligible. Societal influences fall into the

category of environmental factors that influence how we choose to define ourselves, and demonstrate that there is more to an individual than just genes.

As alluded to previously, anxiety with regard to the slippery slope of PGD is that it will lead to integration with CRISPR-Cas9 systems to promote genetic enhancement in embryos. Pre-implantation genetic enhancement (PGE) would give parents the opportunity to effectively choose particular genetic traits for their offspring. It can be viewed as a method of improving a genome to ensure that more desirable and superior traits are part of a child.⁴⁰ Speculation exists about how parents come to a decision regarding which traits to choose. During PGD, a parent has the obvious choice to eliminate a disease for which they themselves are known carriers or that is a part of a family's medical history. If PGE is ever used, would parents have the ultimate say about their child's genome, or would scientific policy prohibit them from using the technology to its full potential?

If using PGE, a parent's own autonomy is most prevalent. Since an embryo is not able to provide informed consent, and parents do not have an idea of what that particular child would have wanted, a parent is unable to use 'substituted judgement' as a conventional surrogate would. In the case of PGE, a parent is exercising the 'best interest' standard for substitute decision-making, in the belief that enhancing their future child's genome is in the offspring's best interest.⁴¹ Although some criticize this argument and claim that parents are trying to 'play God' by choosing for their children without any indication of a child's wishes, it can be negated by the fact that parents act in similar manners after their children are born.⁴² Parents have a right to raise their children as they please, and make medical decisions for them until they are old enough to be able to rationally think and make choices for themselves. The 'playing God' argument postulates that parents are disrupting the natural course of development, and giving off

the idea that children are not simply a gift that should be accepted as they come, but a product that can be manipulated to suit a parent's wishes.⁴³

This technology may seem beneficial, in that it could aid parents in removing disease and promoting enhanced traits to help a child succeed in the future. There are concerns, however, that dominate the conversation surrounding preimplantation genetic enhancement. One is a fear of the technology itself, and the room for error that could occur within a genome. For example, in animal models using mice, when a gene was introduced to improve running in mazes, the animals became more susceptible to pain.⁴⁴ Side effects are a major concern, since it is unknown whether the addition or modification of a gene will have other effects within the genome or the body. The only way to combat this worry is to conduct appropriate and safe research. This also becomes problematic, as it may be very difficult for human trials to be done, for unlike a drug trial, there is an increased variance in the genes that would be able to be modified and manipulated. Policy would have to be followed, and informed consent of parents would need to be ensured, to conduct cautious but effective research.⁴⁵

In addition to scientific concerns about PGE, there are also societal concerns that are associated with the technique. It can be questioned whether using enhancement methods limits a child's right to an open future. For example, if a couple wishes to insert or modify a gene that enhances athletic ability, there may be an expectation for their child to become a professional athlete. This is a valid concern, as there is fear that a child will not have the autonomy to determine their own future and will be limited to one career as a result of parental pressure. However, this fear can be allayed, since, as mentioned earlier, genes only partially contribute to an individual's narrative identity. Parenting styles contribute as well, and if parents encourage their child to become engaged in other activities, as well as sports, there is not as much pressure

for a child to conform to their parent's original wishes.⁴⁶ If parents insist that their child participates solely in sports, then the fear is warranted as their child experiences no other options. It can be argued that using PGE is an influential tactic parents can utilize to guide their children, akin to enrolling them in a private school or teaching them religion. A child can be influenced to have certain opinions and pursue various career options, but there should be room for personal growth and thought. If this argument is employed, PGE should be accepted as it is simply a tool to aid in a child's future, not determine it.⁴⁷

In addition, parents may feel that using PGE is an effective way of conforming to societal norms, therefore, making their child's life easier. For example, an African-American family may choose for their child to have a lighter skin color, in order to avoid racism. Similarly, a mother may want to ensure that her future daughter has breasts of a certain size or has a specific gene that makes it possible to avoid weight gain, in order for her to have less of an issue being accepted as attractive within society. This introduces a larger societal problem, in general, as there is certain pressure to look or act a certain way in order to be treated fairly. Racism and beauty standards are prevalent in the world today, and there is a possibility that these issues should be addressed first, to avoid going through genetic enhancement simply for the purpose of societal pressure. These reasons for using PGE are unwarranted, even though they are bringing about presumed benefit for a child, because they promote societal issues and discourage the need for unwanted prejudice.⁴⁸

ii. Parental Control and Sex Selection

Parents may choose to go through preimplantation genetic diagnosis for a variety of reasons that have been listed above, but the most common and most accepted is to prevent a child from having a specific disease. This has already been mentioned, but more detail will now be given

about the types of diseases that are examined. Furthermore, the technique is being used to select for a specific sex, which poses separate ethical considerations.

When couples or individuals consider PGD, they may think about their future child's quality of life. For example, there are genetic diseases that cause immense suffering and offer a poor life expectancy for children born with the illness. Tay-Sachs disease is one example, in which a child sees symptoms after six months and does not live past the age of five. Before PGD, couples may have been given the option for a therapeutic abortion, in which a pregnancy would be terminated if the fetus was found to have this disease.⁴⁹ By using PGD, a couple can still have a child, and know that they are eliminating the chance of Tay-Sachs. This usage of PGD consequently affects a germ line – a child whose genome is free of the gene for Tay-Sachs is not going to pass on the gene to their future offspring, ensuring that the disease does not continue down that germ line.⁵⁰ This usage may also be acceptable, because the quality of life of these children is very low and PGD would definitely improve their quality of living.

There are also genetic disorders, such as Down's Syndrome or Cystic Fibrosis that would impact the quality of life of a child, but not nearly as much as the previous disease example. In today's society, children with Down's Syndrome or CF can lead normal lives that are of a high quality. That is not to say that there are no hardships to overcome, nor that a parent has more challenges to face, but the children have much higher life expectancies than in previous generations. Trying to avoid these disorders is also common, however. Parents who themselves have CF may choose to ensure their child does not have to deal with the same suffering, or parents who already have a child with Down's Syndrome would prefer to prevent another child succumbing to mental disability.⁵¹ These diseases are not life-threatening, but a parent still has a right to choose an embryo without these disorders. Some argue that PGD is an effective method

to avoid non-life-threatening diseases as it will eliminate the frequency of aborting fetuses who have Down's Syndrome, since a parent can choose which embryo to implant.⁵² In this situation, the parents must also believe that embryos do not have moral status, but with any PGD technique, this is already the assumption, as the rest of the embryos which are not implanted will be discarded.

PGD can also ensure that embryos without late-onset diseases are implanted. Some diseases cannot be avoided if an individual has a specific gene, such one for as Huntington's Disease (HD).⁵³ If a parent has HD, their child has a 50/50 chance of also inheriting the gene and eventually of having Huntington's. This incidence rate is high, and some parents will want to ensure that there is no chance their child will have to deal with HD in their future, as there is currently no cure. However, a recent study examined the usage rate of PGD to avoid having children with the Huntington's gene, and its results indicate that usage rates are lower than expected. If a child whose parents suffered from the disease does not have a gene for HD, there is only a 1 in 4 chance that their child will inherit the disease. The risk is fairly low, and parents feel that it is not worth the extra time, money, and effort to undergo PGD. Furthermore, parents may believe that even if their child does inherit the gene, by the onset of symptoms, there may be a cure for HD, making the process of PGD unnecessary.⁵⁴ Ultimately, it is up to parents whether they choose to undergo PGD before pregnancy, and whether they choose to influence their future child's life in this way.

Further debate arises when discussing diseases that are not contingent upon a specific gene. A common example is the BRCA set of genes associated with breast and ovarian cancers.⁵⁵ Mothers who carry these genes or who have suffered from these cancers in addition to their mothers before them, may want to ensure that any potential daughters do not have to worry about

the possibility of getting these types of cancer. These situations are challenging because the BRCA genes are not sure predictors of cancer. Individuals who carry the gene may never see the disease, and those without them can also be at risk of cancers. Although it is a method of avoiding some harm, it can be questioned whether the use of PGD to choose against BRCA genes is necessary.⁵⁶ There are effective treatments for breast cancer that exist, and presumably will only improve with time, which indicates the lesser need for PGD related to breast cancer genetics. As always, a couple has the autonomy to undergo PGD, but as the risk for a lower quality of life is reduced, some may choose to let their child be born and develop without scientific manipulation.

PGD is also being used to choose embryos based on their sex. There are both medical and non-medical reasons for doing this, although the non-medical reasons cause the most ethical concerns. Medically, a mother who is a carrier for an X-linked disorder, such as hemophilia or muscular dystrophy, may choose to implant only female embryos into her uterus, with the assurance that they will not have the disease. There are instances where females have an X-linked disorder, because they received the gene from both their mother and their father, but these cases are less frequent.⁵⁷ If both parents are carriers or have had an X-linked disease, PGD could be used as usual, in selecting any embryo that does not have the allele for the condition. Medical uses for sex selection are accepted as being ethical methods for disease prevention through PGD.⁵⁸ The reason for undergoing genetic testing is not for a social reason, but to help a child avoid future harm and suffering.

Concerns arise when sex selection is used for social reasons. For instance, a couple can use PGD solely for the purpose of choosing a female or a male embryo for implantation. Currently, some clinics only allow sex selection for couples who are already undergoing IVF, and forbid

fertile couples to use PGD for the only purpose of choosing a desired sex.⁵⁹ Arguments for this usage stem from the right to reproductive freedom. It is believed that all individuals in the United States have a right to procreate and determine their reproductive choices for themselves as it is considered a private matter, pertaining only to the individual, not the state. This argument has been used to support abortion, but is also being applied to PGD and sex selection. Reproductive liberty can include couples having the autonomous right to plan their family as they wish, and to use the technologies that exist to do so. They do not see any issues with sex selection through PGD and feel that if the procedure is safe, it is an appropriate method to use to create their ideal family.⁶⁰

Furthermore, a couple may opt to use PGD for sex selection for the purpose of family balancing. This involves parents who choose a particular sex to ensure a balance of males and females among their children.⁶¹ For example, a mother with three sons may wish to have a daughter as well. She does not want many more children and may encounter issues with reproduction as she is getting older. By using IVF and PGD, she can guarantee that a female embryo is implanted, thereby greatly increasing the possibility of adding a daughter to her family. These methods may be justified because there is no element of prejudice against a certain trait. Parents in these situations argue that they would feel the same if the situation was reversed – choosing a male embryo to join a family that already has daughters. Moreover, family balancing is more commonly used in situations where parents already have children, and are not going through their first pregnancy, where there would be an assumed bias if sex selection was done through PGD.⁶²

On the contrary, many believe there are negative associations with sex selection. Some fear that choosing a particular sex is a form of discrimination. This has been historically seen through

the higher value assigned to males. Before PGD was possible, a form of sex selection was abortion after prenatal testing. Female fetuses are still aborted solely because of their sex in societies where females are not wanted, or believed to be of a lower social standing. In countries such as India and China, this has become a concern; not only because it is a human rights issue, but it also causes a major imbalance in sexes, where men are not able to find females with whom to reproduce.⁶³ The practice of aborting female fetuses is still possible, although many countries have laws against this practice. Sex-selective abortion is considered to be wrong, but why is sex selection through PGD considered to be any different? Both situations insinuate that one sex is better than the other, and there can still be a form of discrimination. Some scholars feel that sex selection through PGD is the rich man's abortion. This is no reason for one sex to be valued over the other, especially in a Western society, and there is a fear that some couples will choose males over females as a result of cultural associations. Although it is unavoidable, there should be an effort to prevent sex selection as a result of discrimination.⁶⁴

Another serious issue associated with sex selection is the expectation that parents may have for the gender of their children. Sex indicates, in biological and physiological terms, whether an individual is male or female, but gender indicates it in a social context.⁶⁵ In today's society, there is much more gender education and awareness, but misconceptions can still arise about the distinction between gender and sex, words that are often used interchangeably. By allowing sex selection for non-medical reasons, couples are choosing what they believe are the genders with which their children will identify, even though that may not always be the case in the future. This may result in future disappointment or even abuse, when a parent realizes that their choice may not have produced their expected result. Moreover, some scholars argue that even disclosing the gender of a fetus during a pregnancy, which is done regularly, is problematic as it sets pre-

determined gender roles for the unborn child. They argue that it should not matter whether the fetus is a female or a male, and disclosing the sex may, in fact, be misinformation as sex and gender do not mean the same thing. Sex selection may be considered to promote sexism and undermines the need for societal gender equality.⁶⁶

B: Organizational Issue: Emerging Genetic Technologies

Medicine is consistently progressing and finding new ways to rid patients of disease and solve common healthcare problems. New technologies that are able to combat illness and improve the lives of patients must be put into practice within healthcare facilities. Multiple factors influence a hospital's method of implementation of these new advancements, and all of them must be considered to ensure that all relevant stakeholders who are involved will benefit. The safety and efficacy of new interventions is of the utmost importance, to guarantee that patients are receiving adequate medical care. Furthermore, the emerging technology or treatment should reflect an institution's core values and beliefs. An organization has the responsibility to provide healthcare, but also to stay true to its morals. Once these steps are taken, the implementation of the treatment needs to follow a policy or protocol, to ensure that it is executed with the highest level of efficiency and expertise. These concepts are relevant to current new additions to healthcare, but also apply to future advancements, specifically genetic therapy and genetic enhancement.

i. Patient Safety

When a patient seeks medical aid at a hospital, it is assumed that all aspects of their care will be executed safely, and that no adverse effects will occur. While this is an ideal situation and medical errors can happen, it should be the goal of any organization that provides medical care to ensure safety for their patients.⁶⁷ Historically, adverse events have caused a hospital to reevaluate

their policies to avoid a similar problem in the future. Medical professionals are expected to be skilled and knowledgeable about their respective fields, but human error may occur, and it is often blamed on an individual employee. While this person may have made a mistake, a medical organization as a whole is also responsible for the welfare of patients and must create an accountable system designed to ensure patient safety.⁶⁸

Patient safety is affected organizationally by a system, and practiced on an individual level, as nurses, physicians, and other medical professionals are responsible for preventing errors when possible, and creating a safe environment. These employees are expected to have an elevated level of competence in order to achieve this task. A patient assumes that their physician is well-trained and, therefore, able to perform the medical intervention needed, as well as discuss it and support their patient in making an autonomous decision. Within medicine, however, there may be little monitoring of skills training or recertification for safe practices, as there would be in other professions. In a field that is directly responsible for human lives, there should be more supervision to ensure that physicians and nurses, in addition to all other health professionals stay up to date on current safety measures and strategies.⁶⁹ This should result in less human error by physicians or those who are charged with the prevention of adverse events. Medical institutions as a whole also have a duty to ensure patient safety. Individual incompetence is not always the issue.⁷⁰

In view of the information discussed above, it is important that medical facilities practice extra caution when introducing new treatment techniques or interventions. The level of risk must be evaluated to ensure that patients are not harmed. While clinical trials deal directly with the biological risk that a new technology may have, an organization must determine whether there are other risks that could arise.⁷¹ Risk is primarily encountered at an institutional level, not at an

individual level, and an organization should implement strategies to prevent or control levels of risk associated with any medical procedure or practice. There are a number of ways in which healthcare can conceptualize risk, including as an energy that should not be released, or a result of deviations which lead to multiple approaches to medicine.⁷² Regardless, it is up to an institution to manage risk through various safeguards.⁷³

To control a problem and minimize patient risk, an institution must implement various measures to ensure that patient safety is continuously considered and promoted. Traditionally, this is achieved through education, checklists, and investigations into prior mishaps to make sure that they do not occur repeatedly.⁷⁴ However, creating system-wide policy that aims to decrease risk and increase safety can be difficult. Education is a crucial component, but it can be expensive and exhausting for employees who already feel they are competent enough to do their job.⁷⁵ There must be training in patient safety to guarantee that all healthcare professionals are aware of patient issues and are capable of solving them. This creates a trusting relationship between staff members as well as between patients and their medical teams. If an individual trusts the system, they may be more likely to report a concern without the fear of being reprimanded. This allows an organization to solve a problem immediately, instead of allowing it to develop into a more complex issue affecting patient safety.⁷⁶

All of the components of patient safety that have been mentioned should have a higher priority than the novelty of a new medical treatment. It is unacceptable to promote medical research and scientific breakthroughs that may be unsafe or unproven as priorities above the wellbeing of patients. Clinical trials are expected to be responsible for determining the safety and efficacy of new technologies or interventions, but if a certain advancement has FDA approval and is able to be implemented within a hospital, for example, immense caution should be used to

ensure that patients are being considered first and foremost, as opposed to a potentially successful intervention that could lead to acclaim.⁷⁷ Additional safeguards should always be put into place within a system if a technology is in its infancy or still experimental.

ii. Organizational Accountability

In order for any new technology or system to be implemented effectively within a healthcare facility, an institution must create methods to demonstrate its accountability towards its stakeholders and the individuals it is serving, making it clear that it is concerned with public trust and values quality and safety.⁷⁸ Accountability measures are often associated with plans to achieve a specific new goal, or to routinely monitor and adjust staff performance. Creating a specific accountability plan allows the organization to have a common goal to strive towards and to achieve at all of its levels, and should lead to a sustainability plan to ensure that a goal's accomplishment can be upheld in the future.⁷⁹ The introduction of a new technology or procedure will require staff members to become familiar with new information, and leadership is required to ensure that the new technology is administered and provided safely and adequately.⁸⁰

If a new technique is established at a hospital, physicians, nurses, and any other health team members must be periodically evaluated to ensure that they are providing high quality medical care and that they are performing that technique properly. Furthermore, the technology itself must be assessed to determine whether it is aiding patients in the best way it can, and to identify any improvements that can be made in the future to achieve a higher level of success.⁸¹ To begin this process of review, various goals need to be established. This may include looking at clinical performance, professional behavior, the system that regulates staff and patient complaints, or administrative management strategies. All of these components contribute to having an accountable organization.⁸² Once an initial system is created, it would be carefully

sustained, so that future review would be efficient, accurate, and able to provide useful information. Moreover, having known review systems in place increases transparency with the general public and would increase the level of trust associated with the institution and with the new technology being introduced.⁸³

In order to successfully review a new procedure, a leadership team must be in place and prepared to facilitate the process. Any performance review or accountability plan requires vertical collaboration between a hospital board and individual units, for example, as well as horizontal collaboration between employees. Vertical relationships promote accountability, as levels in the healthcare institution would hold each other responsible for doing their jobs well. It also encourages a more open governance structure that supports communication between all employees in an organization. Horizontal teamwork is useful to stimulate learning across units, and to encourage social needs and specific objectives that need to be met.⁸⁴ Both of these types of relationships ensure that a new technology or procedure is executed with the highest level of accuracy and safety. It is also beneficial to create specific committees that are responsible for monitoring the progress of the review, which can provide insights from various disciplines dealing with the new technology. Such committees may be able to provide additional information throughout the process that explains workers' responsibilities and tasks that should be improved.⁸⁵

Once a performance review or a technology evaluation is complete, it is important that there be transparency of reporting. It can be daunting to release data publicly, especially if it is negative, but by being honest and allowing the public to view truthful statistics and results, they are more likely to trust that an organization is honest and takes responsibility for its actions. It also allows an institution to demonstrate that they are able to improve. This is ideal, and it is

common for institutions to put out only the minimum information requirement.⁸⁶ Typically, the internal (within the organization) and external (for the public) reporting is the same in terms of requirements, and the two reports mirror each other, meeting the established guidelines set out by external bodies. However, it may be useful for organizations to consider providing a different type of report internally, to ensure that the information is valuable and applicable to the work of the institution's staff. A report may be general, but there should also be an effort to ensure that employees who are not performing adequately are given appropriate feedback to stimulate improvement.⁸⁷

In order to achieve the aforementioned internal improvements, additional resources may be necessary to allow staff members to self-report and for employees to practice skills.⁸⁸ With regard to reporting, a new method of encouraging staff to self and peer-report would result in errors or concerns being addressed sooner, and inspire staff to perform at their highest level.⁸⁹ By promoting that patient safety and quality care are of the greatest importance, it is hoped that physicians and nurses, for example, will strive to achieve success. Furthermore, including physicians and staff from various disciplines in the creation of programs for development of staff skills and knowledge would increase the quality of care, as these individuals would be able to provide insights from various areas of medicine and contribute first-hand accounts of the most beneficial services for patients.⁹⁰ Any new plan that is implemented to improve employee performance promotes accountability and sustainability, which leads to success.

The actual process of implementing new technology into a healthcare system is complex and involves numerous steps. It begins once a type of technology is proven to demonstrate some benefit to patients.⁹¹ Clinical trials follow, as they are the gold standard for testing the safety and efficacy of a new medication, procedure, or system. They allow organizations such as the Food

and Drug Administration (FDA) to approve new technologies with the highest certainty. The process should be able to provide information about the level of risk and potential side effects of the new technology. There must be evidence that patients will benefit from the new techniques and that it would be worthwhile for hospitals to invest in it.⁹² One issue with clinical trials is that they are extremely costly and require immense funding to ensure they are comprehensive, especially in the case of genetic therapies. Organizations such as Medicare may provide a certain amount of coverage for clinical trials that demonstrate some promise of success, but their prevalence will also depend on public and private policymakers and payers, as well as on government.⁹³ Another issue is that testing takes time, in order to ensure that the data are accurate and analyzed properly.

Once clinical trials have been conducted and have provided evidence that an emerging technology may be beneficial, a hospital or medical facility must decide whether they feel that its implementation would be advantageous. Certain criteria would have to be met and steps would have to be taken to ensure that the introduction of a new medical procedure or drug goes smoothly.⁹⁴ For example, a group of individuals, such as doctors, administrators, and nurses, would have to evaluate the accuracy, availability, and treatability of the targeted disease, as well as the cost of a technology, in addition to many other factors. Furthermore, pilot protocols could be created to test whether a specific policy regarding the use of the technology would function in a particular hospital system. Other steps, such as discussing staffing, standards of use, and confidentiality, would also need to be taken.⁹⁵ It would also be beneficial if an advisory committee were created to monitor the success and efficacy of the new technology in practice, with modifications being made as necessary. This would highlight the emphasis on patient safety and accuracy of medical care that are valued by the healthcare organization.⁹⁶

One of the most important factors for an institution to consider is the amount of risk or benefit that the new technology would provide. For techniques that target terminal diseases, the risk of dying from the illness would need to be weighed against the risk of death caused by the technology.⁹⁷ While some new procedures may be dangerous, they may not be more harmful than if no treatment was administered, making them acceptable for use. Clinical trials would provide some of the data for patient safety, but there would still be a need for continuous monitoring to ensure that patients are safe. Riskier practices would require more regulation and assessment.⁹⁸ Risk and benefit should be the most important contributing factors when deciding whether to endorse a new technology, and although financial gains or losses may play a small role, they should not be the driving force when making decisions for implementation.⁹⁹ For example, a new technology that has not had adequate testing may bring in significant finances for a hospital, but, ultimately, it may not be safe for patients. It would be unacceptable for an institution to offer unsafe procedures solely for financial benefit. The newest technology may not always be best technology.

In addition to hospitals having a responsibility to consider quality over cost, physicians also have a moral and legal responsibility to focus on care rather than economics when treating patients.¹⁰⁰ It would be worthwhile for hospitals to consider physicians during the process of implementation, as they are able to provide insights into how a new technology may benefit or harm patients. Medical professionals may feel marginalized if they are not included in the assessment and execution phases of this process. They may be able to advocate for individuals and provide expertise on medical gains, as opposed to the financial benefits or burdens with which a hospital board would be concerned.¹⁰¹ Physicians should also have the ability to decide on a case by case basis whether the newly implemented technology would be an appropriate

recommendation for their patient. In order to do so, a doctor must have adequate knowledge about the new technique and its implications.

If a new technology is chosen to be implemented within a healthcare facility, staff obligations must be considered, and proper education must be provided. This may include the preparation of information pamphlets that briefly explain the uses, techniques, risks, and benefits of a new procedure. It may also require that physicians, nurses, or technicians attend specialized classes that teach how the technique should be administered. Conferences that provide detailed information and examples of use may be beneficial as well.¹⁰² The education process may be expensive and time-consuming, but it cannot be bypassed. If it is, patient safety would be in jeopardy and legal challenges may arise, causing conflict.¹⁰³ It is crucial that staff feel comfortable discussing the new technology and its risks and benefits, and that they have the ability to decide whether it would be beneficial for a patient. They must also be able to perform the new procedure or administer a treatment with confidence and ease, which contributes to the trust between a physician and their patient.

In order for a new technology to be successfully put into operation within a medical institution, the previously outlined steps must be taken, and there must be a collaborative component to the process. Vertical collaboration between suppliers and vendors, and between providers, payers and purchasers is necessary. This system functions within the administrative side of a hospital and would make it possible for a technology to be accessible. There should also be horizontal collaboration between health systems which would promote partnership between institutions and may provide a wider access to the new technique or procedure. Cooperation and teamwork is preferred in order to improve information and learning techniques as well as ease of implementation.¹⁰⁴ There will also be a need for public and private policies. For example, there

may be a need for government involvement to approve technologies, but networks of stakeholders are required as well to provide funding for adoption techniques. Overall, numerous players would have to become a team in order for the technology to be introduced successfully.¹⁰⁵

Aside from the factors previously discussed, a medical institution must also consider and compare the benefits that a new technology would bring for patients, with the benefits it would bring to the organization. A successful balance between the two must be achieved. The initial introduction of a new technology may be based on public pressure. For example, media or research organizations may promote a potential new cure for a disease, such as the use of gene therapy. This may pique the interest of patients, who begin to inquire about the availability of these new techniques.¹⁰⁶ Physicians may also feel that it would be beneficial to offer certain new technologies to their patients, and begin to pressure the organization to consider their availability. Therefore, external as well as internal pressure may influence an institution to begin the process of considering a specific new treatment, and it may be worthwhile for hospitals to take a proactive stance with regard to increasing their usage of emerging medical advancements.

Part of the public pressure to introduce new technologies may come from patients who are seeking more innovative treatments for their ailments and illnesses. Along with innovation, they are also looking for expertise and security. It is known that patients rely on medical professionals for the most accurate information about healthcare interventions.¹⁰⁷ While family, friends, or the media may contribute to a patient's knowledge about medical treatment, a physician is considered to be the most trustworthy source of communication, as they would ideally have a relationship with their patient. Individuals would like honest information about the side effects and evidence of success for a new technology, and depend on healthcare institutions

to provide them with it. For this reason, it would be beneficial for a hospital who is implementing new procedures to educate their staff about the new technique, even if it is costly. Patients feel that having the most advanced technologies is beneficial and would increase the quality of their healthcare, but prefer to know all the necessary information in order to weigh the risks, benefits and potential effects on their lives.¹⁰⁸ For the sake of the patient, and to increase trust in the medical system, hospital staff must be informed.

Pleasing patients is an important component of a successful healthcare business. Promoting new technologies through informed staff is one method of doing so, but having new technologies also serves the purpose of making a hospital competitive. Competitive markets in healthcare do not always focus on which organizations make the most money, but, rather, on which have the most advanced technology in order to provide the most appropriate treatment for their patients.¹⁰⁹ Patients are frequently willing to pay more in order to have access to better care, which can include access to new techniques or procedures.¹¹⁰ A hospital may wish to be competitive, but it must also consider what would happen when a patient seeks care, but is unable to afford the new technology. Would their care be of a lesser quality simply because of their economic disadvantage? The current American healthcare system accommodates cases like this, but it would be unethical to deny a patient access to life-saving healthcare even though they are unable to afford it, especially in a hospital that is advertising these advancements.¹¹¹ Furthermore, not all technology is beneficial, although it may have been newly developed. Organizations must focus on quality as opposed to quantity to make sure that its patients have access to the best care possible.

One example of an emerging technology that is beginning to be implemented is telemedicine. This may include electronic meetings and exchanges of information between

patients and their physicians. This method of consultation may be beneficial for specialists, who would be able to see a patient's home environment, for example, or to monitor a patient's progress if they are immobile. It may also be a useful tool for record-keeping, in that a physician or a patient would be able to re-watch a meeting to repeat and confirm information. However, telemedicine may prove to be difficult, as it would require additional training for physicians, and may run into common technical difficulties. It also removes, somewhat, an important aspect of the doctor-patient relationship – the human interaction portion, which can improve the relationship and make it more personal.¹¹² A physician may seem distant if they are communicating with a patient by means of a screen. For this reason, telemedicine may not be suitable for all medical disciplines, but may provide benefit in some areas. An evaluation of its uses is necessary for the highest level of success to be achieved.¹¹³

iii. Organizational Value Conflicts

Organizations, including hospitals and healthcare institutions, must be rooted in a set of values that reflect their goals.¹¹⁴ A mission statement or value statement reflects the organization's guiding values and principles, and encompasses the primary function of the institution. In medicine, providing care to patients is the most prevalent value, but a mission statement may also specifically describe religious, research, or community-based outreach.¹¹⁵ These principles encourage stakeholders to hold the organization accountable, and to ensure that the delineated values are being upheld.¹¹⁶ By insisting that all systems, policies and employees consider and follow these guidelines, ethical decision-making that corresponds with the healthcare institution's goals should prevail and create a positive moral culture.¹¹⁷ This also implies that any procedures or interventions within the hospital are in accordance with these values and are considered ethical.

In order to achieve this high standard and an ideal moral culture, organizational decision-making or moral reasoning should be influenced by the values outlined in the value statements described above. Within hospitals, effective moral reasoning can be implemented at a high level, influencing the creation of policies to reach goals and uphold values.¹¹⁸ If the systems, which all work dynamically to ensure a successful medical organization, reflect the values of the hospital, ethical decision-making should, in theory, be guaranteed, which enforces the morality of the institution itself. However, there is always room for error, even if a system or policy is created with specific ideas in mind. When a system fails or promotes an unrealistic message or goal, there is a chance that the individuals who are responsible for implementing the policy, as well as the method of decision-making that is being promoted, will not be able to uphold the core values of a moral organization.¹¹⁹

While the moral culture within an organization should reflect the moral agency of the institution, the moral culture outside of the facility should also be considered, as it can influence the internal culture. A healthcare organization and the community it serves are dependent on one another, as they are both striving to achieve their respective goals: a community member is in need of medical care, while the hospital, needs patients to remain open.¹²⁰ The moral culture of the community can be influenced by outside factors that are not associated with a healthcare institution, such as religion, resources, or age. These factors may not be included among the specific values of the corresponding medical center, but should be considered when tailoring care to a specific community.

In an ideal situation, the multiple departments and systems that make up an organization and reach out to its community are rooted in established values. This encourages the employees of the institution, as well as the public, to associate the organization with ethical and value-based

practices. As a result, a positive moral culture is created that upholds the agreed-upon ethical principles within an organization. A moral culture is directly influenced by the moral reputation of an organization.¹²¹ For example, hospitals must provide services to their local communities, but it is evident that some hospitals have a better-perceived moral standing than others. The moral culture of medical centers that are regarded more positively for any reason, the higher their moral culture is considered to be. This implies that the hospital is acting in line with their organizational values, and aligning more closely with the moral culture and values of a community.¹²² A moral culture may become negative, however, if decision-making about policies becomes unethical or unregulated. It still exists, but it will transition to one which may not be in accordance with the values of the patients it serves or the established goals and mission. This increases risk to patients and jeopardizes the moral identity and reputation of the organization.

If there is a shift from a positive moral culture to a negative one, as described above, the moral agency of an organization will also change. Any modification to the internal systems or the general moral culture within an institution will fuel a cycle of constant change. For example, if a hospital were to approve a policy that upholds its organizational values, the moral culture of those abiding by the policy will reflect achievement. However, if employees begin to deviate from the policy and dispute it due to mistrust, the moral culture at that level will be negatively influenced causing a shift, which will continue to change at other levels within the organization. As a result, a new system or a modified one will emerge, causing the organization to re-evaluate its values and goals or emphasize the need in a policy modification.¹²³ While it may not result in a change in procedures, there may have to be a re-evaluation of how the systems within an organization contribute to a moral culture that aligns with the values established initially.

When introducing any new medical intervention, hospitals and medical facilities must evaluate whether the advancement fits into their moral culture and aligns with their core values. A new technology may be beneficial to patients with a specific ailment, but it may have ethical concerns associated with it that do not correspond to the culture of the institution. All employees have a responsibility to uphold the mission and belief system of their organization, and should advocate against an intervention if they feel it should not be practiced. Nevertheless, new interventions should be considered in great detail, to ensure that patients have access to life-saving medicine. There may be solutions or modifications that can be made to a new procedure, for example, that would allow it to be performed, even if it does not fit completely into an organization's value system. An example of this type of procedure is physician-assisted death, as described in the previous chapter. It is up to each institution to consider these implications and understand how medical advancements may or may not contribute to their moral culture.

Conscientious objection allows healthcare workers to object to a treatment or procedure if it is contrary their own personal beliefs and would violate a deeply held moral value. In some situations this can include religious practices, such as a physician not performing abortions, or it can include a nurse not wanting to participate in care for a brain dead patient whose family refuses to withdraw ventilators.¹²⁴ Conscientious objection requires an individual or an institution to determine that a certain medical intervention is morally wrong and that it would damage their integrity as a person or organization.¹²⁵ When an organization is considering medical advancements, they must reflect upon their values in order to decide whether there is a need to object. The institution must also insist that its employees always have the option to conscientiously object to interventions that they find morally unacceptable, but it cannot abandon or place the patients and communities they serve at a disadvantage.

If medical organizations do not promote this option to object, its employees may experience moral distress. This circumstance can occur at an individual, team, administrative, or organization-wide level. Personal moral distress can arise when an employee either witnesses an event that they personally feel is unethical or wrong, or when they are required to perform an activity or procedure which they do not believe to be an ethical one.¹²⁶ Either of these situations may not be immediately addressed in environments in which speaking up about an issue is not encouraged, and the tension can build up, causing more damage.¹²⁷ Within an ideal moral culture, all employees should be able to exercise conscientious objection if they have a personal disagreement with a procedure, and should not hesitate to speak to a director or administrator if they feel uncomfortable with an issue or event in the workplace.¹²⁸ The accumulation of conflict negatively affects the moral culture within an organization, and can damage a system as well as the integrity of an institution. The best solution is to promote effective communication in order to solve problems efficiently and effectively.¹²⁹

Organizations have a responsibility to ensure that its employees are able to make autonomous choices, but it is also an institution's job to monitor the reasons for conscientious objection. For example, a physician may 'conscientiously object' to treating a particular patient, because of their race or ethnicity, which is not exercising objection for moral reasons, but, rather, as a result of a discriminatory opinion. These views are not tolerated in modern healthcare and must be discouraged. It is crucial that organizations educate physicians with regard to their rights, which include conscientious objection, but also promote their responsibilities and duties, and implement methods through which their services can be executed effectively. For example, if doctors are aware of certain procedures that they are unwilling to perform, it is their duty to explain to their patients how they feel and to refer them to someone else. By engaging in this

conversation early on in a patient-physician relationship, there is more time to address an issue, and ensure that a patient is able to procure an intervention with which they would be comfortable. It should also be noted that organizations have a role to play to ensure that the integrity of individual employees is upheld, which can include having records of which physicians are willing to do specific controversial procedures, or those that have associated ethical concerns.¹³⁰

Genetic advancements will be discussed in detail below, but are mentioned here as examples of how conscientious objection may be exercised in practice. It can be assumed that individuals who have a moral problem with genetic manipulation or embryonic research would not choose to work in fields of medicine that deal with these areas of interest. However, many individuals who feel that pre-implantation genetic screening is immoral due to the possibility of embryo destruction, for example, do become obstetricians or work in the field of reproductive medicine. These employees have the right to practice conscientious objection, which would allow them to withdraw from a particular case, but it does not preclude them from providing all of the necessary information to their patient. They do not have the liberty to choose which options they present, as those would then only correspond to their own personal values and not the values of their patient. This distinction is important to make in order to ensure that patients are being treated with respect and are able to make autonomous decisions. To avoid any conflicts, physicians should be honest with their patients and disclose any objections they have prior to taking on a new patient.¹³¹

Conscientious objection can also apply to an entire institution. The best example of this is Catholic healthcare systems and hospitals that do not provide certain medical treatments or procedures because of religious belief.¹³² These organizations are very forthcoming about their

beliefs and will explain why they are unable to perform various procedures. Facilities such as these conscientiously object to interventions such as abortion and sterilization, which they believe to be morally wrong since they would cause great moral distress. Although these procedures are legal in the United States, these institutions have permission to uphold their religious values. However, these organizations also have a responsibility to cooperate with public policy about specific healthcare interventions, and may, at times, have to compromise with regard to how a technique is implemented. This may also include referring a patient to another facility that is secular and willing to perform a procedure.¹³³ However, these hospitals must also exercise caution when an individual's life is on the line.¹³⁴ For instance, an indirect abortion may be performed if it would save a woman's life. These organizations have a greater responsibility to balance their beliefs with the safety of their patients.

iv. Cost of New Genetic Technologies

An example of promising medical technology that is gradually being introduced into the healthcare system is gene therapy. Gene therapy could be used to reverse a multitude of diseases, such as forms of cancer, haemophilia, and HIV. The process is conducted through the introduction of vectors by way of a virus into a patient's body with the hope of modifying their genetic material, making it resistant to the targeted illness.¹³⁵ This therapy specifically focuses on attacking the cause of the disease, and not its symptoms, and if successful, could be curative. However, while there are predicted benefits, there are also many known risks. For example, gene therapy may result in dose-related toxicity and neutralization of antibodies, in addition to other side effects specific to each procedure.¹³⁶ Since genetic material is being manipulated, there is an increased level of risk for patients undergoing this treatment.¹³⁷ However, for many patients, there are no other successful treatments available to them, making gene therapy worth the risk,

and worth the extremely high cost. Experimentation with gene therapy is in its infancy, but it is progressively demonstrating promising results for treatment.

Since gene therapy is a relatively new technology, its implementation into healthcare has been limited. Clinical trials are the main source of access to such therapies. The number of trials has spiked in recent years initially due to the approval of a particular therapy in Europe, used to target Familial Lipoprotein Lipase Deficiency (LPLD). Between 1989 and 2020, there have been over 2000 research trials involving gene therapy, demonstrating an increasing interest and optimism in its success.¹³⁸ Clinical trials are extremely important for gene therapies, since they are able to safely monitor the efficacy of the procedure, as well as determine its risks and benefits. However, many trials attempt to publish their findings quickly to satisfy the demand for innovative treatments. This is not beneficial to patients, who could be at risk as a result of immature evidence of effectiveness.¹³⁹ It is crucial that clinical trials also focus on long-term feasibility, success, and risks associated with the therapy. This may be time-consuming, but would provide more accurate results and findings that promote patient safety.¹⁴⁰ It is also important to discourage the discontinuation of trials for reasons not related to efficacy. For example, it seems unacceptable to terminate an experiment as a result of a lack of funding, because the work being done is so valuable to patients. These are extreme circumstances, but there is a fear that if trials end prematurely, the information gained will disappear and never benefit anyone.¹⁴¹

In the course of experiments (if they occur in the medical facility) or once clinical trials are completed, it would be necessary to apply the steps outlined above to the process of implementation. Primarily, an organization would need to be certain that the appropriate staff was highly trained in gene therapy techniques and had the ability to discuss the implications with

their patients. This may require the creation of skills clinics in order to teach physicians and technicians how to perform techniques, as well as how to analyze results. It is expected that researchers who are conducting the clinical trials would be able to share their knowledge with their colleagues; in order to make the technology widely available, and to reduce some costs.¹⁴² Furthermore, a hospital may choose to create a separate genetic clinic once gene therapy becomes more developed. This would provide patients with a specific clinic to attend with the expectation that its entire staff is experienced in the highly advanced technique. This would be a goal for implementation in the future, once gene therapy is more widely used and becomes more beneficial.¹⁴³

Although gene therapy shows immense promise in treating and curing disease, the most significant issue preventing its full realization is its high price. In general, a factor that affects almost all decisions about the implementation of new technologies is cost. Medical advancements are often expensive, and it can be difficult for clinical trials to occur due to low funding, in addition to difficulties with wide-spread introduction and accessibility. In the current healthcare climate, insurance covers the vast majority of basic healthcare, but coverage for new and potentially experimental technologies could be challenged. Medicare covers some clinical trials that demonstrate a suitable promise of success, and they are also willing to cover the costs when patients are participating in research trials.¹⁴⁴ However, coverage for clinical care may differ. Separate criteria may be necessary to outline which individuals would receive coverage for new technologies. This may include patients suffering from the targeted diseases with no other treatment options available. The amount that a health plan pays for a new advancement may limit its accessibility to patients. If no one is able to afford a new treatment, it may not find

success.¹⁴⁵ For this reason, hospitals must try and find methods of reducing the cost of technology so that it becomes available to a higher number of patients.

Gene therapies that are on the current market cost anywhere from hundreds of thousands of dollars up to \$2.4 million for a one-time treatment.¹⁴⁶ As a result, there is fear that individual patients will not be able to afford this life-saving technology. One way to promote the use of gene therapies, despite their costs, is to consider their effect on someone's overall use of health care resources. While other treatment methods may exist for a disease, such as haemophilia, a gene therapy that would eliminate the disease would be ideal for a patient in the long run. When compared to the amount of money a patient will spend on ongoing treatment, undergoing gene therapy may actually be more economically feasible than paying for medical interventions for an entire lifetime. For example, haemophilia patients spend about \$20 million during their lifetime for treatment, but would only spend about \$1 million for gene therapy once it becomes available.¹⁴⁷ Nevertheless, the amount is still extremely high, and payment strategies must be created to relieve patients of this financial burden. For example, Kleinke suggests the possibility of a healthcare mortgage that would allow a patient to pay for a treatment over time.¹⁴⁸ Tiered pricing may offer another solution, since the price of a procedure is based on the patient's income.¹⁴⁹ Insurance coverage may be possible if gene therapy proves to be able to cure common diseases, such as Parkinson's or Alzheimer Disease, but would still require significant changes to the models that are used today.¹⁵⁰

Further cost burdens arise for patients who are using gene therapies to cure rare diseases, such as LPLD mentioned above. Patients with these illnesses still warrant treatment, but finding a way to pay for an expensive treatment that can only be offered to a select number of individuals may be challenging. In spite of this, patients with rare diseases might also be willing

to pay more for a treatment, especially if other interventions do not exist. They would be eager to try a specialized new treatment that would bring them relief.¹⁵¹ In these situations, it would be difficult for a payer (i.e. the patient or their insurance coverage) to pay for the procedure in its entirety at the beginning of the procedure and, as was discussed, new methods of payment would need to be created. Carr suggests an annuity-style payment model that would spread a payment over time of efficacy. For example, if a gene therapy is expected to cure a disease, there would be more time to pay off the procedure, but if it was only predicted to bring relief for five years, the payment period could be longer. Furthermore, if a gene therapy is not effective in these situations, the manufacturer or research institution might be expected to reimburse a patient for unsuccessful treatment.¹⁵²

Glybera, the world's first approved gene therapy was previously approved to target LPLD, and cost approximately \$1 million for a one-time treatment. The treatment disappeared from the market, however, because it was not profitable. There is currently no available treatment or cure for this condition, and the approval of Glybera brought hope and relief to patients suffering from LPLD. Only one sale of Glybera was completed in Europe, and it never became available in the US or Canada, which has the highest number of patients living with LPLD.¹⁵³ This demonstrates the need for effective cost solutions to ensure that patients have access to life-saving treatments. Currently, the National Research Council of Canada has begun a study to determine whether a new version of this treatment can be revived at a lower cost.¹⁵⁴ Solutions and innovation will be required by governments, researchers, health systems and individual organizations in order to make these treatments accessible.

Overall, pricing for gene therapy will be challenging, as it currently costs more than most other available interventions. However, the more advanced this technology becomes, the lower

the cost will eventually be. An example of this type of process is the sequencing of the human genome. In the past, this process was extremely expensive, but it has now lowered its cost due to scientific advancements and efficiency.¹⁵⁵ Ideally, a decrease in cost would also occur in the case of gene therapy as it becomes a regular practice in medicine. Moreover, gene therapy has the potential to provide cures for many illnesses, and would be a valuable treatment option that many people will want to access. It would be extremely worthwhile for academic institutions, private foundations, biotechnology companies, and hospitals to invest in this technology and allow its researchers to improve their technique in order to save the lives of countless patients worldwide.¹⁵⁶

The same line of thought can be applied to the eventual use of CRISPR, or Clustered Regularly Interspaced Short Palindromic Repeats.¹⁵⁷ Its use can lead to the elimination of specific diseases associated with a gene, such as Cystic Fibrosis or AIDS. The CRISPR-Cas system is beneficial because it allows for multiple genes to be targeted at once, as many diseases have been discovered to affect more than one genetic sequence.¹⁵⁸

It is necessary to discuss the CRISPR/Cas-9 system because it will inevitably become a part of standardized medicine and available treatments in the future. This method of gene editing shows immense promise for eliminating specific diseases from society, such as malaria and various forms of cancer.¹⁵⁹ This may be done through somatic cell gene therapy, such as the described gene therapies, but it may also be accomplished through germline modifications. While there are numerous risks and ethical concerns associated with this practice, the predicted benefits may outweigh them.¹⁶⁰ CRISPR is considered to be a revolutionary technology, one whose consequences are unpredictable, but whose benefits may be astounding.¹⁶¹ Currently, the CRISPR technique is the most accurate method of gene editing, and achieves its job in the

quickest way, significantly reducing the time it takes to complete experiments. For this reason, many scientists consider CRISPR to be the gold standard of techniques for gene modification, and expect that research regarding gene editing will continue.¹⁶² It is important, therefore, for institutions to prepare for the future and establish a plan to manage and employ such new and emerging technologies.

It has already been pointed out that gene enhancement using CRISPR has seldom been achieved in human embryonic cells, but research using animal models is being conducted. As with any new technology or procedure, clinical research must be done initially to explore the technique's effect on other species, and to predict its safety and efficacy in humans. Once enough evidence has been gathered, clinical trials can commence in order to properly test the method in human beings.¹⁶³ Clinical trials using CRISPR will involve an immense amount of risk, since future generations will be affected if the germline is modified. While this may be considered beneficial if specific diseases, such as Huntington's, are eliminated, we should also keep in mind that future generations will not have consented to having their genome scientifically manipulated, which raises ethical concerns. Only after these concerns are addressed and clinical trials have begun, can the notion of distribution begin to be discussed. Clinical trials are expected to last approximately 15 years for CRISPR, and it may require hospitals and medical institutions to work alongside researchers to monitor patients and allow them to have access to this experimental technology.¹⁶⁴

Teamwork is crucial in order to promote safe distribution and introduction of CRISPR within society and healthcare institutions. The concept of solidarity is often discussed with regard to scientific research, as many experimenters feel that if a technology is able to provide benefit to the general public and improve the general condition of humanity, it should be the

primary goal, as opposed to financial gain. Solidarity among researchers, clinicians, and research participants is essential to further the common good. This encourages participation in research, and leads to a common core of values.¹⁶⁵ Although this notion of solidarity is important, it may be unrealistic within the framework of a society that has polarizing views about the CRISPR technique, but it should still be a reasonable goal toward which to strive.¹⁶⁶ Ideally, the quality and potential for successful healthcare should be the ultimate goal.

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Chapter 6: Genetic Therapy and Gene Editing

Gene editing is quickly becoming a promising method of combating illness. Gene therapies, like the ones mentioned previously, employ gene editing techniques and demonstrate favorable results in treating diseases such as cancer or sickle-cell anemia. It is expected that they will continue to exceed our expectations by helping to discover a cure for many other medical anomalies.¹ In order to better understand the global effort of the CRISPR-Cas9 technique, ethical issues that arise should be addressed, alongside advancements in science. Genetic modification is gradually becoming a medical reality as a result of numerous scientific breakthroughs in gene editing that go beyond editing for disease elimination. As it becomes possible for researchers to alter or edit an embryo's genome through germline modification, the possibility of genetic enhancement will become more plausible. Genetic enhancement may then lead to transhumanism, the introduction of post-humans, who possess augmented capabilities, and are designed to be superior versions of currently existing human beings. Will a new set of human rights be in order? Should we fear these new developments, or embrace the future that may be in store for us?

A: Gene Therapy and Gene Editing

The basic elements of gene therapy and its utilization of the CRISPR-Cas9 editing techniques must be examined before exploring the future of this technology. A brief history of gene editing methods will be presented, along with a summary of current and expected research projects. A distinction between somatic cell gene therapy and hereditary cell gene therapy must be made and their corresponding ethical concerns will be explained. Finally, prospects for the future will be discussed, including the oversight that will be both necessary and expected, as well as the potential for human enhancement beyond medical needs. Gene editing has the potential for

extraordinary accomplishment within the field of medicine, but its use is accompanied by a unique set of ethical questions that must be considered and addressed.

i. Uses of CRISPR-Cas9 Technique in Practice

Historically, gene editing has been occurring for many years, but the process has been tedious and time-consuming. The discovery of the CRISPR technique has drastically changed the editing landscape, making the task easier and more efficient.² Research into previously-used methods, as well as studies using CRISPR, have elevated scientific discoveries, and have the potential to bring about success. However, safeguards must be put into place to ensure research remains ethical as well as promising.

Before the discovery of the CRISPR-Cas9 system, other techniques were and still are being used by scientists to try and manipulate genes. These methods, which target protein recognition, use meganucleases, zinc finger nucleases (ZFNs), and transcription activator-like effector nucleases (TALENs) to target specific genes in order to modify their genetic makeup. Such techniques are being studied as new methods of gene therapy. These studies, however, are very expensive and time-consuming, which puts both scientists trying to make advancements, and patients who are desperately waiting for medical treatments that do not yet exist at a disadvantage. Although CRISPR is considered a solution by some experts, the research using these other techniques should continue, as they exhibit strengths that CRISPR does not. For example, TALENs are better suited for specific gene editing, such as repairing or inserting a mutation, and are more effective than CRISPR at doing so. There is a possibility, however, of combining any of the mentioned techniques with the CRISPR-Cas9 system in order to reap the most benefits.³

CRISPR, or Clustered Regularly Interspaced Short Palindromic Repeats, is so far the simplest and most cost-effective mechanism for gene editing in mammalian cells. Researchers found that CRISPR acted as a defense mechanism in archaea and bacteria to fight off viruses, and was altered in order to be applied in human or mammalian cells.⁴ As described in the previous chapter, CRISPR itself is made up of repeating DNA sequences and associated genes that can make proteins which act as scissors with the ability to make cuts within certain targeted gene sequences, and subsequently insert a modified sequence in their place. A new sequence can instruct the cells in a body to act differently, thereby eliminating or reducing symptoms of a certain disease. The efficiency of this mechanism is highly beneficial since geneticists have identified that multiple genes affect diseases.⁵ Currently, research is being conducted on both somatic and hereditary cells, although the latter is only being done ex-vivo in embryos, in accordance with regulations for embryonic research.

As with any scientific method, there are challenges to be met. With CRISPR/Cas9, there is a significant risk of off-target mutations occurring when the Cas9 protein cleaves identical sequences that are not originally targeted to be removed. This could result in mutations or cell death. Furthermore, it is difficult to produce guide RNA (gRNA) that steers the proteins to the intended sequence to be modified.⁶ These difficulties arise due to the sheer size of the Cas9 protein and its guiding RNA, which is unable to fit inside small human cells. There are solutions being tested to eliminate this issue, such as using a smaller gene to encode the Cas9 enzyme. A specific gene that encodes Cas9 in *Staphylococcus aureus* was smaller than that of the gene used previously. Along with RNA, it was added to a virus called AAV, which is used to transport new genes into existing cells, and proved successful.⁷ Solutions like this may provide scientists with methods of improving the CRISPR system in order for it to be more successful in human cells.

Each cell in the human body contains copies of DNA that were inherited from one's parents. During cell replication, alterations to one's DNA can occur and those mistakes may not be caught by the body's self-editing system. If multiple genes have some sort of alteration, they can each lead to the emergence of a disease, such as cancer or haemophilia.⁸ Diseases that are caused by one single mutation are easier to target, as opposed to disorders that are created by multiple gene mutations which all contribute to an outbreak.⁹ By modifying the genetic material of somatic cells, it is ensured that the next generation will not be affected by the changes that were made to an individual's genetic code.¹⁰ Somatic cell gene therapy is often referred to as simply 'gene therapy' and from this point forward, gene therapy will only refer to the somatic cells being affected.

In order to alter the genetic material within a cell, viral vectors are introduced into the body that are programmed to attack and modify specific targeted cells. The targets are the cells that are causing a disease, and by 'turning off' the genetic instruction that allows an illness to develop, it is hoped that a disease will be eliminated.¹¹ Traditionally, this is done through gene replacement, but the use of CRISPR has given scientists the capability of simply editing a gene, which is thought to be more specific and effective in eliminating the problem.¹² Many conditions are a result of multiple genetic errors, making it difficult for researchers to introduce a virus that targets all aspects of a disease. However, advancements are being made that are proving that this may be possible in the future.

Unlike somatic cell gene therapy, which allows an individual to decide whether to manipulate their genome for themselves, heritable genome editing requires prospective parents to choose a specific genetic path for their future children.¹³ While the techniques are similar to somatic cell gene therapy, there are differences, and hereditary gene therapies have more

significant ethical questions associated with them that must be answered before proceeding with treatment.

Hereditary gene therapy uses similar techniques as somatic cell gene therapy, primarily CRISPR, to modify the genetic material in cells that make up an embryo. This changes all of the cells of that organism, and would continue to be passed on through multiple generations. This type of gene therapy requires that embryos be created and then manipulated ex-vivo, by editing out a specific marker, such as one for Huntington's disease. An embryo with an altered genetic makeup would then be implanted into a uterus with the hope of development. This type of treatment is specifically useful to target multiple tissues or cells that may cause a specific illness, such as cystic fibrosis.¹⁴ While somatic gene therapy is useful when targeting one location, hereditary therapy would have greater control over more areas before they develop, and can, therefore, influence the future development of those tissues or cells to ensure that a mutation is non-existent.¹⁵

With any new scientific technique, an appropriate course of research must be conducted in order to allow the new method to be safely incorporated within hospitals or medical systems. In the case of CRISPR and gene therapies, research is primarily being done in laboratories, using pluripotent stem cells or somatic cells.¹⁶ Only recently have embryos been allowed to be used for genetic research, and protocol states that embryos must be destroyed after a few of days of development.¹⁷ This ensures that embryos are not able to develop enough to be implanted into a uterus to become a human being, although it is expected that this course of study will reach that point in the future, as illustrated by the case of Dr. He, which will be reviewed below. In addition to embryonic safeguards, which are determined by the state, regulations exist that stipulate what type of research can be done. A clinical trial can be conducted after successful

laboratory results, with oversight from an institutional review board (IRB), and afterwards, the treatment, if effective, can be submitted for approval to the Food and Drug Administration (FDA).¹⁸ At that point, the therapy is able to be used across the country in medical centers.

This entire research process is in its infancy with regard to gene therapies using CRISPR. While few studies have progressed beyond the initial lab research phases, some studies have emerged that have demonstrated success. Physicians successfully used CRISPR to alter T-cells in patients with leukemia, and this treatment, known as CAR-T, has been approved by the FDA as a quicker and more effective cure for the disease. While it is not a complete cure, the patients who did receive the altered T-cells went into remission. This treatment may seem effective, but the long-term effects are unknown, and it would cost a patient hundreds of thousands of dollars for a single treatment.¹⁹ This method of altering T cells in order to treat certain types of cancer is also being used in a variety of other clinical trials, with the CAR-T treatment. For example, researchers at the University of Pennsylvania used CRISPR to knock out the CD5 gene in mice in order to inhibit its activation. This caused a reduction in tumor size, higher levels of T-cell proliferation in their blood, and demonstrated better survival outcomes compared to mice without the edited T-cells.²⁰ The success of this work makes it clear that the use of CRISPR-Cas9 in somatic cells is crucial for the development of effective treatment and disease control.

The first in-human trial using CRISPR has also begun in 2020. Patients with Leber's Congenital Amaurosis 10 (LCA10) benefit from gene editing that aims to remove the mutation in the *CEP290* gene that causes LCA10, which currently has no effective treatments, and is the leading cause of blindness in children.²¹ This is also the first time that CRISPR is being used in-vivo; scientists are inserting CRISPR directly into the patient's eye, as opposed to editing the genes in the lab and then re-inserting them into patients.²² Other studies are also in progress,

many of which are actively recruiting eligible participants. Researchers are frequently targeting diseases which have known genetic causes and which would be helpful to a significant number of patients.²³ As previously explained, it is more difficult to gain funding and support for a potential treatment that would only be useful to a miniscule percent of the population, making CRISPR appropriate. For example, many of the trials are studying cancer, as well as eye, skin, and liver diseases. Blood diseases are also being closely researched.²⁴ There are trials specifically aimed at reactivating fetal hemoglobin in blood stem cells, which would alleviate the symptoms of diseases, such as Sickle Cell disease or Beta Thalassemia.²⁵ It is evident that the number of clinical trials using CRISPR in somatic cells is increasing, which holds a great deal of promise for a variety of medical treatments and practices.

Scientists in Oregon have also performed the first successful gene editing using CRISPR on human embryos that solved previous problems of incomplete or off-target editing. While this is not directly linked to a clinical trial, the improvement of the technique to combat those issues demonstrates that it could be successful in future medical applications.²⁶ Other research has been conducted targeting hereditary cells in embryos, but due to strict restrictions in the many countries conducting the research, the embryos have been destroyed before development or implantation.

The one known exception to this happened in China in 2018. This dissertation has mentioned the work of Dr. He Jiankui, who announced that he had successfully implanted embryos that had been edited using CRISPR-Cas9. Dr. He's experiment was internationally condemned due to the perception that ethical and safety concerns were not addressed or considered.²⁷ Dr. He attempted to edit the *CCR5* gene, which is linked to the prevalence of a specific strain of HIV. By knocking out the *CCR5* gene, HIV would not be able to enter the white blood cells in the body, thereby

eliminating the chance of inheriting HIV from a parent. The goal was to manipulate the embryo early in its development so that the germline would be changed in any fetuses that develop successfully. The CRISPR-Cas9 protein was injected into the embryo with the intention of causing a 32-base pair deletion in *CCR5* which is found on Chromosome 3.²⁸

Dr. He's clinical trial recruited couples where the male had HIV, and the couple was interested in having a child who would not inherit the virus. It was disclosed that eight couples agreed to participate, and one eventually withdrew. A total of 13 edited embryos were implanted and 2 of the women in the trial got pregnant. One woman gave birth to twins, resulting in Dr. He's announcement and the world's attention. The other woman's progress or status has not been disclosed.²⁹ The twins, however, demonstrated that this process is not perfect and the results are not guaranteed. In one twin, CRISPR only edited 1 of the 2 chromosomes in a pair so that some of the cells would express *CCR5* in reduced amounts, which could still lead to HIV. In the other twin, both chromosomes in the pair were altered, but only some of the cells had this modification, making the twin a mosaic, where cells in a person's body have different DNA. This result indicates that CRISPR did not work as planned.³⁰ Dr. He's story is also filled with many gaps and has been questioned by scientists, academics, and ethicists around the globe. The ethical concerns involved in this research will be discussed below.

It is evident, based on Dr. He's work in China, that the genetic modification of hereditary cells is a fast approaching possibility for parents, and if successful, it will become a technique which they may be able to use to ensure that their future child is not burdened with a specific disease. Parents may choose to use this technique for this reason, as well as to eliminate economic or emotional burdens that accompany a debilitating illness.³¹ While the benefit of eliminating a disease for multiple generations may seem ideal, there are also known risks, as well

as undetermined consequences that may occur, due to the novelty of this new technique. Parents must be aware of potential risks and consequences associated with the elimination of a disease as they make their decision regarding the implementation of genetic modification. While there are alternatives to hereditary genome editing, such as not having children, pre-implantation genetic screening, or selective abortion of affected embryos, this hereditary gene therapy seems to be the most effective if a parent wishes to have genetically-related children, and does not want to destroy an embryo or terminate a pregnancy.³² It would still require individuals to use in-vitro fertilization (IVF) to harvest embryos, which poses its own risks, but they may seem minimal compared to the birth of a healthy child free of a specific disorder or disease.

ii. Organizational and Ethical Oversight

There have been many ethical concerns about gene editing, whether somatic or hereditary genes are being modified. It is clear that the bioethics and science communities have doubts about the ‘right’ way of conducting this type of research, but it is evident that somatic cell gene editing is more accepted, supported, and promoted, because the associated ethical issues can be resolved. All of the previous chapters of this dissertation have described ethical issues that should be addressed in the near future so that somatic cell therapies can become more acceptable and available.

A medical treatment that only affects an individual and not their descendants evades the issue of advanced consent regarding hereditary gene therapy. A patient who seeks out gene therapy should be making an autonomous decision based on their beliefs and values. Somatic gene therapy is often preferred to hereditary therapy, simply because the patient is the only one affected and only their autonomy is relevant. If they give consent, further questions or concerns do not need to be addressed with regard to others being affected by this medical decision.³³ Of

course, a patient must be deemed capable of making a decision, or they have to be of the age of majority, in countries with that requirement. In research with children, parents would be required to consent to gene therapy on behalf of their child, but they are expected to act in the best interest of their child and to protect them from a situation of high risk without high benefit.³⁴

Regardless of whether a patient or their guardian is making a decision, one must consider if gene therapy, and participation in a risky research trial is the best option. It is important to weigh the risks and benefits as well as make a comparison with other available treatments in order to determine which course of action would be most beneficial.³⁵ For example, cancer treatments such as chemotherapy or bone marrow transplants are fairly common, but bring risk and uncertainty along with any benefit that may occur. Gene therapy may be an alternative that is significantly less invasive and painful, with better results.³⁶ This type of decision is difficult to make, however, because there is little research published on gene therapies that demonstrates positive results, therefore, pursuing a medical treatment that is in its infancy can be problematic.

Researchers have a responsibility, as the fourth chapter of this dissertation explained, to take additional precautions when working with vulnerable populations, especially ones who are suffering because of their disease-state. Clinical trials have a duty to ensure that participants are not being coerced to take part, and that they have accurate information about the study. Gene editing therapies are new, and while they may be exciting and offer hope to people who in the past were not able to access effective treatment, they may not be as useful as is expected. Researchers must explain the risks and benefits of the treatment, as well as disclose that the intervention may not work. While this may discourage some people from participating, it does comply with all of the requirements for informed consent.

Gene therapy with somatic cells is much less criticized than research targeting hereditary germline edits, but some have questioned the effects of hereditary germline editing on humanity, and whether humans should be able to intervene in future generations. Some scholars are against hereditary gene editing because future generations did not consent to having their genomes genetically edited or to experiencing unknown side-effects.³⁷ Furthermore, Cwik brings up the concept of intergenerational monitoring. Because scientists do not know how future generations' genomes will be affected by hereditary cell edits, it would be in the best interest of research to follow up with second and third generations, from infancy to adulthood, of those who originally had their genes edited using CRISPR. This process would be extremely difficult, however, because all descendants of the original participant would have to provide informed consent, which they may not wish to do. There would also have to be systems in place to ensure confidentiality and privacy, especially for the information of those who do not consent to participate. Cwik also examines the concern about revealing to a future descendant the actions of their predecessor and the choice to edit their genes. This could be traumatizing, and also lead to familial abuse or exploitation. Precise mechanisms to address these issues must be in place, in order to protect the information and wellbeing of all generations who are involved.³⁸

It is also debated whether some genetic mutations, such as being a carrier of sickle cell anemia, might actually be beneficial, as demonstrated in geographic areas with high rates of malaria. It has been shown that individuals who have a mutation for sickle cell are actually resistant to the malaria virus, and this is commonly seen in people who live in certain areas of the world. Such benefits may be used to argue that not all elimination of genetic disorders is warranted.³⁹ Moreover, some may argue that disabilities that could be eliminated through the use of CRISPR, are actually just differences, and would enhance the life of the person who have

them. It is known that members of the deaf community feel that their disability is not, in fact, a disability at all, and may prefer their children to have this mutation. They may use a gene editing technique to alter the DNA of their future children to ensure that they will be members of the deaf community.⁴⁰

A primary ethical concern with regard to hereditary gene editing is how to balance individual benefits with social benefits, once children begin to be born with manipulated genomes. While individual children and parents may benefit, the utilization of this editing mechanism may cause social and cultural harm. There is a possibility that individuals whose parents did not use gene editing will be at a disadvantage, while others argue that this technique will become more accessible and will simply be another method of fighting disease, similar to vaccinations.⁴¹ In the United States, legal regulations and the Bill of Rights may be used in court to argue for or against using hereditary gene editing for a specific purpose. It is difficult to predict whether issues will occur, and how they may be argued legally, as well as if further regulations will be implemented that do consider the social implications of this technique, and, therefore, protect an individual who chooses to use it.⁴² Human dignity comes into question, as the uniqueness of individuals, natural components of life, and a lack of humility about the power of a person, are all debated.⁴³ This discussion also leads to concerns about eugenics and whether research ought to be done that could lead to a 'new human race.' The next section of this chapter will explore the concept of transhumanism and eugenics in detail, as well as the ethical issues that arise as a result of public anxiety over the implementation of these concepts.

Many of the ethical concerns discussed, both for somatic cell editing and for hereditary cell editing, can be contextualized in the case of Dr. He's scientific research using CRISPR-Cas9. Little genuine information is known regarding many aspects of He's experiment. The

information that is available may be unreliable, and various versions of his work have been publicly presented.⁴⁴ One significant ethical concern about He's trial was informed consent. Based on the consent forms that were available for public viewing, He's trial participants were not properly informed, despite researchers claiming that the process was done appropriately. The form was 23 pages long and was referred to more as a contract rather than a consent form. It also did not include much information about the CRISPR technique and the goal of implanting edited embryos. The goal of the trial was described as being the beginning of an AIDS vaccine development project, which is quite misleading. Furthermore, it is evident that the form did not include adequate information about the risks associated with the genome editing, the pregnancy, or the child after being born. Dr. He claims, however, that the verbal conversations with the participants was robust and did include this information, and that they understood the risks and benefits of the procedure.⁴⁵

It is also unclear how Dr. He weighed the risks and benefits in this study, and how he deemed the potential results worth the risk of going forward. Typically, when conducting research on a new technology, a researcher is expected to run many trials in the lab and use animal studies in order to determine as many risks and benefits as possible before beginning human trials. He claimed to have done immense research on animals and human embryos, but never published any findings. Furthermore, why He chose to focus on HIV and the *CCR5* gene comes into question.⁴⁶ When doing research, especially with vulnerable populations such as future fetuses and pregnant women, an investigator must determine whether there is a safer treatment that is available. In this case, HIV can be avoided in future generations through sperm washing and using IVF. This removes the seminal fluid and ensures that the potential offspring do not inherit the virus. However, in China, it is illegal for couples who have HIV to use

Assisted Reproductive Technologies (ART), making the option of gene editing more potentially appealing to the trial participants.⁴⁷

It is also known that HIV is a complex virus that is affected by many genes, not just *CCR5*, making it an odd choice to start with since there is a high risk that the future child could still inherit HIV. Some scholars have wondered, whether *CCR5* was chosen specifically, because there is some evidence that it affects cognitive abilities. *CCR5* is known to improve memory and allow someone to recover from strokes quicker than someone who does not have the same expression of *CCR5*. He's previous publications have explicitly stated that he does not support enhancement through the use of CRISPR, but the potential of cognitive enhancement still may have played a role in the decision to target this specific gene.⁴⁸

Furthermore, transparency was lacking in He's work, both before and during the clinical trial. It is unclear how He's research was approved, as many institutions have not agreed with the research taking place. There was also a lack of documentation indicating that this clinical trial was proceeding, which prevented monitoring by other academics in the genetics field, who could have prevented the pregnancies from going forward. Because of the near-consensus in the international scientific community that embryos should not be implanted after modification, it is evident that Dr. He's research would have violated many requirements about germline genome editing research. This calls into question He's integrity as a researcher, and whether an appropriate oversight procedure took place.⁴⁹

As gene editing techniques continue to improve and gene therapy becomes more accessible, there will be a need for oversight by organizations and governments in order to ensure that trials are conducted ethically and that therapies are performed safely. Once diseases are conquered, this oversight will need to extend to regulating the potential of gene editing being used for

purposes beyond medicine, such as manipulating genomes to have specific social traits leading to transhumanism. Genetic therapy will play a significant role in molding society in the near future. Appropriate precautions must be taken to safeguard both researchers and patients.

As with any new medical treatment, appropriate oversight must be conducted to maintain safety and efficacy. Somatic gene therapy is already being studied, and has gone through the research phases described above. However, it is still necessary for researchers to follow up with patients and monitor their progress. This tracks any long-term side effects that are currently unknown and provides more information about both problems and continued benefits.⁵⁰ It is also crucial that mechanisms exist that can allow the appropriate individuals to cease or block unauthorized uses of the therapy, and to ensure that somatic cell therapies are not affecting hereditary cells.⁵¹ The same long-term contact would be necessary for children born with hereditary genetic modifications. These follow-up sessions would provide information about the efficacy of the treatment and could determine whether the treatment achieved its goal, or if complications or side-effects occurred.⁵²

Specifically regarding hereditary cell editing, there must be international oversight to monitor research. Dr. He's story confirmed the belief that there should be a mechanism in place to ensure that research is abiding by reports and recommendations, such as the Nuffield Council on Bioethics Report on Genome Editing, as well as a similar report from the National Academies of Sciences, Engineering and Medicine. However, it is very difficult to create an organization or a controlling body that could apply to all researchers across the globe. One function of such group would be to act as a committee to hear concerns about unethical research. Currently, it is unclear where a scientist could report studies that are violating international agreements, for example, and it is unknown whether acting as a 'whistle-blower' would be detrimental to one's

reputation, breach confidentiality, or result in punishment. Moreover, is there an obligation for fellow researchers to monitor each other, and would this lead to inappropriate reporting or misreporting in cases of professional jealousy? This type of committee would have to establish the rules by which scientists would have to abide and the consequences that would have to be accepted if regulations were breached.⁵³

In addition, it is important that general regulatory bodies conduct a cost-benefit analysis and monitor who has access to gene therapies. It is feared that only wealthy individuals will be able to afford somatic and hereditary genetic treatments to eliminate disease, even though individuals of all economic backgrounds suffer from illnesses that could be cured using these techniques. While some may argue that research participants may be from any economic class, and that eventually these treatments will become available to everyone, there is cause for concern that a “parallel population” will be created, one in which particular diseases do not manifest themselves because of access, and another which has to deal with illness, yet has access to only mediocre healthcare as a result of financial status. Healthcare is a right, and while the American healthcare system still has to improve access to all medical services, regulatory bodies should be cautious when advertising the success of new genetic technologies. They may exist, but until they are available to everyone, they should not be deemed integrated.⁵⁴ The next section will examine the concept of equal access in the context of genetic enhancement.

In order to address some of these concerns, it would be extremely beneficial to involve the public in discussions and decisions about genetic editing and its oversight. This will also become an important factor when genetic enhancement is introduced, but at the moment there is a significant amount of research being done, and it is important that all of the relevant stakeholders, including the public and vulnerable communities, have a seat at the table. One

aspect that could be informed by community representatives is how genetic editing research is perceived by the general public. Research has been done examining this question, and it was found that more men are in favor of it, more left-leaning (politically) individuals support it, and that African-Americans are more hesitant about these studies. It was also discovered that younger people, as well as those with higher education levels, are more supportive of gene editing. Despite some contrasts in opinions, there was a consensus that research in this area is beneficial, and that it is important to weigh the risks and benefits of each research trial. While this study did provide important information about the support of genetic editing research, it also demonstrated the difficulty in engaging the public.⁵⁵

Some of those difficulties stem from how the media portrays the uses of CRISPR and how its coverage affects someone's opinion of genetic editing. There tends to be a lot of misinformation in the media about gene editing using CRISPR and its potential uses. Much of the discussion centers around eugenics and the potential creation of a 'new human race' as opposed to the research being done in somatic cells. The media focuses on such fictitious uses of this research, and amplifies the possible negative consequences that may ensue.⁵⁶ It is clear that scientists do not always represent the values and opinions of general society, and academic discourse may not reflect what the public should know. For this reason, involving the public would help bridge gaps in information and ensure that the information that is being disseminated is clear, concise, accurate, and easy to understand. This could be achieved through the inclusion of community members on ethics committees that would be able to provide a non-scientific perspective on a new technology, such as CRISPR-Cas9.⁵⁷

Ideally, oversight of the uses of CRISPR-Cas9 and other genetic editing studies would involve a group of individuals, institutions, and cultures that could work together to advance this

technology in a manner that is universally agreed upon. Groups with all three of these “Giants” of leadership would ideally ensure transparency and objectivity, and address disinterest and skepticism.⁵⁸ The ‘individuals’ category would include individual scientists and academics who are doing the research, as well as administrators, lawyers, and ethicists. It would also include other individual stakeholders, such as clinical trial participants and volunteers from the public, who recognize the need for input to benefit the greater good. ‘Institutions’ would go beyond the individuals, and include representatives from research partnership programs, such as educational centers and social structures that provide stability and security, in addition to biobanks, that would need to publicize their work to benefit the research being done. Recommendations must also be made through a cultural lens, which would focus on promoting the greater good when commercial deals are made, which often results in a lack of public access to information and treatment. A cultural perspective would also aim to bridge the differences between public and private institutions. This would challenge frequently vague explanations about corporate benefits without being critical of the processes in place. Cultural sensitivity would also encourage a more informed discussion about short and long-term goals.⁵⁹

Overall, a dynamic, diverse, but integrated group of stakeholders would be able to appropriately promote the risks and benefits of genetic editing research. This would include accurate information for both academics and the general public. However, when translating genomic information for distribution to the public, it is important that the facts are distributed into three categories: conceptual (how can the difficulties of gene editing be explained practically), scientific (how can a framework be created to foster trust, promote progress, and encourage investment) and political/social (how can everyone work together to promote the common good?)⁶⁰

This same oversight should also be applied to research itself. The concept of ethical research has already been discussed throughout this section and the dissertation as a whole, but it would be wise to place genetic editing research into its own category, since it includes many aspects that are not typically encountered in biological research studies. There are uncertainties about how to regulate genetic editing research, especially across jurisdictions, when countries have differing regulations about compassionate use or medical exceptions for unapproved treatments.⁶¹ Furthermore, there is a debate about CRISPR-Cas9 itself. There are disputes about patenting certain genes and aspects of CRISPR, and it is unclear whether it can be considered a procedure or a product, which would need market approval. This also leads to the debate between public and private research and whether there should be more control over gene editing research in order to make it all public.⁶² Dr. He's situation comes to mind, in that private funding may have allowed him to proceed with inappropriate research, whereas public research boards may have prevented it from taking place at all.⁶³

Doubts and debates also arise as to how the research is being conducted. Since the use of CRISPR-Cas9 has a very specific purpose and aims to target diseases, placebo or double-blind controlled trials are difficult to administer, because the patient who needs this treatment is so specific and often unable to receive adequate treatment elsewhere. CRISPR-Cas9 trials have mostly required tissue to be taken from a participant, then modified, and then put back into the same patient, which is a new way of conducting research, which requires additional supervision. This oversight would need to include periodic review of trial protocols to ensure they are being administered safely and that the researchers are acting in an ethical manner, which would include frequently weighing new risks and benefits as further information emerges. Oversight is also crucial when uses for CRISPR-Cas9 begin to include genetic enhancement.

B: Human Enhancement and Transhumanism

It is important to start by exploring the background of genetic enhancement and transhumanism, and whether modifications to our current genome would impact human nature and how humans evolve. Would this genetic practice and its result potentially lead to parents being able to ‘design’ their future children? If post-humans did emerge, their moral status could be questioned. A new set of rights for such trans-humans would need to be created, and the existing rights of ‘conventional’ humans might also need to be redefined and safeguarded.

Although a discussion of theoretical issues dealing with the humanity and morality involved in these technologies is necessary, practical implications and risks must also be analyzed. A common argument against genetic enhancement is that it might give rise to the popularization of eugenic beliefs and practices. Some might feel that this would be neither dangerous nor disadvantageous, but others may view such an occurrence as a negative consequence of the therapy. Moreover, there is a risk that economic gaps among societies and communities might develop, and that justice issues, such as the diminishment of equality among all human beings, would develop. Such concerns could be dealt with through strict organizational oversight, both locally and internationally, but should also be presented to the public, so that opinions and value statements can be gathered in order to determine the best method for ensuring the safe introduction of this new technological possibility, similar to the mechanisms described above. In the past, transhumanism and genetic enhancement may have seemed like a hoax, but as genetic modification becomes plausible, the ethical considerations associated with enhancement must be seriously considered and thoroughly addressed.

CRISPR has allowed scientists to go beyond targeting somatic cells, and has enabled them to experiment with embryos or hereditary cells. This technique directly modifies a germline

and affects all future generations of that particular embryo.⁶⁴ As discussed above, researchers hope that by starting editing at this initial stage of development, they will be able to ensure that all cells of a potential person will have a desired modification so that children will not be susceptible to hereditary diseases, such as Huntington's or Sickle Cell Anemia.⁶⁵ Editing the genetic makeup of embryos poses numerous ethical questions and concerns, of course, predominantly concerning the possibility that non-medical traits, such as intelligence, height, or athletic ability, will be able to be added to or modified within an embryo, allowing for the resulting potential being to become enhanced.⁶⁶

It was mentioned above that one of the factors that is hindering hereditary genome editing research is the regulatory practice with regard to the use of embryos. Currently, each state with the US is entitled to mandate its own specific laws and policies regarding embryonic research. Most states prohibit embryonic research, including on donated embryos from In-Vitro Fertilization (IVF).⁶⁷ Some states, such as California and Connecticut, do permit embryonic research, but insist that no individual is paid for the embryo that is donated.⁶⁸ Along with these restrictions, the National Institute of Health (NIH) does not fund any gene-editing research projects involving human embryos, requiring scientists to pursue private funding and resources in order to conduct these studies.⁶⁹ Globally, many countries require that, if embryonic research is conducted, the embryo must be destroyed after 14 days to ensure that development does not continue and to prevent moral concerns from arising.⁷⁰ These restrictions may actually be hindering research, since they prevent scientists from truly discovering whether the CRIPSR – Cas9 technique could be successful. While these regulations may be intentional from a governmental standpoint, they may not be ideal from a scientific perspective.

If and when embryonic research becomes less restricted, and the CRISPR-Cas9 technique comes to be more widely used to edit embryos, scientists may be able to target specific genes that go beyond medicine.⁷¹ Information from the Human Genome Project, as well as ongoing studies looking at which genes are responsible for specific traits, have provided evidence that genes do, in fact, code for specific parts of personality or character traits. These include intelligence, empathy, and athletic ability, as well as others that may be attractive to future parents.⁷² By knowing which genes influence these social traits, there may come a time when parents will be able to choose which genes their offspring will have, in the hopes that their child will grow up exhibiting the desired qualities. Ethical implications of so-called ‘designer babies’ and whether genes will be solely responsible for a child’s ultimate character will be discussed in more detail below.

If this new medical advancement is successful, parents who can afford to use it will have the opportunity to choose the specific genes that their child will have, genes that focus on non-medical aspects of a child’s character or identity.⁷³ Initially, gene editing was promoted as being a simple and effective way to rid individuals of terrible diseases, but now considerations have to be taken into account regarding what may happen when this mechanism is used beyond the scope of medicine, and whether it will eventually create a new type of human being.

i. Does Enhancement Interfere with ‘Human Nature?’

With scientific advancements continuously evolving, there is the potential that genes that do not code for medical issues will begin to be targeted. If researchers know which set of genes indicate a higher intelligence or an increased musical ability, for instance, they may be able to give prospective parents the option of choosing specific traits that they wish their child to have.⁷⁴ These choices clear the path for enhanced human beings to be born, and their implementation

generates ethical questions, as well as feelings of fear and uncertainty. The theory that future generations could all be genetically modified intimidates scholars and lay people alike. Some philosophers believe that enhancing human beings is not right and should be prohibited because it tampers with human nature, or because it might only be available to those who can afford the technique, which would create a further gap between the wealthy and the poor.⁷⁵ Other scientists feel that genetic enhancement does not have many troublesome issues associated with it and, therefore, should be allowed everywhere, with the goal of creating human beings that are better suited to succeed.⁷⁶

Those who feel that it would be dangerous to pursue this type of research argue that the creation of post-humans would spin out of control, and would render the world that we currently live in unfavorable to 'mere' humans.⁷⁷ It is important to recognize that this doubt and apprehension are causing some scholars to advise that research should not even be started; that it is better to stop now and never go beyond gene editing for somatic cells as a way to treat disease.⁷⁸ This line of reasoning can be debated, since it is not always wise to be so cautious, for it prevents any new and potentially beneficial research from being conducted.⁷⁹ Nevertheless these fears should be acknowledged, because dealing with ethical issues about an unexplored concept is difficult. The future becomes less terrifying if we openly approach and wrestle with issues before a concept becomes a reality. Debate also benefits scientists who may forget about ethical implications and focus only on a novel scientific possibility.

Other scholars have the opposite view and feel that enhancement to the point of creating trans-humans would be beneficial, and should be pursued if it can be done safely.⁸⁰ These academics feel that we actually have a duty to enhance ourselves if the means to do so are available.⁸¹ They believe that it is a part of evolution and that it would not be detrimental to the

current human race. On the contrary, developing post-humans would be an improvement on the human being living today, and these new individuals would be better equipped to deal with life and its hardships.⁸² These same philosophers and scientists feel that introducing enhancement technologies or even presenting the benefits of becoming enhanced would follow a process similar to that which has been seen with vaccinations around the world. Some individuals feel that vaccines are, indeed, enhancements, since they equip the body with a new method of fighting disease that was not previously present, and that they have improved lives through avoidance of disease. The process which was used to promote immunizations and demonstrate their advantages could be replicated or expanded upon when presenting the idea that enhancement could be beneficial.⁸³

It is universally understood that enhancement could improve the health of post-humans, by eliminating diseases with known genetic markers, as well as by making human organisms better able to adapt to the environment and cope with the onset of illnesses. Furthermore, mental, as well as physical disabilities could be reduced. By improving general cognitive capacities, disabilities could be dealt with in a more effective manner, since innovative ideas might be easier to conceive.⁸⁴ While these enhancements go beyond the capacities of a current human being, there may first be a need to simply bring certain traits up to a desired level. For example, some individuals are not able to demonstrate empathy as well as others. By using enhancement techniques, it would be possible for a person with a lower capacity for empathy would have it raised to the 'normal' level of a kind and compassionate human being.⁸⁵ This also brings with it the problem of deciding what 'normal' means and which current human beings possess ideal levels of such traits.

In addition to genetic enhancements, there are other examples of enhancement that may lead to the creation of post-humans, such as enhancing drugs or technological limbs. While these modifications might not result in generational changes, they would allow humans in the present to arm themselves with advantages.⁸⁶ For example, students who take medications that increase their ability to focus and retain information may be better suited to succeed in academia.⁸⁷ These are considered enhancements, since they allow students to perform better than their peers who do not use these drugs, or it allows them to perform as well as others who are naturally able to succeed in school. Furthermore, the use of technological limbs for amputees has enhanced them to be able to function like an individual who has all of their limbs, and in some circumstances, the person with the artificial limb performs better. This enhancement demonstrates what it may mean to be a post-human in the future. The major concern with any enhancement is that a being may be created or will exist who is ‘more’ than human. They would have both mentally and physically enhanced capabilities, making them a ‘post-human.’⁸⁸

Going forward, it is important to keep in mind that research using genetic enhancement techniques is in its infancy, and practically non-existent.⁸⁹ The scenarios that are discussed are hypothetical, but the consideration of them is extremely important and real. If ethical issues regarding genetic enhancement and transhumanism can be addressed in advance, it may make the inevitable introduction of these possibilities less daunting and more positive. It is also important to continue having ethical discussions about enhancement and transhumanism so that the public can remain informed and engaged, and scientists can direct their research and approach their findings from a broader ethical perspective.

A primary concern that bioethicists have with enhancement is that it interferes with human nature. They believe that any disturbance to our natural being should be avoided.⁹⁰ Having

children, a natural human behavior, will most certainly be deeply affected by enhancement as the concept of ‘designer babies’ comes to fruition. Parents might have the ability to pick and choose which genes they wish their child to have, which would impact the type of person, both physically and mentally, that would emerge in the future. The nature vs. nurture debate must be entered into if a decision is to be made regarding the accessibility of enhancement, and how it should be made available to those wishing to use it.

All human beings are said to possess a general ‘human nature’ as an inherent component of their human identity – one which involves how we act and make decisions.⁹¹ Some scholars feel that genetically enhancing future children directly distorts human nature. Both the act of modifying, as well as specific modifications, are not considered natural.⁹² Therefore, they argue that any form of enhancement should be avoided, as human beings today are considered to be at the pinnacle of their capabilities.⁹³ This line of thought may be common, but it might not be completely valid. In the past, enhancements, such as the introduction of literacy, have exposed human beings to information and inspired reflection of the very traits that make up their human nature. Significant benefits have been generated, including an enriched self-awareness of human nature, and a desire to promote our positive characteristics and behaviors rather than our negative traits. While this was not a genetic enhancement, it does demonstrate that enhancements can have a beneficial impact on human nature.⁹⁴

While the fear that human nature would be tarnished is understandable, it is important to realize that it would take an extensive amount of time for a change to actually occur. In order to truly modify human nature, the human species as a whole would have to change. Considering that there are billions of human beings living on earth, and only a small percentage would have access to enhancement technologies, it seems unrealistic that human nature would ultimately be

altered.⁹⁵ However, small modifications could gradually occur over time, as more people gain access to enhancement techniques. For example, improved cognitive capacities may develop more quickly than entirely new post-humans in general, since these modifications can only happen on an individual level. Genetic enhancement will not happen quickly, as opposed to an environmental occurrence, such as climate change, which would be more likely to change such new humans in a physical way, bringing with it the ability to withstand warmer temperatures, for example.⁹⁶

Furthermore, if a goal to improve or change human nature was, indeed, set, the feasibility of it would need to be thoroughly analyzed and assessed. For example, we would have to ascertain which traits would need to be different in order to effect a true change in the nature of humanity, an exercise which would lead to a consideration of what it means to be a human, and what comprises our inherent nature. These questions will not be answered in this dissertation, but they are serious issues that merit serious thought. A governing body would have to be established to oversee all scientific developments that would be capable of improving human nature and it would need to be in place for an extended amount of time, until this change becomes a reality. Organizational considerations will be discussed below.⁹⁷

Another common argument that scholars make against enhancement is that it defies the natural evolution of human beings and, with it, human nature, and that we should not interfere with evolution or try to speed up the process.⁹⁸ Evolutionary biology dictates that evolved traits within humans are simply improvements, and not necessarily the best possible solution. For example, human beings still have physical parts that are not efficiently used, such as the appendix, which evolution may eventually eliminate. Conversely, interfering with progression should not be seen as a negative act, as enhancement would be doing the same job that evolution

does: improving the species physically, as well as changing human nature. This viewpoint is controversial, since some people also feel that human beings cannot be improved upon and we should strive to maintain our current physical and mental status for as long as possible. However, it may actually be beneficial to enhance ourselves, as it could correct mutations for disease or make human beings more efficient.⁹⁹

Although evolution may be regarded as a natural process that takes place over the course of many years, it is impossible to deny that the use of technologies has allowed human beings to control aspects of evolution and improve the human condition. Enhancement may be a method through which traditional ‘Darwinian’ evolution can actually advance by speeding up the process, which brings benefits and improvements sooner than expected.¹⁰⁰ In the past, animals aided the course of evolution, and it took time for an organism to adapt to an environment. While adaptation may still take time, technology has replaced the role of the animal and is playing a central part in the evolution of humans.¹⁰¹ Giorgio Tintino presents the idea that the post-humans created through enhancements would not be entirely new beings, but rather a hybrid version of the humans we are familiar with in the present. These hybrids would presumably be better suited to adapt to the environment and exhibit a more advanced fitness for survival. These beings may eventually be known as homo-technologicus; a species more evolved than homo-sapiens, which were improved upon by technology.¹⁰² When looking at the process of enhancement and creation of post-humans from this perspective, the benefits seem to outweigh negative aspects, and the interference with human nature seems minimal.

Behavior plays an important part in how we define human nature. It seems to be a recognized human behavior that we always strive towards improving our character and ensuring that we act morally and can interact positively within society. As a result, some scholars feel that

character should be a factor in the debate about enhancement and transhumanism. Judgement is often passed upon those who are proponents of enhancement, and it is said that they are of questionable character, simply because they feel this may be beneficial for society. Anyone who feels that human nature should not be protected, or believe that post-humans should exist, is considered to be of poor character.¹⁰³ Furthermore, it is also felt that anyone who is eventually enhanced will have their character compromised as a result of the enhancement. Individuals who believe this feel that an embryo whose genetic markers have been tampered with may not exhibit the same characteristics or be able to have the same type of character that is associated with a moral human being.¹⁰⁴ This argument is questionable, since character would be affected by more than just genetic makeup, and would rely on environment and society to be shaped and determined.

Just as enhancement is seen to directly interfere with human nature, it is also believed to negatively impact the natural process of having children. The CRISPR technique described previously indicates that germline modifications would be done at the embryonic stage of development, and would have to be done ex-vivo, unless the technique becomes advanced enough to do while an embryo is in utero. This process entails the use of In-Vitro Fertilization (IVF) in order to create an embryo.¹⁰⁵ The concern with this method of editing is that once a few traits have been discovered to have genetic influence, others will follow, and parents will, essentially, be able to design the genetic makeup of their child so that it is born with particular traits which they feel are advantageous. This leaves very little to chance, and the fear is that diversity among children will decrease. The effects this practice would actually have on society are currently unknown.¹⁰⁶

It is important to note, however, that it has been demonstrated that children are not predestined to a specific future based on their genetic makeup. Environments and parenting styles seem to have more of an influence on children than their genes do.¹⁰⁷ For example, if a parent decides that their child will have a gene manipulated so that they have advanced musical abilities, they may assume that their child will become a talented musician. In addition to a genetic modification, it is known that a parent must also instill specific habits in their children, such as motivation and discipline, in addition to ensuring that they practice their skills.¹⁰⁸ Without these additional elements, a child may not exhibit their genetic predisposition for musical talents and may choose to pursue another career path. It is important to remember that while genes do have an impact on an individual's life, especially with regard to disease susceptibility, they do not completely make up a person, and other factors do contribute to the development of an identity.¹⁰⁹ For this reason, even if genetic enhancements did become more frequent, they may not completely change the way individuals end up living their lives.

In any event, the notion of 'designing' may be a very appealing capability to a parent. It is human nature for a parent to want the best for their child, and providing a method of parental control designed to try and equip their child with traits that will help them in life is tempting.¹¹⁰ Furthermore, a parent should think about their goals before beginning the process of embryo-editing in order to ensure that what they want is possible. For example, some parents might want to modify genes so that their child has an increased level of happiness, whereas another set of parents might wish for their child to be more rational and self-governing. While both of these goals are valid, scientists may be able to do only a fraction of what is requested. As discussed previously, genetics only contribute slightly to a child's ultimate personality or identity. It may

be possible to be genetically disposed toward happiness, but it is the environment the child experiences and how they are treated that matters more for overall joy in life.¹¹¹

During the process of determining enhancement goals, parents may be overwhelmed by the eventual options available regarding which traits can be chosen. Hughes provides a list based on universal virtues that he believes can be impacted through genetic enhancement. They encompass various character traits as well.¹¹² He has created four categories of virtues: self-control, which includes restraint, consciousness and temperance; niceness, which corresponds to agreeableness, extraversion, empathy, and fairness; intelligence, which contains open-mindedness, curiosity, love of learning, and prudence; and positivity, which encompasses a lack of neuroticism, emotional self-regulation, bravery, and humor. All of these traits seem ideal for a child to possess, but parents should understand that creating a perfect child is not yet possible, and all of these traits, while they have genetic components, are not proven to be fully influenced by a set of particular genes. However, Hughes' list provides a detailed inventory of the character traits and virtues that a parent may be able to modify within their future child's genome.¹¹³

The listing given above is quite detailed, and suggests that if a parent could choose all of those virtues they would, which would create a presumably 'perfect' child. The idea of perfection can be both subjective and objective, especially when discussing favorable character and behavioral qualities. A subjective view of perfection allows an individual to decide for themselves what it means, and when applied to enhancement, would allow each set of parents or individual parents to choose what they felt were the best components of their child's genome. Subjectivity, however, may lead to relativism and would permit parents to choose objectively unfavorable qualities for their unborn child. The parents' level of education, societal pressures, and the inability to relate to a community may all influence which traits are chosen for a specific

embryo.¹¹⁴ An objective view of perfection also creates social challenges. It is unreasonable to think that all members of a society, especially a diverse and multicultural one, would agree on which traits lead to perfection and which should be ideal for a child to possess. If a parent chooses a quality that does not fit into the objective view of perfection, they might experience discrimination, causing them to make a choice that is not ultimately autonomous. The ideal balance between subjectivity and objectivity allows parents to choose which traits reflect their vision of perfection, but there may also need to be some oversight to ensure that children are created safely.¹¹⁵

Although it may seem in the best interest of an unborn child for their parent to choose genetic enhancements, it also brings up the question of whether a parent is benefitting as well, and if they are modifying a genome for the correct reasons. A parent may choose for their child to become enhanced in order to decrease the burden of having to care for a disabled or sick child, or one that will need additional supports in school, for example.¹¹⁶ Parents often underestimate their parenting abilities and feel that making the child more desirable and ‘normal’ will help them in their role as a parent. Furthermore, it must be ensured that the child is not being considered a product as opposed to a person. This is especially the case for parents who might use genetic enhancement to create a ‘savior sibling’ for an existing child. Savior siblings are conceived to be organ or tissue donors for disease-stricken siblings, since it can be ensured that they would be a match. While this topic will not be discussed in detail, this type of practice should be discouraged, since it often places unfair expectations on a young child, and it does not recognize the savior sibling as a person in their own right. It can be exciting for parents to be able to pick and choose desirable traits for a son or daughter, but it should be understood that this embryo will still become a human being, and their decisions may alter their expected course of

life. Parents are expected to love their children unconditionally, and must recognize that although one can attempt to manipulate the genetics of an embryo, it may not grow up to meet their expectations, and should be loved regardless.¹¹⁷

ii. A New Set of ‘Human Rights’

Another common concern with regard to enhancement is what a post-human’s moral status would be, compared to a ‘mere’ human being. Our conception of morality would need to be adjusted in order to accommodate these newly enhanced individuals. We would have to decide whether creating post-humans is favorable morally, and if enhancing ourselves to do so should, perhaps, be compulsory. Some scholars feel that it might ultimately be detrimental to society, hence they recommend ceasing this line of research.¹¹⁸ If, however, the research continues and there is the potential for others to have a higher moral status than we have, it would lead to a discussion of human rights. The question of whether post-humans would have the same human rights that we do now, or if they would be entitled to their own set of rights, rendering unenhanced humans a lesser kind of human, would have to be posed. There is a fear that ‘mere’ humans could not follow the moral reasoning of post-humans, which would reduce their status to disposable humans, akin to animals, and would certainly result in little respect being shown to them. A discussion of morality is often missing in the scientific literature, but must be added to research conversations and goals to ensure that we are thoroughly prepared when enhancement becomes a reality.

Currently, all human beings have equal moral status. They should be able to discern right from wrong and make decisions that are in accordance with their beliefs and morals. All human beings are in theory, therefore, considered equal, and this baseline allows individuals to be moral or immoral.¹¹⁹ Based on this, all humans, regardless of their genetic makeup, are the same with

regard to having moral status, implying that genes do not define us as humans. If a genetically enhanced individual is created from embryonic research, do they have the same moral status as an unenhanced individual? The definition outlined above would imply that they do, because a genome does not define a person. Furthermore, other considerations, such as the environment in which a person is raised, would be more influential than genetics with regard to determining the person they become.¹²⁰ However, opinions are abundant regarding whether moral enhancement would generate a new level of moral status in post-humans, and whether we ought to pursue the creation of such beings if this is indeed the case.

The notion that a post-human could have a higher moral status than the humans of today seems unlikely to some scholars, but possible to others. Wasserman, for example, feels that since post-humans would presumably have a higher cognitive ability than we do, we would not be able to understand post-human moral reasoning, elevating them to a higher moral status.¹²¹ Hauskeller, on the other hand, feels that post-humans would simply have morality, and that it would not exceed ours in degree, since we are unable to identify exactly what a higher moral status entails. Furthermore, Buchanan feels that we have already reached the highest moral status possible.¹²² It is plausible that a higher moral status might exist, even if we do not understand it or cannot imagine it. For this very reason, post-humans might be able to experience and think about issues and actions differently, rendering them more evolved.¹²³ If an increased morality is truly possible, it raises the question of how 'mere' humans who do not have the highest level of moral reasoning will fare in a new society. It can be predicted that humans may be treated the way that we currently treat animals, allowing post-humans to sacrifice 'mere' humans for research or in emergencies.

Since we cannot predict the nature of an enhanced morality, we should focus on whether to pursue the creation of post-humans with moral enhancements at all. Savulescu and Persson argue that moral enhancements should be compulsory for every human being once the technology is safe to use.¹²⁴ Since the moral choices we make are not solely caused by genes or biology, there would be little harm in enhancing what we can through genetic modification to aid us in making moral decisions. This would simply complement the morality we exhibit already. Vojin Rakic argues against this view, however, maintaining that this obligatory enhancement deprives human beings of their freedom to make autonomous choices.¹²⁵ While this may be true, it can be disputed with the fact that not all limitations to freedom are negative. For example, society puts limits on all citizens by emphasizing and teaching that everyone should act morally. Furthermore, biology allows us to show and feel disgust, which can protect us from disease if we are aware something would not be appealing to consume. If we did not have any instinctual control, we might be inclined to partake in unhealthy actions that would, to a 'regular' person, seem disgusting and that would cause harm.¹²⁶

Nicholas Agar feels that the creation of post-humans would be extremely dangerous and should be avoided.¹²⁷ He argues that the existence of morally-superior beings would not be beneficial for current human beings, and the unknown factors related to their existence and capabilities should convince us not to pursue further research.¹²⁸ He even postulates that moral enhancement would make individuals less adept at moral reasoning. He argues that enhancing their morality would actually bestow a more utilitarian nature upon post-humans, and that, as a result, they could more easily justify killing or acting destructively than most 'mere' humans do now. For example, physicians would, presumably, never take a heart or lung out of a healthy individual for the sake of decreasing the number of patients waiting on a transplant list. While it

is acceptable to donate a kidney to a loved one, or harvest the organs of a brain-dead patient, physicians would not be able to morally justify the removal of an organ that sustains life. Post-human doctors, however, may have no issue with this, since they would see taking organs as helping others and contributing to public need.¹²⁹ Agar feels that utilitarian aspects of post-human populations should discourage the public from supporting enhancement techniques.

Agar also argues that genetic enhancements may not be able to completely transform the morality of a new human being. He feels that morality is ultimately informed by reason and needs three parts to succeed: cognitive, affective, and behavioral components, which all contribute to making a moral decision or acting morally. Enhancement techniques may only be able to target one of these areas, making it a “piece-meal” process of augmentation. This type of enhancement would be beneficial for individuals who are lacking in one of these areas, in order to get them to a ‘normal’ level, but it would not create a post-human that would have a greater impulse to act morally and be better at moral reasoning.¹³⁰ Hughes, however, feels that moral enhancement could go beyond the three areas mentioned, and has four essential virtues that would also contribute to a moral individual. It is predicted that an eventual post-human would exhibit an equal balance of all of Hughes’ described virtues, self-control, niceness, intelligence, and positivity, and would be able to make morally sound decisions.¹³¹ However, the process of creating a post-human with an equal or ideal balance of these four virtues might, in fact, realize Agar’s “piece-meal” prediction.

If post-humans are considered to have a higher moral status, should they have a different set of rights that corresponds to their enhanced morality? Some scholars predict that enhanced individuals will feel different enough from unenhanced people to warrant the creation of a varied set of rights specifically for post-humans. Post-humans may feel that they deserve more or are

more valuable to society, and that they need, therefore, a set of post-human rights that only apply to themselves. This seems extreme, especially if enhancement technology is only available to a small number of individuals, as a larger enhanced population would take many years to actually create. However, a risk exists, as mentioned above, that these post-humans will feel different enough from the unenhanced to consider themselves eligible for new rights that are advantageous for them, and exclusive of others.¹³²

It does seem possible that if post-humans are created successfully, their cognitive abilities will exceed ours, and they will feel entitled to things that ‘mere’ humans might not understand. Post-humans may not even recognize that they have an increased moral status, and would simply believe that ‘mere’ humans who were not enhanced do not matter as much as they do.¹³³ Many philosophers currently agree that there are three levels of morality: the lowest for inanimate objects (rocks, for example), the next for animals, and the third for humans. A fourth would need to be added for post-humans, and they would simply treat the individuals or objects lower on the list in the same manner with which we do now.¹³⁴ Yet other scholars recognize that this may not be an ideal way to approach the comparison of humans, animals and objects. Some believe that post-humans would treat humans as if they were lesser versions of themselves, but it would not be to the extent that humans now treat some animals. It is difficult to predict how post-humans will act and how they will behave toward other humans in society.¹³⁵

It has already been mentioned that a fear exists that ‘mere’ humans will be sacrificed or harmed by post-humans. For example, post-humans may institute the enslavement of unenhanced individuals if they are seen as lesser beings, which would lead to a further division between the enhanced and the unenhanced, and bring up human rights issues.¹³⁶ Post-humans might feel as though ‘mere’ humans do not contribute enough to society and can be used as

required. For instance, the process of organ donation may be applicable, which would allow post-humans to take healthy organs, albeit unenhanced ones, from ‘common’ people and use them as they see fit.¹³⁷ There might also be an unfair distribution of resources, which is already experienced today. A gap in moral standing would convince post-humans that ‘mere’ humans would not deserve certain commodities, such as food or shelter. They would do so only after all of the post-humans were taken care of.¹³⁸ It is hoped that post-humans would recognize that harming other beings is immoral and should not be done, similar to how many human beings today would not hurt animals for items like fur or horns. While there are those individuals who do not see these actions as problematic, post-humans should be able to determine the moral way to regard others.¹³⁹

Although post-humans might be able to treat human beings with respect, it can be questioned whether ‘mere’ humans would be used for research purposes, similar to the ways scientists use monkeys and other animals today. Unenhanced people would be ideal candidates for post-human research since they closely match the biology of a trans-human. Researchers would be able to conduct experiments similar to those ones being done at present. However, if this were to occur, a set of policies and guidelines should be created to ensure that research studies were ethical and that they treated people fairly. Humans who were not enhanced would probably insist on a set of rules, similar to the ones in place today for human research that follow strict guidelines to ensure safety. But post-humans may argue against this, and compare human subjects to animals that are frequently not treated ethically and are abused in order to gain useful results. Furthermore, sick humans may not receive adequate treatment. Currently, when a treatment is discovered through animal research for humans, the animal with the disease, whether given to them by a human or naturally-occurring, will not have access to the treatment,

unless humans are all cured and there are leftover resources. The same could potentially happen between post-humans and unenhanced individuals.¹⁴⁰

Scholars have suggested that a two-tiered set of rights may be created. All individuals, both enhanced and unenhanced, would have a basic set of human rights that applied to everyone. This would include a right to freedom, a right not to be discriminated against, and a right to healthcare. However, there would also be a second set of rights that only applied to post-humans, which may include a right to a specific type of education or a right to political involvement. Since morality is not determined by genetics, it would be clear that all individuals, whether or not they were enhanced, should have the same moral status, but having this system of different rights would not support that.¹⁴¹

This type of tiered system may be difficult to imagine, but it already exists to a degree in today's society, with regard to mentally disabled individuals. All human beings, regardless of their mental capacities or environments, have the same basic human rights in theory, but often, people who are mentally incapable, such as those with Down syndrome, are considered to be 'lesser' people, simply because they are unable to perform in ways others can. This provokes a debate, on one side of which are people who believe that the mentally-incapable should not have the same moral status. On the other side are individuals who feel that they have the same moral status and the same rights as everyone else, and that they should not be treated differently. Further debate arises when physically-disabled people are considered, as they still have basic human rights and should be able to exhibit the same morality as everyone else, but sometimes are not afforded the same opportunities as individuals without disabilities. In a sense, there is even now, a two-tiered system of rights in existence, in which healthy, mentally-capable people are better able to succeed in society, have access to more opportunities, and regard those who do

not as ‘lesser’ people.¹⁴² This should be avoided as it is unethical, but if it already happens currently, there is the potential that similar contrasts will occur in the future with regard to post-humans and the unenhanced.

iii. Potential of Eugenics

Philosophers have postulated numerous theories about what would happen to human nature and our moral reasoning skills if post-human societies emerge. These hypothetical theories must also include practical concerns. The majority of scholars that discuss genetic enhancement and transhumanism are worried that eugenic actions will unleash justice issues among communities and societies worldwide. While eugenic practices are a serious fear, it is important to recognize that they may not be as detrimental as they are believed to be. Furthermore, other risks, such as a wider divide between the rich and the poor demonstrate the need for organizational oversight and guidance to ensure that these techniques are executed safely and carefully. There must be a neutral body that is able to take liberal and conservative viewpoints into consideration and be mindful of who might benefit from, and who might be harmed by the creation of post-humans. This discussion must also include public opinion, to prevent scientists, philosophers, and politicians from unilaterally making decisions that ultimately affect the public.

The term ‘eugenics’ has a negative connotation associated with it as a result of atrocities that have occurred throughout history. The concept of eugenics, however, was initially presented as a scientific method to advance the human race, and was viewed as a positive idea.¹⁴³ At first, individuals of the middle or upper class were held to a higher standard than those in the lower class, which was encouraged not to reproduce in order to decrease the number of people in poverty.¹⁴⁴ In the present, this logic would not hold, since it is known that genetics do not determine social status or economic class. Originally eugenic measures went beyond

socioeconomic concerns. The United States was one country that favored such measures. It promoted and sometimes forced sterilization on citizens who had a particular disease or were seen as a lesser human being not worthy of reproducing on the basis of mental incapacity.¹⁴⁵ The main association with eugenic practices is the extreme abuse that occurred in wartime Germany, where it was deemed acceptable to end a life in order to eliminate the chance of a similar human being born. Physicians there were committing eugenic acts even before the Nazis, when they killed infants and children suffering from terrible diseases. Afterwards, the WWII Nazi regime justified their eugenic actions with the notion that they were creating a superior human race.¹⁴⁶ It would be appalling for events like these to repeat themselves, and when the term ‘eugenics’ is brought into the conversation about genetic enhancement, many people feel that similar events will occur once again. However, if we consider what eugenics really means, improving the human being, we may be able to alter the negative connotation of this term.

Eugenic practices are aimed at promoting a better version of a human being. While it should not be permissible to end the life of a living individual so that they will not be able to reproduce, it may be acceptable to enhance humans to become better versions of themselves. This new liberal eugenic movement would allow individuals to choose to either enhance themselves, if possible, or enhance future generations of their lineage. Many scholars insist that this should be voluntary so that autonomy is upheld and so that it does not become a coercive practice. From this perspective, the goal would not be to improve the human race, but rather to improve specific individuals. In addition, it would remove unfavorable disease-bearing elements from individuals, making them more likely to live a life free of suffering from illness.¹⁴⁷ This practice still causes unease, but it redefines how society interprets the word ‘eugenics’ and shifts

the connotation from completely negative, toward a more positive and appealing meaning that indicates possible improvement.

One of the concerns associated with the eugenic nature of genetic enhancement is that the genetic diversity of society will decrease. For example, cognitive diversity might suffer. It has been proven that having a team of individuals who have different cognitive strengths is more successful in cooperating, solving problems, and accomplishing tasks.¹⁴⁸ It would be problematic if everyone used enhancement technologies to achieve the same cognitive enhancements, thereby decreasing the diversity among a large group of people. If every person had the same cognitive strengths, society would suffer since people would have a harder time working together. This fear may be unwarranted, however. It is difficult to determine universally beneficial cognitive traits that everyone would wish to possess. If all people could choose which cognitive aspects were being enhanced, the diversity among a community would remain the same or increase. If it was possible, it would be beneficial to pursue methods of enhancing our cognitive abilities, while still ensuring that diversity among communities was abundant.¹⁴⁹

Furthermore, the diversity of other traits may decrease if the traits are essentially eliminated from society. Some see this as a negative side-effect of genetic enhancement, since communities will see more uniformity among people, and children will be raised to ignore and no longer embrace differences. For instance, de Melo-Martín postulates that if there were genetic components associated with sexuality and a new generation was born that was completely heterosexual, homophobia would be more prevalent, as a result of not having homosexual individuals within the community. There might be an increase in single-minded opinions as well as the potential for abuse should any of those children come into contact with a homosexual

individual. This example is extreme and unlikely, but demonstrates the idea that diversity is necessary to promote acceptance and peace within a society.¹⁵⁰

There are practices being pursued today, such as pre-implantation genetic diagnosis (PGD) and abortions, that some would consider eugenic. Currently in the United States, it is common for some parents to terminate their pregnancy if they discover that their fetus has a physical abnormality or suffers from Down syndrome, for example, or they may choose an embryo with a preferred genetic makeup.¹⁵¹ This, in a sense, is a form of eugenics, since parents are determining which factors would give a child the best life and, thereby, discarding a fetus or unfavorable embryo. This practice is widely accepted, both socially and legally, even though it has eugenic undertones that people may not consider.¹⁵² Is there really a difference, therefore, between choosing favorable genes for a child to possess through enhancement and ensuring that those with diseases are not being born by way of PGD or abortion? Genetic enhancement may actually be better-received if compared to these actions. While abortion and embryo destruction is permitted, it is not accepted everywhere. Gene editing through CRISPR would eliminate the need to destroy an embryo, because its genes could simply be modified as opposed to just looked at and analyzed. There would be no need to dispose of an embryo with unwanted genes.¹⁵³

If we frame eugenics in a more positive way, it may seem that the desire to improve our biology can be considered to be a preferred act. While many scholars feel that we should cease any research that may lead to post-humans and that risk eugenic practices, it is more realistic to proceed with caution.¹⁵⁴ Scientists will continue to develop enhancement techniques, and the field of bioethics should participate in ensuring that negative or historic eugenic actions do not repeat themselves. Promoting a 'kinder and gentler' view of eugenics as a necessary component

of the natural evolution of humans may make genetic enhancement more attractive to the public, and ease the fears of some philosophers that it will lead to catastrophic ethical events.

A major misgiving that is associated with genetic enhancement is whether wealthy individuals will be the only ones able to access this technology. Similar to advanced medical techniques, the process of genetic enhancement is predicted to cost a significant amount when it is introduced, and it is feared that only a small percentage of even the wealthy population will be able to afford these modifications, leaving everyone else without it. This would add a new moral dimension to the already existing economic gap between the wealthy and the poor.¹⁵⁵ It emphasizes that individuals who could not afford it, or who would not get access to the procedure were 'lesser' in a way, which may eventually lead to the concerns that have been discussed. The creation of a wealthy enhanced population may lead to exploitation of poorer individuals, and if this population continued to grow, the definition of being 'poor' would eventually have less to do with money, and more to do with being unenhanced.¹⁵⁶

An increased economic gap emphasizes the need for scholars to promote equality just as much as liberty when discussing genetic enhancements. Generally speaking, individuals in the U.S. are at liberty to freely make decisions that work best for them and their families. For example, if a family is able to afford them, it will certainly send its children to elite private schools.¹⁵⁷ The same is true with regard to healthcare. If a patient has insurance, they will seek the best and most advanced medical services. However, equality is not guaranteed, since medical care is not available for all citizens as a result of insurance issues or lack of access to health centers. Once enhancement becomes a reality, it is expected that these technologies will also not be readily available to everyone, which further increases the inequality between groups of people living in the same country.¹⁵⁸ Liberty is important within this society, but equality must also be

considered to ensure that people are being treated fairly and that there is no potential for the abuse of individuals who cannot afford it by those able to become enhanced.¹⁵⁹

This would also apply to the currently existing relationship between developed and underdeveloped countries. There is a significant disparity gap in access to healthcare around the world, as the United States, for example, has vaccinations and hospital services readily available in most areas, whereas countries in Africa do not have the means to provide these interventions for all of its citizens.¹⁶⁰ The introduction of genetic enhancement would increase that gap, making those living in developed countries even more fortunate than those who do not have it made available to them. This issue will continue indefinitely if developed countries only pursue research for themselves, and do not consider the injustices in the rest of the world. For this reason, many scholars believe that genetic enhancement should not be the focus of research and funding, because it would only benefit a small number of individuals, whereas a better focus would be to develop better ways to provide basic healthcare to those in need.

While justice issues are probable, there may be a solution or an assistive body that could combat disparities. Buchanan suggests the creation of an oversight organization that would be responsible for creating policies and monitoring enhancement progress as this technique continues to develop and integrate itself into society.¹⁶¹ While this type of group would be beneficial to ensure that human rights were maintained and that scientific and medical standards were being upheld, it would be difficult to create one organization that would be able to achieve these goals for multiple countries, especially those with differing values. It may also be challenging to obtain accurate information about all the research being done and to be aware of who is being enhanced. Currently, many countries have an oversight committee or regulations, at least, about embryonic research and whether enhancement is permitted to be studied. In the

future, these organizations may want to broaden their responsibilities, and it would be ideal for countries to collaborate and cooperate to uphold safety. Since the idea of genetic enhancement is still only an idea, it is difficult to predict which hardships oversight committees will face, and if there is an overarching solution that would allow multiple nations to work together.¹⁶²

When discussing the potential to have oversight committees and organizations create guidelines about genetic enhancement research, one factor that is often forgotten is the opinion of the public. Ensuring that communities have correct information can be difficult, especially when media has a tendency to oversimplify or over-exaggerate research triumphs and exciting possibilities. For this reason, lawmakers and scientists do not always include the public when making decisions or formulating regulations. Since this new technology could be used by all individuals and they would be the ones deciding whether to enhance themselves or their future children, it is crucial that the public be part of the conversation. Public engagement should include citizens from all walks of life, with varying education levels, in order to gain a true depiction of what communal opinions are regarding genetic enhancement. This step should not be omitted, especially if the majority of the public feels strongly one way or another. While this process might be considered tedious and time-consuming, it is an important aspect of debating and deciding how genetic enhancement should affect our futures.

As genetic therapies become more prevalent, the possibility of genetic enhancement and transhumanism becomes ever more realistic. While there are many scholars who feel that going down this path would be detrimental to the human race, others are strong proponents. Although there are fears and concerns, this technology will continue to develop, and it is crucial that related ethical issues are discussed. Among the topics that need to be addressed are the elements and development of human nature, the moral status of both humans and potential post-humans,

including the possibility for the formation of a different set of human rights for the latter, the risk involved in the consideration of eugenic practices along with ensuing justice issues that might occur, and finally, the organizational oversight efforts which would need to exist to monitor progress. While many questions remain unanswered, it is necessary for us to continue asking them, as humanity may be called upon to accept post-humans as members of our society in the future.

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Chapter 7: Conclusion

This dissertation has presented and examined the different ethical considerations that medical organizations must bear in mind when embarking upon the introduction of genetic therapies and the use of CRISPR-Cas9 as an editing technique. It provides a foundation of ideas and methodologies that should assist these institutions with their decision-making process, policy development, and education process, in order to promote safety and comfort among both staff and patients. While it may be quite some time before genetic editing and enhancement becomes a regular practice, it is beneficial for health care organizations to recognize how gene therapies are perceived at this time, and how they can be safely and effectively incorporated into our current health care system. This work does not include all of the ethical concerns associated with gene therapy and gene editing technologies, but it does consider many practical aspects of these new treatment options that will help to achieve the goal successfully introducing these medical advancements.

There are many steps in the process of introducing CRISPR into the current health care system, including ensuring an initial understanding of how the technique works, educating workers who are able to administer the treatment, and communicating information to patients and families about the risks, benefits, limitations, and success rates of genetic editing. All of these practical components are complemented by ethical understanding that applies to the current uses and short-term expectations of genetic therapies. This dissertation is unique in that it explores the more practical considerations of this undertaking, as opposed to focusing entirely on the ethical fears for the future. While enhancement and transhumanism must be included in all ethical discourse about using CRISPR for genetic editing, there are other ethics-related topics that contribute to a solid basis for the development of an understanding of this new technology

and its implications. In addition to the scientific and economic information that will become available in the near future, organizations would benefit from ethical guidance reflected in the points made in this dissertation with regard to keeping multiple perspectives and ethical considerations in mind, during both their individually-based and hospital-wide decision making process

One of the driving forces in how decisions are made regarding CRISPR is relational decision-making autonomy. Capable patients have the right to make their own choices about which treatments to try, despite any known risks. If a patient suffering from cancer, for example, discovers a clinical trial using genetic therapy, they have the right to decide for themselves whether this treatment is something they wish to pursue. However, when a patient is not capable of making a decision, especially one of the magnitude of altering their genome, an organization has a higher responsibility to ensure that autonomy is upheld. Substitute decision makers (SDMs) have to follow established guidelines when providing consent on someone else's behalf, and it is up to both individual physicians, and institutions to ensure that this process takes place appropriately. In the case of a novel technology such as gene therapy, strong relationships between physicians and patients or SDMs will contribute to a successful consent process and a positive medical experience. Understanding why autonomy is at the pinnacle of a modern health care system, and what role providers can play within it, will ideally lead to more professional and public confidence when introducing CRISPR.

Even closer attention should be paid when SDMs are parents making decisions for their children, who frequently do not possess adequate decision-making capacity to consent to the use of genetic therapies or editing systems. A parent has the unique responsibility of deciding when to pursue a risky procedure and whether the risk is worth it in order to save their child's life. The

process of obtaining consent is similar to one with adults and their SDMs, but must also include the opinion of the child if possible. For example, a child with cancer may not be able to fully understand their available treatment options, but they are able to express how they feel, which could influence whether they should participate in a clinical trial using gene therapy. Researchers have an additional responsibility to consider all of the stakeholders in this situation, and how their decisions impact the patient. All aspects of a choice, including ulterior motives, socioeconomic factors, and parental values, should be disclosed in order to achieve an outcome that is in the best interest of the child.

While autonomous decision making relies on individual's making choices in accordance with their own beliefs and values, autonomy may also be influenced by factors that are out of a patient's control. Therapies that use CRISPR are extremely expensive, and there is significant concern that accessing and affording them will be impossible for most, except for a small group of wealthy people. This apprehension speaks to the fact that not only are there differing standards of health care around the world, but also within a single country, such as the United States, despite the global consensus that humans have a right to health care. It can be daunting to address health disparities that exist with regard to basic needs, such as nutrition and clean water, let alone inequalities with regard to accessing genetic editing. Differences in health care must be considered, however, because organizations who are implementing these new technologies have to determine how they are going to promote equitable access while maintaining the highest level of care possible. If this aspect in the implementation process is not taken into account, if the research process has been completed and the procedure is approved at an institution outside of local boundaries, and if the desired procedure is being offered at lower cost abroad, individuals will seek care elsewhere, leading to an increase in medical tourism.

Individualized decisions are clearly relevant, but the best interests of a population or community must also be taken into account when implementing a new genetic therapy. Genetic enhancement and individual therapies do not only affect the patient receiving them, but also have an impact on the public around them. Current discourse includes the question of how genetic enhancement could affect society, but does not touch upon how genetic therapies could be integrated into public health models of prevention. Many public health measures are designed to lead to disease prevention as opposed to providing curative options, in order to reduce burdens on the health care system and to improve the overall health of a community. In order for a public health campaign to be successful, utilitarian practices must allow for the guarantee of autonomy, which allows for individuals to make some of their own choices with regard to the resources that are available. Understanding this concept ensures that once genetic editing becomes more popular and accepted among the medical community, it may be able to be marketed as a public health tool for screening and elimination of certain diseases. Its use also promotes the human right to health as well as the right to health care.

Currently CRISPR is being used in research studies, and requires a specific focus on informed consent. Many of the components that make consent informed for medical treatment apply to research as well, but when a new technology is being researched and some of the risks are unknown, informed consent is more important than ever. Researchers must exercise extreme caution and be transparent about their work in the course of discussions with patients regarding risks and benefits. This would assure organizations who are introducing these techniques, either during or after clinical trials, that they are able to ensure patient safety and treatment efficacy. While significant safeguards to protect patients from harm already exist, there are groups who remain vulnerable when they are involved in research, many of whom would be targeted for

genetic therapy studies. For example, pregnant women are rarely included in scientific research generally, but they will be the main focus in future research using hereditary gene editing, such as the case with Dr. He's work in China. Additional vulnerability must be recognized and addressed in order to ensure that ethical research results in findings that are applicable to all.

Vulnerability is especially prevalent at the beginning and end of life, when difficult choices must be made, but an individual may not have the capacity to make their own decisions at that time. It can be challenging to make choices that might end in death, for example, and patients and families use a variety of methods to make those choices. Religious beliefs often influence a patient's end of life decisions, and also figure prominently when choices are being made at the beginning of life, such as in the case of abortion. It is important to be aware of how religious traditions affect patient's feelings about how CRISPR is being used, since it may be a treatment option at the beginning of life through embryo manipulation, or at the end of life as it provides treatment for a fatal cancer. Ultimately, a patient or SDM's choice based on religion is justified and upholds autonomy in decision-making. It is up to them how to make decisions regarding controversial procedures, and organizations should have a process in place that respects these choices, and allows patients to express their opinions and feelings about genetic editing.

Organizations do not yet have concrete data about the feasibility and efficacy of using CRISPR in embryos. They are, however, employing Pre-Implantation Genetic Diagnosis (PGD) as a technique that allows parents to choose which embryo to implant based on their genetic makeup. Conversations about the use of PGD include controversial topics, such as IVF, destruction of embryos, and its use to choose non-medical characteristics such as the sex of the child. Institutions can learn from the implementation of PGD and tailor the introduction process

of CRISPR to address some concerns already being raised. For example, if a Catholic organization does not allow IVF to be carried out within its walls, it seems reasonable to predict that the use of CRISPR in embryos will also be prohibited. The opposite may be true at hospitals with robust fertility clinics, therefore, risks regarding sex selection will have to be addressed. Having a foundation for discussion and implementation supports organizations, especially with regard to understanding the implications of germline manipulation, and can inform the planning of the introduction process for genetic editing.

More generally, an organization should examine how it has previously introduced new technologies. Common considerations apply regardless of the nature of the new technology, such as prioritizing patient safety and ensuring accountability to the institution's stakeholders. This recognizes the hospital's commitment to the community that it serves and also upholds its corporate values. The organization would have to consider how a technique such as CRISPR would affect patients and families, staff who may disagree with the practice, and other individuals who would be newly tasked with administering this recent technology. Additional resources would have to be allocated to create education platforms for staff and methods and means of communication to patients. In addition to these resources, cost must be addressed and plans should be created to consider how this procedure could be covered for individuals without insurance, or for those who cannot afford this technique, especially when CRISPR is being employed to eliminate a disease. The information and discussion presented in this dissertation is meant to bring to the attention of medical institutions the many ethical considerations that could inform the mechanisms that be put into place in order to appropriately introduce genetic editing into their organizational framework.

All of the above-described ethical issues are valuable to consider, but it is also beneficial to understand the progress of the CRISPR technique in practice. Gene therapies targeting somatic cells are most frequently being researched because there is more control in the consent process, and there is no risk of future generations being affected. There are a variety of clinical trials being conducted which provide hope to patients dealing with different types of cancers, blood diseases, and other illnesses related to the eye, skin, and liver. Along with supporting research, organizations can play a role in overseeing the research that is being done both locally and globally, in order to avoid further inappropriate research on hereditary genes after the work of Dr. He in China. The need for oversight is paramount in order to ensure that research is being monitored from a variety of perspectives, including on behalf of the public who will be affected by the studies being conducted.

While somatic cell gene therapies are accepted for the most part, hereditary germline editing is feared, mainly due to the risk of using CRISPR-Cas9 to enhance a person beyond medical traits and create a new human race. Scholars believe that using CRISPR to edit genes that code for social traits, such as intelligence or reasoning abilities, will lead to a significant difference in what it means to be human. A new set of human beings – ‘post humans,’ would be created, which would include a change in the fabric of our human nature. The possibility of such a future would require broad thinking about how to treat these new ‘post-humans;’ would they have different human rights than unenhanced people? Would there be a risk to mere humans? The most significant worry is that eugenic practices will take place and that the enhanced population will only want to pursue more enhancement. However, eugenic practices that arise due to genetic enhancement need not be considered negative if appropriate oversight takes place and if the use of enhancement technologies becomes widely available. Nevertheless,

apprehension is warranted, since it is not expected that enhancement will be possible in the near future. Attention should be directed toward current ethical concerns first.

As an extensive source of material relating to ethical issues around genetic editing and the implementation of new technologies, this dissertation should provide organizations with ideas that will support the evolving process of CRISPR-Cas9 use. It proposes that there are many factors that contribute to the successful introduction of this new technology which should be considered at each step of implementation. In the short-term, work such as this dissertation will be able to inform high-level discussion about somatic cell therapies and their contributions to science and health care. Cost and accessibility considerations involve ethical issues that can be addressed at once, and would be of benefit to future plans for CRISPR's use in hereditary gene editing. Furthermore, beginning the education process for physicians, health care staff, insurance companies, and the public would give all stakeholders the time to understand the intricacies and implications of the use of CRISPR and provide the opportunity to ask questions about its uses in health care systems.

Beyond these practical suggestions, the research highlighted throughout this dissertation should inspire organizations, and individuals alike to ponder what it means to be human, and whether enhancement would be a positive or a negative contribution to modern medicine. Dr. He chose to go forward with germline editing research, despite a lack of international support. While this may have triggered an unofficial global moratorium on hereditary gene editing, it is only a matter of time before another scientist makes the same attempt. This dissertation does not address or answer all of the questions raised about the unknown risks and uses of CRISPR, but it does lay a foundation upon which organizations can begin to construct their positions with regard to how humanity will change in the future. It is a worthwhile exercise for all humans to consider

the implications of genome editing, and to get involved in or at least make themselves aware of the scientific discourse around this topic, in order to prepare for the new future of humanity.

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