

A Brief Introduction to the Ethical Considerations of Preimplantation Genetic Diagnosis and Potential Regulatory Mechanisms

What is PGD?

Preimplantation genetic diagnosis, or PGD, is a procedure that allows parents to test the DNA of embryos developed outside the womb during in-vitro fertilization (IVF). If the embryo has a genetic abnormality or a certain disease, then the parents have the option of discarding that embryo and implanting only the ones they deem to be healthy. Although this procedure initially was developed to detect serious diseases, it can now be used for other purposes, such as selecting an embryo that is an immunological match for a sibling, selecting a particular sex (even in the absence of any sex-linked diseases), or selecting against an embryo with a particular disability. Embryo selection has raised many controversial issues, a few of which this paper will attempt to address.

Tissue Matching

One of the most complex problems that arises when discussing PGD is that of HLA (human leukocyte antigen) matching. This procedure is utilized by parents of a diseased child with the hopes of finding a perfect donor to rescue that child. Generally, for procedures like bone marrow transplants, the diseased individual requires a donor whose cells will have a minimal reaction to their new host. HLA matching allows parents to choose an embryo that will have leukocyte antigens that match the older sibling. Stem cells taken from the umbilical cord of the newborn will not induce an immune rejection when implanted in the sibling's body because the host cells will recognize the donor cells as their own. This process greatly enhances the

success rate of such procedures, offering potentially life saving solutions for very destructive diseases.

For instance, many parents of children affected by thalassemia have employed PGD to give birth to a second “savior” child. Thalassemia is an inherited blood disorder that causes mild or severe anemia due to reduced hemoglobin and fewer red blood cells.¹ Treatment for the disease requires frequent transfusions (every 3 or 4 weeks) and daily iron chelating treatments to remove the body’s excess iron after the repeated transfusions. Thalassemia has been cured using bone marrow transplants, but the procedure is only possible for the few patients that have a suitable donor². Many would find it hard to argue with parents who have successfully used the stem cells from their second child to save their first child the pain and suffering associated with this disease. Not only do these parents get to welcome another child into the world, but they can breathe easier knowing their first child is free of disease.

However, as per the theme of today’s biological advances, with each successful procedure emerge additional ethical issues. This use of the technology has a significant impact on the traditional family structure. With HLA matching, the parents are using their second child as a tool to provide relief for their older child. In a country where we value the childhood experience and punish the exploitation of our youth, should we permit parents to use their children as a means to an end? The President’s Council on Bioethics questions the effect that this technology will have, wondering “Is it proper to assign to an unconceived child the burden of being a savior of a sibling, and then give that child life on condition that he or she fulfill that role?”³ This question holds even more bearing when considering the possible failures

¹ http://www.nhlbi.nih.gov/health/dci/Diseases/Thalassemia/Thalassemia_WhatIs.html

² http://www.marchofdimes.com/professionals/681_1229.asp

³ <http://www.bioethics.gov/reports/reproductionandresponsibility/chapter3.html>

encountered with these procedures. If the matching does not work, how do you tell a child that they failed to do that which they were, quite literally, born to do?

Another issue that arises is the general concern that being able to choose the child you have should not be allowed. There exists a valid concern that although this sort of selection is medically oriented and has life-saving potential, it could lead the way to a slippery slope of producing “made-to-order babies” that are the products of conscious parental design. While some may agree on principle that selecting a future child simply for the benefit of the first is improper, it would be hard to come up with an effective means of regulation to prevent parents from doing so. However, in light of reproductive freedom, we must consider if this kind of regulation is necessary or justified. If parents desire an additional child, then what should prevent them from enjoying a healthy new child while also providing desperately needed relief to their first-born?

Sex Selection

Choosing the gender of a child via PGD is becoming increasingly common these days. Various diseases are associated with certain sexes only. Diseases resulting from either dominant mutations on the Y chromosome or recessive mutations on the X chromosome are much more common in males than females. Selecting the sex of the child, via PGD, could be viewed as a legitimate use of the technology if it were to eliminate the possibility of the child having a certain disease. For instance, the UK’s Human Fertilisation and Embryology Authority (HFEA) requires that “Centres may not use any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, to select embryos of a particular sex for non-medical reasons.”

However, when this kind of selection is employed for non-medical reasons in other countries, like the US, many ethical issues arise. In certain cases, families may choose to implant only males to balance out a family that only has daughters. Within American society, this seemingly innocent practice may not elicit any immediate ethical outcries from the general public. However, it is important to consider the situation in other cultures. The Center for Genetics and Public Policy points out that “given [the] history of discrimination and existing cultural preference for boys, some observers see using PGD for sex selection as having the potential to devalue women.”⁴ We have already seen the effect that sex selection has in countries like India, where the number of males significantly outnumbers the number of females. While having a son may have once conferred an advantage to the parents, that marginal advantage is becoming slimmer. Essentially, if selecting a child’s sex becomes common practice, it could eventually become self-defeating. The resulting gender imbalance could have serious effects on our society.

Allowing scientists to use biology as an opportunity to reinforce social biases is a dangerous practice indeed. We would be once again vulnerable to the patterns of thought that brought about the Violence Initiative in the 1980’s, where scientists at the NIH sought a biological determinant of crime among America’s urban populations while ignoring blatantly obvious social, cultural and economic factors that were more likely contributors. Although this project has been long criticized as an improper use of science, we can see how important it is to not immediately turn to biomedical technology as a savior for the social and political problems we are unable or unwilling to solve.

Regardless of the motivation behind sex-selection, whether for medical or non-medical reasons, it is difficult to understand how this procedure could effectively be limited or regulated

⁴ www.dnapolicy.org/images/reportpdfs/PGDDiscussionChallengesConcerns.pdf

in a country where abortion is legal. Abortion is the ultimate and most decisive among reproductive choices available to prospective parents. However, there are those that argue that “the genetic manipulation of our offspring can not be without limits just because we have the ultimate reproductive decision (i.e. abortion) at our disposal.”⁵ Clearly, as new genetic technologies develop, we must consider exactly how we will let science change the traditional family, and ultimately social, dynamic.

Disability Rights

One of the most convincing arguments in favor of PGD entails giving parents the ability to prevent bearing a child with a debilitating disease. This new technology gives these parents the power to ensure that their child has a very strong chance of leading a healthy life. If both parents are carriers for a disease, like Tay Sach’s, that would cause nothing but pain and suffering for the newborn child, then they may use this procedure to select against embryos that have the diseased mutations, thereby guaranteeing their child’s health. While parents have traditionally strived to give their children the best through the provision of things like a strong education, PGD now equips them with the ability to provide their children with stronger genes.

Generally, most people can agree that there are certain diseases that are *prima facie* bad for anyone who has them, regardless of their personal situation. These diseases prevent the individual from developing the capabilities to participate in their society and maintain autonomy in choosing among a variety of life plans.⁶ However noble an enterprise as this may seem, many people have very strong ethical objections to using PGD to select against diseased individuals. Most striking among these arguments is deciding how the line between acceptable and unacceptable conditions can be drawn. In making this distinction, we would essentially be

⁵ <http://www.dreamababy.com/sex-selection.htm>

⁶ Buchanan et al., From Chance to Choice: Genetics and Justice

determining who among diseased individuals has the right to live and who does not. Moreover, many disability rights advocates argue that the label “disease” or “disability” is more subjective than we may believe. Would a child with Down’s syndrome necessarily enjoy life less than a child without the disorder? How severe does one’s dwarfism need to be for them to be selected against? Furthermore, if the embryo has a disease like Huntington’s, should parents be allowed to select against this embryo that, if given the chance, would live for about 40 years? Is a disease that takes away your retirement years more devastating than one that perhaps limits your mobility in some way? Who gets to make these kinds of decisions?

Conversely, many feel that using PGD to avoid a genetic disorder is practically an obligation for carrier parents using in-vitro fertilization. Despite different interpretations of what “the best” may be for each parent, everyone should be able to agree that a baseline level of health is indeed desirable. Some feel that if we have the technology to prevent certain diseases, then we should be able to use that same technology to provide certain genetic advantages to our children. If we legally allow parents to be overbearing and push their children onto life paths that they might not genuinely want for themselves, why should we preclude them from making genetic choices for their children as well? Defenders of this position claim that their opponents are genetic determinists: they assume that one’s genes are the ultimate determinant of one’s physical, emotional and intellectual capacities. Choosing embryos with certain genes would, at best, increase the likelihood of the children having a certain trait or ability—it would by no means force them to make the choices their parents want them to make.

Opponents to this line of reasoning cite the liberalism and pluralism that characterizes American society. In our culture, we generally hold that there are many different and equally valid conceptions of a “good” life and that we are bound to respect each one of those. This sort

of neutrality must be incorporated into the parent's responsibility to maintain their child's "right to an open future."⁷ Proponents of this argument feel that parents are obligated to provide their children with a baseline quality of life without shaping their offspring, genetically or environmentally, "in ways that facilitate pursuit of [the parent's] ideals for a good life."⁸ This argument holds more weight when we consider using PGD not just for therapeutic purposes, but for enhancements as well. Given the pace of genetic discoveries, it is not hard to imagine that one day parents will be able to select an embryo based not only on the lack of disease genes, but on more complex traits such as musical ability. For many people, the idea of allowing so-called "designer" babies affords parents too much control over their unborn child's life.

Finally, one of the commonly cited critiques of PGD is that it will lead to an increased gap between socioeconomic classes. Because PGD is inherently tied to IVF, only those that use the procedure will be able to reap the benefits of PGD. Consequently, since the patient base for IVF tends to be white families from an advantaged economic background, they are the ones that will employ PGD to eliminate certain diseases from their families. Author Lee Silver imagines a world where socioeconomic classes are effectively replaced by gene-rich and gene-poor classes. Embryo selection, in his mind, could lead to a fundamentally different and inescapable divide between the social strata, where "well-off parents provide their children not only with the best education that money can buy, and the best overall environment that money can buy, but the 'best cumulative set of genes' as well."⁹ In such a society, certain diseases could genuinely become diseases of the poor, not only because of the lack of proper nutrition or medical care, but because of the lack of genetic selection prior to implantation. Thus, although far off, the

⁷ Buchanan et al., [From Chance to Choice: Genetics and Justice](#)

⁸ Buchanan et al., [From Chance to Choice: Genetics and Justice](#)

⁹ Silver, Lee; [Remaking Eden](#); *The Virtual Child* pg 263-264

consequences of widespread embryo selection could have significant consequences for our society as a whole.

Regulation – a brief discussion on current regulatory options

Currently, there are no real effective means of regulation for PGD. The federal government does have various organizations under its Department of Health and Human Services that can regulate issues related to PGD, such as in-vitro fertilization. These organizations include the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the Center for Medicare and Medicaid Services (CMS). While the scope of this paper does not include the intricacies of the regulatory mechanisms involved in each of these organizations, it may suffice to say that there are indeed gaps in the regulation of PGD because of its novelty and its inextricable tie to personal reproductive choice.

Typically, the federal government allocates the regulation of medical practice to the states. However, if regulation of PGD takes place at the state level, regulatory shelters could emerge, allowing doctors to offer their services in a state nearby one that has strict regulation surround PGD. Informal regulation via professional groups or patient advocacy groups perhaps would be ideal, but seems as though it would lack any significant enforcing power, rendering its regulatory policies useless. Federal oversight might take two different forms: Congress could enact a new law regulating PGD or establish a new federal agency to oversee the procedure. Although the process leading up to creating such laws or agencies would be extremely difficult, this approach would create clear and legally enforceable rules.¹⁰ Concerns regarding this approach include the intrusion into private medical practice, infringement on parental autonomy in making reproductive choices, and limits on PGD would not necessarily prevent parents from terminating pregnancies using other forms of prenatal testing.

¹⁰ www.dnapolicy.org/images/reportpdfs/PGDDiscussionChallengesConcerns.pdf

Because this procedure has the capacity for such immense controversy, we must ask ourselves: is an attempt at regulation even worth our effort? Should we attempt a project that would necessarily involve very personal reproductive and ethical choices? Francis Fukuyama argues that we have an obligation to make these difficult choices. He cites the ambiguous attention deficit-hyperactivity disorder (ADHD) as an example, claiming that although the distinction between health and illness is almost always unclear, “regulatory agencies *make and enforce this distinction all the time.*”¹¹ The regulation of novel genetic technologies should not be exceptional when discussing the push and pull involved in reaching a democratic compromise. For example, the previously mentioned HFEA in the UK has taken up the challenge of deciding exactly which diseases should be allowed for negative selection with PGD.¹² In an attempt to scale the slippery slope of allowing certain conditions to be selected against, this organization has been making decisions about these unclear issues in an effective and meaningful way.

Furthermore, Fukuyama goes on to say that existing regulatory bodies, such as the FDA, would be stretched too thin to effectively regulate such a new and controversial technology. Therefore, we need to establish an agency responsible for the oversight of PGD. However, immediate concerns about this kind of an agency would involve choosing who gets to participate in the regulatory discourse. How much influence should be afforded to scientists, doctors, disability rights groups, feminists, the lay public, etc.? Clearly, because the impact of regulation ultimately affects not just individuals but society at large, the interests of all these groups must be taken into consideration. Consequently, if a new regulatory agency is formed, the role of advisory groups (as employed in the FDA) to the core members of the organization should be

¹¹ Fukuyama, Francis; *Our Posthuman Future; Policies for the Future*; pg 210

¹² <http://www.hfea.gov.uk/AboutHFEA/HFEAPolicy/Preimplantationgeneticdiagnosis>

very substantial. This could be accomplished by using a consensus conference or citizen panel model, where the public is actively engaged in defining the causes and consequences of certain problems and understanding the problem from the perspectives of various stakeholders.¹³

Scientific self-regulation has lost much credence among the general population, as people want an increasing level of transparency in science to ensure that scientists are not doing fascinating but dangerous or unethical things in their ivory towers of academia. However, it is imperative that scientists play a significant role in the regulation of technologies, like PGD, because they have the most intricate knowledge of the procedure. A regulatory agency should ideally include members of the scientific community that are well versed in disciplines like philosophy or legal studies. This approach would ensure that these professionals could engage in both technical and social discourses with equal effectiveness. Although this may sound suspiciously similar to Plato's idyllic "philosopher king" model, finding these kinds of people should not be as hard as it once was considering the expanding number of professionals engaging in multi-disciplinary fields.

Conclusion

Although this paper has likely not come close to addressing all the moral concerns associated with PGD, it hopefully has brought to light some aspects of the major issues people have with this new technology. While many of the advantages of this procedure seem beneficial at face value, it is important to consider the long lasting repercussions that may exist. From tissue matching to sex or disability selection, the benefits of each procedure are readily apparent. Yet it is important to stimulate dialogue about the underlying ethical issues so that we may ultimately come to some kind of consensus about how PGD should be regulated. Although a

¹³ <http://www.loka.org/policy.htm>

federal oversight agency may appear to be the best solution in this writer's eyes, it is by no means the only option we have. More consideration must be given to PGD and other genetic technologies to let public policy catch up with the breakneck speed of scientific progress.