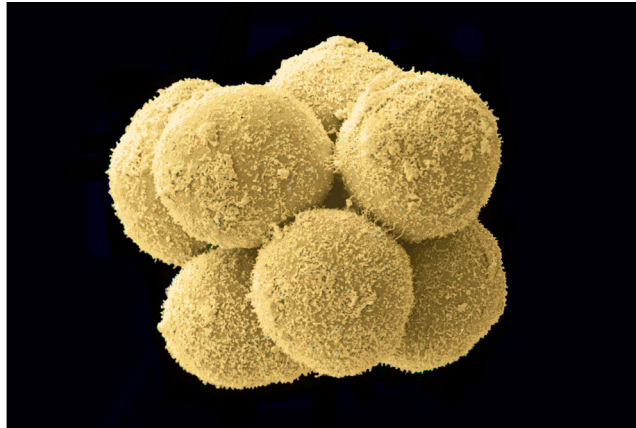
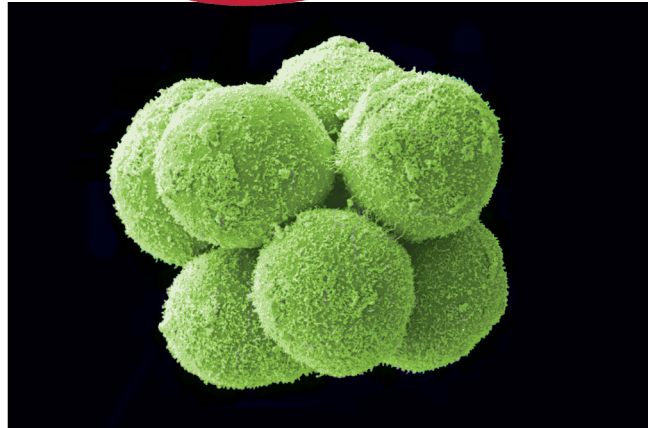
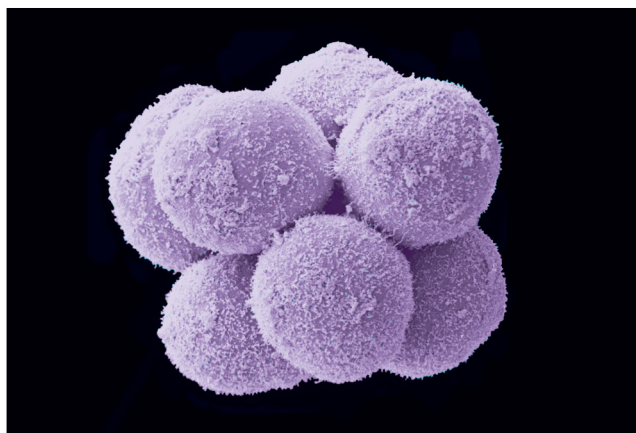


Professional Issues

HEALTH CARE LITIGATION ■ MEDICAL EDUCATION ■ ETHICS ■ PROFESSIONAL REGULATION

SOURCE PHOTO COURTESY OF DR. YORGOS NIKAS/PHOTOTAKE



TO TEST OR NOT TO TEST

The largest American public opinion survey about preimplantation genetic diagnosis was in 2004. Accompanying focus groups found that although most people were sympathetic to parents who wanted to test embryos for fatal diseases, many were worried about the potential for an unregulated industry to move toward so-called designer babies. The results below show what percentage of the public approves of different types of PGD tests, and people's support for regulation.

SUPPORT FOR TESTING

68%
Fatal childhood disease

66%
HLA match

58%
Adult-onset diseases

40%
Nonmedical sex selection

28%
Intelligence/strength traits

SUPPORT FOR REGULATION*

37%
Regulate safety & ethics

24%
Regulate safety only

20%
Complete ban

17%
Do not regulate

1%
Regulate ethics only

*NOTE: MAY NOT ADD TO 100 DUE TO ROUNDING.

SOURCE: GENETICS AND PUBLIC POLICY CENTER AT JOHNS HOPKINS UNIVERSITY, SURVEY OF 4,834 AMERICANS, APRIL 16 TO MAY 9, 2004.

Testing embryos & ethics

Embryo screening usually helps infertile parents have a healthy child. But some are concerned about how far the quest for the perfect baby will go.

Story by Kevin B. O'Reilly

What if your parents could have specified which gender child to have? What if they could have chosen to give you a head for figures, or an artistic bent?

Preimplantation genetic diagnosis technology, a testing process that costs thousands of dollars and is offered to couples using in-vitro fertilization, allows today's parents to choose whether to have a boy or a girl.

Embryos also can be tested for hundreds of fatal birth defects, childhood diseases and even some diseases that don't occur until well into adulthood. Doctors can test to ensure that an embryo's umbilical cord blood or bone marrow will be a match for a sibling who needs a donor. And just as physicians can use PGD to help deaf parents avoid giving birth to a deaf child, so, theoretically, could doctors use it to help them have a child who is like them.

Physicians working in this field face a seemingly overwhelming array of demands from different stakeholders — parents, bioethicists, anti-abortion critics, disabled-rights groups. As the field advances, individual doctors for now must determine where and how to draw the line between the craft of medicine and the specter of

eugenics and fears of so-called designer babies. No U.S. law specifically restricts the uses for which doctors and patients can use embryo screening, though several European countries ban or severely restrict PGD. Meanwhile, professional societies such as the American Society of Reproductive Medicine and the Preimplantation Genetic Diagnosis International Society have published guidelines related to embryo screening.

"There are a number of guidelines that it is suggested we follow, but there really are no consequences for clinics that choose not to follow these guidelines," said Jeffrey Keenan, MD, an anti-abortion reproductive endocrinologist at the Southeastern Fertility Center in Knoxville, Tenn. Dr. Keenan's clinic does not make use of PGD because "even in the best of hands it does result in the destruction of some normal embryos."

Dr. Keenan is a minority among IVF clinicians. Of the 25% of clinics that do not offer PGD, the reason most often cited is "lack of resources" followed by "inadequate market demand," according to a recent Genetics and Public Policy Center survey. Only 14% cited harm to embryos as a reason why they do not offer PGD. While most physicians and ethicists don't hold the purist anti-abortion position, many are concerned

Continued on next page

Continued from preceding page about where the principles inherent in the current practice of embryo screening ultimately could lead.

Test evolution

In-vitro fertilization has been hotly debated since Louise Brown, the first IVF baby, was born in 1978. The ethical questions surrounding PGD have mounted as its capacity and scope have increased. PGD was first reported in medical journals in 1990. It is unclear how many babies are born after PGD in the U.S. each year. The Genetics and Public Policy Center at Johns Hopkins University, however, estimated based on a recent survey that between 4% and 6% of all IVF cycles in the U.S. each year include embryo screening.

PGD usually is performed at the eight-cell stage, when one or two cells are removed from a 3-day-old blastocyst and commonly sent to an outside PGD clinic for testing. Embryos can be screened for diseases such as Down syndrome, cystic fibrosis and even Alzheimer's disease. PGD also can be used for Human Leukocyte Antigen typing, which can confirm that an embryo is free of a genetic disease that affects an older sibling, or be used to find an immunological match for an existing sibling who is seriously ill.

Robert P. George, PhD, a Princeton law professor and a member of President Bush's bioethics council, said that once screening embryos for disease is widely accepted, it is difficult to draw the line at more controversial uses, such as non-medical sex selection or testing in favor of the presence of deafness or dwarfism.

"That's the way slippery slopes work," Dr. George said. "Whatever comes next just seems like the next logical step. ... If we are saying it's OK to treat some embryos as discardable because they are deaf, then it is hard to say what's wrong with allowing people to say we'll discard embryos because they're not deaf."

Nigel M. de S. Cameron, PhD, president of the Institute on Biotechnology and the Human Future at Chicago-Kent College of Law, sees the matter in even starker terms.

"This is not going to Best Buy to decide what appliance to purchase," Dr. Cameron said. "This is about another child who will live in the community." The uncertain nature of the "miracle of birth," he added, "is crucial to our treating children as persons rather than property."

Law professor Elizabeth R. Schiltz's 11-year-old son, Peter, has Down syndrome. Amniocentesis let her learn his condition during the pregnancy. She was surprised and hurt when acquaintances asked if she knew of the condition before his birth, implying that she should have ended the pregnancy. She worries that PGD could make it socially unacceptable for parents to give birth to disabled or otherwise less-than-perfect children.

"People are not out to create a master race," said Schiltz, associate professor of law at the University of St. Thomas School of Law in Minneapolis. "But if we translate every one of these individual decisions to something we'd have to vote on at the other end, I don't think we'd be comfortable with where we're going."

Designer fears

While those who oppose PGD even for use in detecting fatal diseases or disabling conditions are in the minority, the controversy over when parents should be allowed to choose a

Congratulations, it's a (your choice here)!

While science-fiction writers feed the public's fears about so-called designer babies being hatched in the lab, one dilemma that physicians and parents face today is whether it is ethical to screen embryos for sex and select them on that basis. Here is how IVF clinics handle this vexing matter.

35% Inform parents about sex and transfer the embryo to the parents desire

30% Reveal sex only if asked

15% Reveal sex, but only transfer specific sex embryos for "family balancing" with second or subsequent children

10% Never reveal sex of the embryos for nonmedical reasons

8% Transfer the best embryo without regard to sex

2% Have not yet had to deal with the issue

SOURCE: GENETICS AND PUBLIC POLICY CENTER AT JOHNS HOPKINS UNIVERSITY, SURVEY OF 190 U.S. ASSISTED REPRODUCTIVE TECHNOLOGY CLINICS, APRIL 27-MAY 31, 2006.

child's gender is raging. In 1999, the American Society of Reproductive Medicine issued guidelines saying that although the practice should not be outlawed, "the cumulative weight of the arguments against nonmedically motivated sex selection gives cause for serious ethical caution."

In early February, the American College of Obstetricians and Gynecologists came out against nonmedical sex selection. The group's ethics committee said in an opinion paper that physicians who bow to parental preferences might be supporting "sexist practices."

Those arguments say the practice has the potential to become widespread, and if most parents chose one sex over another, it could throw off the country's gender ratio. Most experts say that scenario is unlikely in the U.S., where most parents opt for whichever gender they feel their family is lacking.

A majority of clinics refuse to offer PGD solely for sex selection. But if parents opt for PGD for another reason, many clinics will tell the parents the gender and let them choose the embryo.

Pasquale Patrizio, MD, a Yale Medical Group ob-gyn and reproductive endocrinologist, said he and his colleagues decided not to offer sex selection to parents, because the risks of the IVF pro-

cedure outweigh benefits that are essentially nonmedical. "If the woman is fertile and it's really just to have the baby of that sex, you're really putting a lot of importance on the sex," Dr. Patrizio said.

Thomas Murray, PhD, president of the Hastings Center, a Garrison, N.Y.-based bioethics research institute, agreed. Nonmedical sex selection means "giving in to a parental whim where that whim is not particularly significant, and when there's not a compelling reason for having more choice and control in children, we probably ought not to encourage it," he said.

A decade ago, James A. Grifo, MD, would have agreed. Dr. Grifo, director of the division of reproductive endocrinology at the New York University School of Medicine, said that back then, he was concerned that using PGD for nonmedical reasons would prompt a backlash and eventual regulatory oversight. He worries less about that now, as the use of PGD for family balancing has become more commonplace.

Moreover, he says a lot of the doomsday scenarios PGD critics paint don't mesh with facts.

"This whole technology is self-limiting," Dr. Grifo said. "The talk about 'designer babies' and the 'slippery slope' makes some sense, and I understand the fear, but it ignores how expensive the technology is. It is not 100% accurate, and there is about a 40% pregnancy rate. The thought that we'll be selecting genes for the next Arnold Schwarzenegger is really unfounded. We don't know the genetic basis of success; we don't even know the genes for hair color, and we probably won't know all of these things. They are more complex than any of us is ready to admit."

Dr. Grifo added that he would not in principle oppose screening an embryo in favor of having a child with a disability, such as dwarfism.

"Two dwarfs who are happy with their lives don't see dwarfism as a disease like some people do," he said. "The more you think about the request, it's not so unreasonable. Who should make this decision? ... Don't you think a dwarf couple know what it's like to be a dwarf? Why shouldn't they be the ones to choose that, if that's what they want?"

Yury Verlinsky, MD, director of the Reproductive Genetics Institute in Chicago and a past president of the Preimplantation Genetic Diagnosis International Society, disagrees.

"We are not participating in this kind of request, because our goal is to prevent disease, not to create disease," he said. "I can't judge someone who wants to have, for example, a Down syndrome child, but it does not have to be us to participate in it. That is not our goal as scientists and medical professionals."

For now, it appears it will be up to doctors to decide how to use PGD. Whether parents' seemingly intrinsic desire for the perfect baby will, or can, lead to a nightmarish future rests on the community's ability to draw meaningful distinctions, said Laurie Zoloth, PhD, a bioethics professor at Northwestern University's Feinberg School of Medicine.

"Slippery-slope arguments are usually bad ones, for in any real society, rules, norms and community engagement set up boundaries and fences," Dr. Zoloth said. "That is the difficult and entire point of having bioethicists at all — so that we can reflect on the nature, goal and meaning of our actions and think in advance about how to create a world we think is just and morally good, so that we can raise questions to parents and doctors that create serious conversations about their actions." ♦

SPECTRUM OF SERVICES

The most commonly performed embryo screening is aneuploidy, which in a recent survey constituted 66% of all PGD cycles. The test can identify when there is an extra or missing chromosome, such as in Down syndrome and Turner syndrome. But the same survey revealed that many clinics are offering other types of embryo testing, some of which are controversial among physicians, ethicists and the public.

TYPE OF PGD	IVF CLINICS PROVIDING TEST
Aneuploidy	93%
Autosomal disorders	82%
Chromosomal rearrangements	67%
X-linked diseases	58%
Nonmedical sex selection	42%
Adult-onset disease	28%
HLA typing	24%
HLA match for transplantation	6%
Select for a disability	3%

SOURCE: GENETICS AND PUBLIC POLICY CENTER AT JOHNS HOPKINS UNIVERSITY, SURVEY OF 190 U.S. ASSISTED REPRODUCTIVE TECHNOLOGY CLINICS, APRIL 27-MAY 31, 2006