

POLICY FORUM

Who Should Regulate Preimplantation Genetic Diagnosis in the United States?

Michelle Bayefsky

Abstract

Unlike in many European countries, preimplantation genetic diagnosis (PGD) is not regulated in the United States. As a result, PGD may be used for any condition for which genetic testing is available, at the discretion of fertility specialists and their patients. This essay explores the question of who should be responsible for regulating PGD in the United States. Federal or state regulation of PGD in the United States is likely to be challenging and problematic for several reasons, including the proximity of PGD to the abortion debate. I propose that PGD regulation in the United States can be most appropriately performed by health professionals using professional society guidelines that set standards for clinical practice.

Regulatory Lacuna for Preimplantation Genetic Diagnosis in the United States

Preimplantation genetic diagnosis (PGD) is a technique that can be used during in vitro fertilization (IVF) to test an embryo for genetic abnormalities associated with specific disorders before deciding which embryo(s) to transfer to a woman's uterus. PGD is primarily used to help people have children who will not be affected by heritable disorders, such as Tay-Sachs or cystic fibrosis. While these applications of PGD might seem clearly beneficial, the technique has also been used for more controversial purposes. In the United States, a small number of clinics offer PGD to select for a [disability](#), such as deafness or achondroplasia.¹ PGD is also widely offered for [sex selection](#); a 2017 study showed that 72.7% of US fertility clinics offer sex selection, and 83.5% of those clinics offer sex selection for couples without infertility,² meaning that a couple would only undergo IVF in order to select their child's sex. Furthermore, some worry that PGD could be used to select for traits such as hair color, height, and athletic ability, although these are unlikely to be single-gene traits for which we can easily select in the near term.

PGD can be employed for these "nonmedical" purposes in the United States because there are no legal limitations on the technique's use. It can be used for any condition for which genetic testing is available at the discretion of fertility treatment clinicians and their patients. By contrast, many European countries have rigid legal structures that determine for what indications PGD is permissible.³

This article explores the question of who should be responsible for regulating PGD in the United States. I will argue that federal or state regulation of PGD is likely to be difficult and problematic for a number of reasons, including proximity of PGD to the abortion debate. (For those who believe life begins at conception, there are important similarities between a decision to abort a fetus and a decision to transfer or discard an embryo.) I propose that PGD should be regulated by health professionals using society guidelines that delineate standards for clinical practice. For the purposes of this essay, I take as my starting point that PGD should indeed be regulated, an issue I explore and defend elsewhere in depth.⁴ Given the wide range of potential uses of PGD, the regulatory lacuna in the United States will soon become untenable, regardless of which current uses of PGD one finds acceptable. For sake of comparison, I briefly outline British and French approaches to PGD regulation and policy making.

British and French Regulation of PGD

In the United Kingdom (UK), PGD is regulated by a statutory body called the Human Fertilisation and Embryology Authority (HFEA). The organization maintains a list of conditions for which PGD has been approved, which now includes almost 400 conditions, including BRCA1 and 2, sickle cell anemia, and certain forms of deafness.⁵ For conditions not already on the list, the HFEA considers a number of factors, including “how serious the condition is, the likelihood of it being inherited and the testimony of people affected by the condition before deciding whether to approve it for PGD testing.”⁶ In order for a new condition to be considered for PGD testing approval, a couple must have a licensed PGD clinic apply to the HFEA on their behalf.

In France, PGD is explicitly authorized in the public health code and is permitted only when a couple has a high probability of giving birth to a child with an incurable heritable disease,⁷ as evidenced by the couple already having a child or immediate relative with such an illness.⁸ Before the couple can undergo PGD, their case must be evaluated by a team of experts, who determine whether there is sufficient risk of that couple having a child with a sufficiently serious condition.⁹ An organization called the Agence de la Biomédecine has the power to increase the number of uses of PGD, and, in 2012, the Agence recommended that PGD be allowed for selecting children who can serve as tissue donors for sick siblings.¹⁰

Both France and the UK have robust systems for regulating PGD and determining when PGD can ethically be used. Both France and the UK have also designated agencies responsible for maintaining regulations’ adaptability to changing scientific realities, patient needs, and social views.

US Government Role in Regulating PGD

In the US, there are a number of challenges to federal or state regulation of PGD. First, unlike France and the UK, the US does not have a government-funded national health care system. French and British lawmakers already make determinations about which applications of assisted reproductive technology (ART) should be publicly accessible because they decide which, and for whom, procedures should be funded. For example, in the UK, the National Institute for Health and Care Excellence (NICE) recommends covering 3 cycles of IVF for women under 40 years who have been trying to get pregnant for 2 years and have failed 12 cycles of artificial insemination.¹¹ Women aged 40 to 42 should be offered 1 cycle of IVF if they meet criteria demonstrating their potential fertility.¹¹ (In practice, however, the number of cycles a woman will be offered in the UK depends on her National Health Services locality.)

In the United States, IVF is not covered by federal programs (ie, Medicare, Medicaid, or Veterans Affairs [VA] health benefits), with the exception of VA coverage of IVF for patients who have lost fertility due to a service-related injury.^{12,13} Although 15 US states have passed laws requiring private insurance companies to offer coverage of some form for fertility treatment, only 8 explicitly require IVF coverage,¹⁴ which is necessary to carry out PGD. While it is possible for the US government to regulate IVF and PGD without funding their use, lack of government funding means a state is not required to provide recommendations for the just and prudent utilization of public resources for PGD. Furthermore, there is resistance to regulation among some physicians who argue that, given the lack of funding for ART, the government should not intervene in clinical practice.¹⁵

Another obstacle to federal PGD policy making is the absence of a clear federal actor or agency responsible for regulating clinical practice. The Food and Drug Administration is responsible for ensuring safety and efficacy of drugs and devices but not when and how they should be used.¹⁶ The Centers for Disease Control and Prevention gathers data nationally and annually on fertility treatments, but its purview is limited to data collection and reporting. The Centers for Medicare and Medicaid Services regulates performance of genetic testing, including specimen processing and results reporting, but not the circumstances under which tests can be ordered.¹⁷ Congress could pass a law establishing appropriate uses of PGD, but it would be highly atypical for Congress to legislate when a particular medical treatment can be offered.¹⁸ Federal oversight of PGD would require Congress to assign regulatory authority to an existing agency or create a new agency.

Creating a new federal system for regulating PGD would be challenging due to the proximity of PGD to the abortion debate, which is particularly contentious in the United States.^{19,20} PGD, which is carried out in sequence with IVF, involves creating a batch of embryos and selecting certain embryos from that batch, while the rest are stored,

discarded, or donated to research, depending on patient preferences. Regulating PGD would require accounting for the fate of the embryos that are not selected. Federal legislators have been hesitant to regulate IVF because of the incendiary politics surrounding the creation and destruction of embryos²¹ and would likely be similarly reluctant to address PGD. If PGD legislation were proposed in Congress, there is concern among some that such legislation may be aimed at limiting destruction of embryos rather than maximizing benefits PGD can bring to families.

Historically, government regulation of clinical practice has been left to states. Although there are no laws pertaining directly to PGD, some states have proposed or passed laws related to abortion of fetuses with genetic or congenital anomalies. North Dakota prohibits abortions in cases of any fetal abnormality.²² Indiana and Louisiana passed laws banning abortions for genetic abnormalities, but Indiana's law has been permanently blocked and Louisiana's law has been temporarily blocked by court orders; neither are currently in effect as of the writing of this article.²² In February 2018, the Utah House passed a bill that would prohibit physicians from performing abortions solely on the basis of fetal Down syndrome.²³ If some legislators are attempting to restrict abortions intended to prevent the births of children with genetic abnormalities, they might well oppose employing PGD for the same purpose. While some might distinguish between embryos in vitro and fetuses, and thus view PGD as a means of avoiding abortion, those who believe that life begins at conception might find creating and then rejecting (not selecting) affected embryos to be as ethically unacceptable as abortion.

It is possible to write a law requiring unused embryos to be stored indefinitely so that no embryos would be destroyed. For those who view life as beginning at conception, ensuring that no embryos' lives are ended might be sufficient. For others, the concept of embryos remaining forever frozen is still objectionable; in fact, there is a movement for "[snowflakes embryo adoption](#),"²⁴ the name given to the practice of adopting and carrying to term frozen embryos that genetic parents chose not to gestate. Nonetheless, even for people who object to keeping embryos frozen indefinitely, freezing embryos is preferable to destroying them, since freezing maintains an embryo's potential for growing into a child. A law requiring embryos to remain frozen could be seen as a compromise between those concerned with the embryo's life and those seeking to ensure access to PGD. However, lawmakers primarily concerned with limiting destruction of embryos might attempt to ban PGD outright, which would constitute a serious violation of reproductive autonomy for families who need PGD to have healthy children. Given the inflammatory nature of the abortion debate in the United States, state regulation of PGD could result in laws that are not sufficiently nuanced to both respect the views of pro-life constituents and allow the use of PGD to select for embryos without serious heritable conditions.

Professional “Self-Regulation” of PGD

“Self-regulation” of PGD by professionals applying society guidelines is a viable alternative to government regulation that avoids the potential pitfalls described above. Health professionals, including infertility specialists, OB/GYNs, geneticists, and genetic counselors, are more likely to prioritize the needs of patients when deciding which uses of PGD are ethically permissible. They are also apt to have a keen understanding of the current limitations of PGD, genetic testing, and new developments on the horizon. Allowing medical professionals to decide when PGD should be used is, in some sense, giving them authority to determine which diseases are sufficiently serious to warrant PGD. These decisions are ethically fraught and would be best made by multidisciplinary committees in order to avoid clinicians offering PGD too liberally due to bias or self-interest. Although professional guidelines are not legally binding, physicians face pressure to conform their practices to standards of care, and physicians who choose not to follow guidelines leave themselves vulnerable to criticism, litigation, and possible action against their licenses.

At present, self-regulation of PGD is inadequate because current guidelines effectively allow individual clinicians to decide when and for which conditions to use PGD. This kind of discretion results in an essentially limitless use of PGD, which is precisely what regulation of any kind seeks to avoid. For example, the American Society for Reproductive Medicine (ASRM) guideline on transferring embryos with known genetic anomalies concludes that the decision to use PGD should be left to individual clinicians unless an anomaly would result in extremely severe disability, in which case physician assistance with selecting such an embryo is discouraged.²⁵ In the ASRM guideline on the use of ART for sex selection, decisions are also specified as being within individual clinicians’ purview.²⁶ The American College of Obstetricians and Gynecologists (ACOG) and the American College of Medical Genetics and Genomics do not have committee opinions pertaining directly to PGD, but guidelines on related topics are likewise open-ended.^{27,28} ACOG has historically opposed sex selection, but its guidance on sex selection has been withdrawn and has not been replaced.²⁹ Without more definitive statements to guide future practice, some clinicians could offer PGD for reasons others would find unethical, including to select for superficial traits. Furthermore, if some clinicians offer PGD for any reason requested by the patient, others could feel pressured to follow suit in order not to lose patients to colleagues with more liberal practices on the use of PGD. The decision of when to perform PGD could then fall to the lowest common denominator of the profession rather than being referred to a thoughtful multidisciplinary team of health professionals who are particularly knowledgeable about the technology.

Conclusion

Due to a dearth of PGD regulation in the United States, clinicians and patients are currently able to carry out PGD for any reason. As PGD is offered for more and increasingly controversial conditions, lack of regulation will ultimately become untenable.

However, due to proximity of PGD to the abortion debate, attempts to regulate PGD at state or federal levels would most likely provoke controversy and could even result in outright bans. Professional self-regulation is preferable, but health professions' societies must provide more definitive guidelines in order for regulation to be effective.

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Michelle Bayefsky is a third-year medical student at Harvard Medical School in Boston, Massachusetts. She was formerly a postbaccalaureate fellow at the National Institutes of Health Department of Bioethics. With Bruce Jennings, she coauthored the book, *Regulating Preimplantation Genetic Diagnosis in the United States: The Limits of Unlimited Selection* (Palgrave MacMillan, 2015).

Citation

AMA J Ethics. 2018;20(12):E1160-1167.

DOI

10.1001/amajethics.2018.1160.

Conflict of Interest Disclosure

The author(s) had no conflicts of interest to disclose.

The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.