2010 Nobel Prize for Development of In Vitro Fertilization Technology Not Without Controversy

By Cynthia S. Marietta, J.D., LL.M. (Health Law)
csmarie@central.uh.edu

Introduction

English scientist and former Cambridge physiology professor, Robert G. Edwards, Ph.D, was recently awarded the 2010 Nobel Prize in Physiology or Medicine for his pioneering work in the development of in vitro fertilization (IVF). Since 1901, the prestigious “Nobel Prize in Physiology or Medicine” has been awarded to scientists who have made important discoveries for the benefit of mankind. Edwards’ scientific achievement led to the treatment of infertility, which affects more than 10 percent of couples worldwide. Since the birth of the first IVF infant in 1978, roughly four million individuals have been born thanks to Edwards’ development of IVF treatment. Many of these individuals are now adults and have become parents themselves. According to the Nobel Prize Committee, Edwards’ contributions represent a milestone in the development of modern medicine.

But Edwards’ Nobel Prize is not without controversy. Despite the smiles and joy that IVF has given to infertile couples, the Nobel Prize is also a frank reminder of the bioethical issues and fertility practice misuses that have emerged with the advent of IVF technology. While Edwards’ IVF discoveries opened the door for scientific advancements in stem cell research, human cloning, and pre-implantation genetic diagnosis (PGD), these procedures carry along with them a host of ethical concerns. Moreover, IVF treatment, in and of itself, raises a number of ethical questions and the potential for misuses of practice, such as whether and how much money to pay egg donors, how many embryos should be transfered to a woman’s uterus in a single IVF procedure.

2 The 2010 Nobel Prize in Physiology or Medicine, supra note 1.
4 The 2010 Nobel Prize in Physiology or Medicine, supra note 1.
5 Id.
6 Id.
7 Id.
treatment cycle, what should be done with excess frozen embryos, and to what extent PGD might be used to create “designer babies.” According to one ethicist, Edwards’ work in IVF may have unleashed the most controversial technology of all—using IVF for biomedical enhancement and designing human offspring. Staunch IVF critic and Vatican official, Ignacio Carrasco, argues, “[w]ithout Edwards, there wouldn’t be freezers full of embryos waiting to be transferred in utero, or more likely, be used for research or to die, abandoned and forgotten by all.”

During the 32 years since the birth of the first IVF baby, various religious groups, ethics organizations, and medical professional fertility societies have published papers and guidelines espousing their positions on various ethical issues and suggested practice standards for IVF technology. Yet, despite these publications, the ethical issues and misuses of IVF practices continue. What seems to be noticeably absent in this mix is the existence of an entity with recognized authority to establish and enforce medical and bioethical standards for IVF practices and procedures.

Since IVF technology encompasses medically-based procedures, it seems logical that regulatory enforcement of IVF should be a matter for the medical profession, and specifically, medical fertility specialists. Recognized professional fertility societies in the U.S., such as the American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technologies (SART), attempt to self-regulate the profession by setting guidelines for medical and bioethical standards of IVF practice, but these societies lack the teeth to effectively enforce such standards. State medical regulating agencies, on the other hand, have the authority to enforce standards of practice, but they lack the knowledge and expertise in the field of reproductive medicine to

---

12 Jonsson, supra note 8 (quoting Arthur Caplan, Director of the Center of Bioethics at the Univ. of Pennsylvania, Philadelphia).
15 ASRM is a multidisciplinary organization dedicated to the advancement of the art, science, and practice of reproductive medicine. Its mission is to pursue excellence in education and research and through advocacy on behalf of patients, physicians, and affiliated health care providers. See Am. Soc’y of Reproductive Med., Mission Statement, available at http://www.asrm.org/detail.aspx?id=60.
16 SART serves to promote and advance the standards for the practice of assisted reproductive technology to the benefit of its patients, members, and society at large, and its organizational membership includes more than 90 percent of U.S. fertility clinics See Soc’y for Assisted Reproductive Tech., Mission Statement, available through http://www.sart.org.
effectively establish the standards for that industry. Thus, what seems glaringly apparent is the need for fertility specialists and state medical regulating agencies to join forces in a collaborative effort to effectively establish, police, and enforce ethical violations and standards of IVF and other Assisted Reproductive Technologies (ART) practices.

Historical Perspective on Evolution of IVF and Accompanying Ethical Concerns

Dr. Edwards began his fundamental research studying the biology of fertilization in mice in the 1950s.19 His mission to develop IVF was defined by what he reportedly believed to be the deepest of human desires: to have a baby.20 He had two children of his own and was empathetic about the plight of a childless couple whom he had befriended and was moved by their inability to conceive children.21

Based on his fertilization experiments conducted with mice and the fertilization techniques he had seen other scientists use with rabbits, Dr. Edwards decided to investigate whether similar methods could be used to fertilize human eggs in a clinical laboratory.22 He soon realized that if he could find a way for sperm to fertilize a human egg in the clinical laboratory he may pave the way for infertility treatment.23 He spent years conducting experimental studies to discover how human eggs mature, how different hormones regulate egg maturation, and the time during an ovulation cycle when eggs are susceptible to being fertilized by sperm.24

When Dr. Edwards wanted to find a safe way to retrieve mature eggs from the ovaries, he partnered with English gynecologist, Patrick Steptoe, M.D., one of the pioneers in laparoscopic techniques.25 Together the two developed and refined IVF from the experimental stage to clinical practice. Dr. Steptoe used the laparoscope to remove mature eggs from a woman’s ovaries, and then Dr. Edwards put the eggs in cell cultures in a petri dish and added sperm to fertilize them. The fertilized egg cells then self-replicated to form eight-cell embryos ready for transplantation in a woman’s uterus.26

Drs. Edwards and Steptoe continued their research, and although their early studies seemed promising, the British Medical Research Council decided not to continue to fund the project due to ethical concerns that IVF could lead to overpopulation.27 Edwards and Steptoe were able to continue their work relying on private donations.28 Some critics, including scientists, religious leaders, and medical ethicists, complained that IVF was

---

19 The 2010 Nobel Prize in Physiology or Medicine, supra note 1; Biography: Robert Edwards, supra note 1.
20 See Biography: Robert Edwards, supra note 1; see also Jonsson, supra note 8.
22 Id.
23 Id.; The 2010 Nobel Prize in Physiology or Medicine, supra note 1.
24 The 2010 Nobel Prize in Physiology or Medicine, supra note 1.
26 The 2010 Nobel Prize in Physiology or Medicine, supra note 1.
27 Jonsson, supra note 8.
28 The 2010 Nobel Prize in Physiology or Medicine, supra note 1.
akin to “playing God” and wanted Dr. Edwards to stop his research.\textsuperscript{29} Others believed IVF children would have defects and be seen as Frankenstein monsters.\textsuperscript{30}

In 1978, Dr. Edwards and Dr. Steptoe initiated IVF treatment on Lesley and John Brown who had tried unsuccessfully for nine years to conceive a child.\textsuperscript{31} After undergoing IVF treatment on July 25, 1978, Mrs. Brown gave birth to the first IVF baby, a healthy baby girl named Louise Brown.\textsuperscript{32} Louise was subsequently dubbed the world’s first “test tube” baby.\textsuperscript{33}

As Dr. Edwards’ IVF vision became a worldwide reality, ethical controversies continued. In the United States, scientists sought governmental funding for IVF research, but were rejected.\textsuperscript{34} During the 1970s and 1980s, the U.S. government avoided the topic of IVF funding after the Supreme Court legalized abortion in the 1973 \textit{Roe v. Wade}\textsuperscript{35} decision.\textsuperscript{36} Because IVF entails beginning-of-life issues, the subject of IVF funding got caught in the middle of the heated debates and controversies about abortions and fetuses in the wake of \textit{Roe v. Wade}.\textsuperscript{37}

In 1981, the first American IVF clinic opened its doors with private funding, and later that same year, the first American IVF baby was born.\textsuperscript{38} Subsequently, the IVF “high-tech baby” industry\textsuperscript{39} in the U.S. grew exponentially, but without federal funding,\textsuperscript{40} which meant no governmental oversight or federal guidelines or review processes that are inherent within federal research grant funding process.\textsuperscript{41}

As the “high-tech baby” industry continued to boom, unanswered legal and ethical questions began multiplying, as well.\textsuperscript{42} In 1986, two ethics experts raised a host of legal and ethical questions arising from the IVF baby-making industry and concluded “the law is unclear, the ethics controversial, the psychology uncertain” as it applies to IVF created embryos and the couples desperately seeking IVF children.\textsuperscript{43} Given these circumstances,
these ethics experts emphatically expressed the need for appropriate legal policies, guidelines, and medical standards to address booming IVF technology and practices.44

Meanwhile, despite the pleas for policies, guidelines, and standards for IVF technology, the U.S. government continued to maintain a hands-off policy.45 It was not until 2004, when the President’s Council on Bioethics (President’s Council) addressed the topic of IVF technology and its potential misuses and ethical implications.46 The President’s Council focused on two areas of concern: (1) the novel nature of IVF technology and the lack of long-term longitudinal studies on the health and well-being of IVF children, and (2) IVF patient vulnerability.47 The President’s Council recognized that IVF patients/parents are increasingly vulnerable, given the emotional strain they experience during treatment cycles.48 The emotional strain could push a couple to take undue risks, such as insisting on transferring an excessive number of embryos to increase their chances of pregnancy, especially when coupled with an irresponsible clinician who agrees to do it for the sake of enhancing his success rates.49

Over the course of the past several years, ASRM and SART, along with other professional fertility societies, have stayed on top of these concerns and several others by publishing guidelines and suggested practice standards for assisted reproductive technologies (ART) and IVF procedures.50 Notwithstanding these publications, misuses of IVF practice and ethical dilemmas still exist, most likely because ASRM and SART have no authority to enforce violations of their guidelines and standards other than to revoke memberships in these professional societies.51 For instance, contrary to ASRM’s ethical guidelines on the limited use of PGD to screen embryos for genetic diseases,52 there are those practitioners who may be willing to step across ethical lines and succumb to patients’ desires to use PGD for gender selection and other characteristics to design their baby.53

44 Id.
45 Government Funding of IVF, supra note 34.
47 Id.
48 Id.
49 Id.
50 ASRM Members may obtain ASRM publications on Ethics Committee Reports and Statements and Practice Guidelines online through http://www.asrm.org.
51 Oversight of Assisted Reproductive Technology, supra note 18.
Another example is that of fertility practitioners who may intentionally violate ASRM’s and SART’s guidelines on the number of embryos that should be transferred to a women’s uterus in a given IVF cycle, as in the highly-publicized case of the “Octomom.” In that case, a California fertility specialist blatantly violated ASRM’s guidelines by transferring twelve embryos instead of the recommended one or two embryos. He did so to appease his patient’s adamant wishes to transfer all twelve, but at the same time endangered her life and the long-term health of the babies. He has been publicly flogged in the media after his patient gave birth to eight premature babies, all of whom reportedly will have developmental delays, at best or more serious long-term physical or mental problems and more than likely will require California taxpayers’ financial support. ASRM and SART can only revoke this physician’s membership, but the California Medical Board is currently reviewing and conducting hearings on the case and could potentially revoke his license for violating recognized guidelines and standards in the fertility industry.

Collaborative Effort May Help Reduce the IVF Controversy

The California Medical Board’s involvement in the Octomom case is a prime example of how state medical regulating agencies and fertility professional peer organizations, such as ASRM and SART, could work together to effectively establish and enforce IVF and ART practice standards. But to be effective, the process cannot proceed on a random basis. State medical regulating agencies must call upon the applicable professional fertility peer organizations to provide them with the applicable standards of practice and then notify their respective state licensees that ASRM’s and other peer guidelines for IVF technology and practices will be enforced.

Conclusion

While the 2010 Nobel Prize award may have reigned the controversies surrounding IVF technology, perhaps the Nobel Prize can also effectively serve as the impetus for constructing a workable framework for establishing and enforcing IVF and ART standards of practice. Professional fertility peer organizations and state medical

59 Octomom’s Doctor Learned About Octuplets After Birth, supra note 55.
regulating agencies should work together to form a collaborative plan for establishing and enforcing applicable standards for medical and ethical practices in the fertility industry.

Health Law Perspectives (November 2010)
Health Law & Policy Institute
University of Houston Law Center
http://www.law.uh.edu/healthlaw/perspectives/homepage.asp

The opinions, beliefs and viewpoints expressed by the various Health Law Perspectives authors on this web site do not necessarily reflect the opinions, beliefs, viewpoints, or official policies of the Health Law & Policy Institute and do not constitute legal advice. The Health Law & Policy Institute is part of the University of Houston Law Center. It is guided by an advisory board consisting of leading academicians, health law practitioners, representatives of area institutions, and public officials. A primary mission of the Institute is to provide policy analysis for members of the Texas Legislature and health and human service agencies in state government.