

Should We Regulate Assisted Reproductive Technology?

by Tracy Pfeiffer

1. What is Assisted Reproductive Technology (ART)?

Infertile people seek the help of ART for many reasons today. The first commonly used procedure was artificial insemination, where a woman inseminates herself with frozen sperm donated by either her partner or an anonymous donor. This procedure appears to be very primitive today considering the more recent and advanced technologies that have evolved over the last couple of decades. The following procedures are currently common forms of ART:

In Vitro Fertilization

This is the most common and most effective procedure, where a woman's eggs are removed from her body and combined with sperm in a petri dish. Three to five days after fertilization, healthy embryos are implanted in the woman's womb.¹

Zygote Intrafallopian Transfer (or Tubal Embryo Transfer)

Like in vitro fertilization, this procedure also involves fertilizing eggs outside of the woman's body. However, unlike in vitro fertilization, the embryo is moved to the woman's fallopian tube so that it can implant in the uterus naturally.²

Gamete Intrafallopian Transfer

This more rarely available procedure allows fertilization of the egg to occur more naturally in the woman's fallopian tube by transferring eggs and sperm into the fallopian tube.³

Intracytoplasmic Sperm Injection

This procedure is similar to in vitro fertilization, except that an individual sperm is injected directly into an egg in a petrie dish before being transferred into the woman's body. This method is helpful when the sperm is unable to fertilize the egg on its own.⁴

People choose to utilize ART for many reasons including fallopian tube blockages, endometriosis, low sperm count, and other infertility issues.⁵ The type of problem that a couple or an individual is having will determine which of the above treatments is best for them. If one or both of the partners' gametes are not viable, an egg and/or sperm donor must be utilized. If a woman is unable to carry a fetus to term, a gestational surrogate must be utilized. The increasing number of gay and lesbian couples who are having children are often using ART to conceive. Recently, in the United Kingdom, scientists have even obtained permission to create an embryo that will have genetic material from two mothers.⁶ Science in this area is developing quickly, and the law in the United States has yet to catch up with it.

2. Current ART Regulation in the United States

Federal Regulation

The Fertility Clinic Success Rate and Certification Act of 1992 is the only federal statute that specifically governs ART.⁷ The Act has two purposes: “(1) to provide consumers with reliable and useful information about the efficacy of ART services offered by fertility clinics, and (2) to provide states with a model certification process for embryo laboratories.”⁸

The Act requires each ART facility to submit a report annually to the Center for Disease Control (CDC).⁹ Each report must contain data relating to treatment success rates, patient

demographics, patient medical histories, patient infertility diagnoses, clinical information regarding each ART procedure, and the resulting births and pregnancies.¹⁰ The Society for Assisted Reproductive Technology (SART) is an organization that contracts with the CDC to annually inspect 10% of all U.S. ART facilities.¹¹ During these inspections, the SART committee validates all live births that have been reported by the clinic.¹² In addition, the committee will examine 20 other variables from 50 randomly selected treatments.¹³ The CDC uses all of the validation information to prepare and publish an annual report.¹⁴ If an ART facility fails to comply with the requirements of the act, it is merely listed as “non-reporting” in the annual CDC publication, with no penalties.¹⁵

In addition, the Act provides the states with a model certification program for embryo laboratories that is completely voluntary.¹⁶ No state in the U.S. has adopted this model program to date. Even if a state would adopt the model, ART laboratories are not required to apply for certification.¹⁷ Federal regulation of ART is essentially non-existent since the Act only provides mere suggestions for ART facilities with no actual requirements or enforcement mechanisms.

State Regulation

While many state statutes exist that directly affect ART facilities, they are mostly concerned with issues of access to the procedures.¹⁸ There are some statutes that more directly apply to the procedures, such as limitations of who may handle gametes, specifications of who may receive ART treatments, and sperm screening requirements for donations.¹⁹ A few states have statutes that regulate the complicated family law issues that can arise in more intricate ART methods, such as surrogacy and egg donation from third parties.²⁰ A small number of states have

regulations that limit the research that can be done in conjunction with ART procedures, such as embryo experimentation.²¹

Most state laws that are applicable to ART facilities and procedures involve insurance coverage and certification/licensure requirements. The majority of important legal issues that arise in the area of ART are largely unsettled. An example of one of these issues is the confusion over the legal definition of “parent.” In more complex arrangements such as third party gamete donation or gestational surrogacy, who should a court deem to be the parent of the child in the event of a dispute? Should it be the gamete donor, the woman who gave birth to a child for another couple, or the couple for whom the surrogate mother carried the fetus? Does it matter if the surrogate donated her own egg for the procedure or if the gametes belong to two different people? Very few statutes have answers to these questions.

Other potential issues involve the contractual nature of such arrangements. What if one of the parties dies or changes his or her mind? Should payment to third parties involved in ART procedures (e.g., gamete donors or surrogates) be required? Another contested issue is whether sperm donors may remain anonymous. What if the child that is a product of the donation wants to later obtain genetic information for health purposes? The issue of “designer babies” is also a controversial one. Should parents be able to utilize technology to select the sex or features of their children? The law in the U.S. has a long way to go before it addresses these types of questions in all jurisdictions.

3. ART Regulation in Great Britain

In 1990, the legislature in Great Britain came to the conclusion that more direct regulation of ART techniques and embryo research was necessary. As a result, they passed The

Human Fertilization and Embryology Act (HFEA), which was recently amended in December of 2006.²² Some of the more prominent aspects of the HFEA are regulations that

- (1) prohibit the use of sex selection,
- (2) explicitly grant access to ART procedures to single women and lesbian couples,
- (3) Permit genetic modification techniques that can prevent genetic transfer of certain diseases,
- (4) specifically define the terms “mother” and “father,”
- (5) prohibit monetary payments to third parties who participate with a couple in the ART process,
- (6) prohibit non-human gametes/embryos from being placed in a human woman, and
- (7) provide for a data bank that contains the identities of gamete donors (note: very stringent criteria must be met for a person to gain access to this information).²³

Currently, the United States has very few laws that address the above issues. While it is true that the lack of extensive regulation in ART creates a friendlier environment for those who wish to profit off of such technologies, other ethical and legal considerations must be taken into account. Not only health and safety concerns are at issue, but the lives of the people who participate in such procedures—and are the products of such procedures. The United States would be wise to examine the HFEA and use it as a model for more widespread and effective regulation of ART.

For more information, see:

- The President’s Council on Bioethics, *Reproduction and Responsibility: The Regulation of New Biotechnologies*, available at <http://www.bioethics.gov/reports/reproductionandresponsibility/chapter2.html> (last visited October 30, 2007).

- Centers for Disease Control and Prevention, *Assisted Reproductive Technology*, available at <http://www.cdc.gov/art/> (last visited October 30, 2007).
- Society for Assisted Reproductive Technology, <http://www.sart.org> (last visited October 30, 2007).
- James W. Fossett, *Lessons from Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States*, NEW ENGLAND JOURNAL OF MEDICINE, available at <http://www.allbusiness.com/legal/3587514-1.html> (last visited October 30, 2007).

¹ Womenshealth.gov, *Trying to Conceive*, available at <http://www.4woman.gov/pregnancy/tryingtogetpregnant/tryingtoconceive.cfm> (last visited October 30, 2007).

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ University of Michigan Health System at http://www.med.umich.edu/1libr/wha/wha_invitfer_crs.htm.

⁶ BBC News, *Embryo with Two Mothers Approved*, Sept. 8, 2005, available at <http://news.bbc.co.uk/1/hi/health/4225564.stm> (last visited October 30, 2007).

⁷ The Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. § 263a-1 et seq (2006).

⁸ The President's Council on Bioethics, *Reproduction and Responsibility: The Regulation of New Biotechnologies*, available at <http://www.bioethics.gov/reports/reproductionandresponsibility/chapter2.html> (last visited October 30, 2007).

⁹ 42 U.S.C. § 263a-1(a).

¹⁰ The President's Council on Bioethics, *Reproduction and Responsibility: The Regulation of New Biotechnologies*, *supra* note 8.

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ The President's Council on Bioethics, *Reproduction and Responsibility: The Regulation of New Biotechnologies*, *supra* note 8.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² Human Fertilization and Embryology Act, 1990, c. 37, § 12 (Eng.).

²³ Mariemma Medina-Morales, *Designing a Baby: Why Is It Illegal in the United Kingdom but a Profitable Market in the United States?*, available at [http://www.law.uh.edu/healthlaw/perspectives/2007/\(MM\)DesignerBabies.pdf](http://www.law.uh.edu/healthlaw/perspectives/2007/(MM)DesignerBabies.pdf) (last visited October 30, 2007)