

The Octuplets Tragedy



David Adamson, MD



Elizabeth Ginsburg, MD

The recent birth of octuplets in Los Angeles has generated a media frenzy in the United States and around the world. Although we marvel at the live birth of eight babies, and give recognition to medical science and our colleagues who ensured their healthy delivery, this event has created a firestorm of controversy: How did this happen, especially with in vitro fertilization (IVF), when the number of embryos transferred is controllable? How did a woman who already has six children, is single, is a student living with her parents, and who receives state disability payments undergo IVF? How did the physician who provided care make his decisions? What is the standard of care? Who is going to pay for this? How can this be avoided in the future? Fertility physicians everywhere share all these concerns and are asking for action.

At this time, many medical details that would help answer questions surrounding this rare event are unknown to the public or professional organizations. The American Society for Reproductive Medicine (ASRM) and its affiliated society, the Society for Assisted Reproductive Technology (SART), have formally requested information from the physician who provided treatment so that his practice can be thoroughly assessed through our peer-review procedures. We also have offered to assist the Medical Board of California in its evaluation of this event.

SART, ASRM, and their members long have been concerned about problems created by multiple births, including the best interests of the children born.^{1,2} Guidelines based on sound scientific and clinical evidence regarding the number of embryos to transfer were first published in 1998 and were revised downward in 1999, 2004, 2006, and 2008 as the efficacy of IVF improved.³ These guidelines show the success of professional self-regulation. In vitro fertilization data on fresh nondonor egg cycles show (1) the percentage of deliveries with triplets or higher has been reduced from 6.9% in 1996 to 1.7% in 2007, (2) the percentage of egg retrievals in 2007 that resulted in the delivery of triplets was only 0.6%, and (3) the percentage of embryo transfers that resulted in at least one live birth increased from 28% in 1996 to 34.3% in 2005.⁴

The recommended number of fresh embryos to transfer in a patient younger than 35 years old with a good prognosis (ie, good embryo quality and no history of repeated prior failures of IVF treatment or chromosomal rearrangement) is one or at the most two. Owing to the lower chances of frozen embryos implanting, an additional embryo often is added in frozen embryo transfer cycles. Guidelines allow flexibility among IVF clinics and patients depending on other prognostic factors to allow individualized patient care. Although we do not have all the specific medical information in this case, at this time it is impossible to understand how ASRM/SART guidelines could have been followed.

Some have called for more regulation of IVF. Yet IVF is already one of the most carefully regulated, accredited, and audited areas of medicine. SART sets rigorous personnel and procedural standards, the Fertility Clinic Success Rate and Certification Act of 1992 requires annual

Dr. Adamson is the Immediate-Past President of the American Society for Reproductive Medicine; e-mail: gadamson@argfertility.com. Dr. Ginsburg is the President of the Society for Assisted Reproductive Technology; e-mail: eginsburg@partners.org.

Financial Disclosure

Dr. Adamson is the CEO of Advanced Reproductive Care (Palo Alto, CA), and he receives research funding from, Institut Biochimique S.A. (Pambio-Noranco, Switzerland) and EMD Serono, Inc. (Rockland, MA). Both Drs. Adamson and Ginsburg provide in vitro fertilization services.

© 2009 by The American College of Obstetricians and Gynecologists. Published by Lippincott Williams & Wilkins.

ISSN: 0029-7844/09



reporting of pregnancy and live birth rates to the Centers for Disease Control and Prevention, the College of American Pathologists and ASRM as well as The Joint Commission accredit embryology laboratories with on-site inspections every 2 years, and the Food and Drug Administration regulates many aspects of gamete and embryo donation.^{5,6} These guidelines, standards, licenses, and regulations have been successful in improving the success, health, and safety of women undergoing IVF treatments and their resultant neonates. It should be noted that strict reproductive technology regulations in other countries have not been a panacea and are almost always associated with state coverage of the cost of assisted reproductive technology treatment. Those regulations sometimes have resulted in reduced pregnancy rates and denial of treatment to many women based on demographic factors and have promoted cross-border reproductive care.

However, in the United States, private reproductive and parenting decisions never have been regulated, and this includes the decision parents and their physicians make regarding the number of embryos to transfer in IVF. Although some have suggested regulation in response to this extremely rare birth of octuplets, such action would ignore the success of professional standards and self-regulation, not only in this area of medicine but also in many others. Such action would be particularly troubling in reproductive medicine, where issues of personal choice and reproductive rights should be protected for everyone, not just for infertility patients. Furthermore, no regulation will completely prevent substandard, immoral, illegal, or unethical behavior on the part of physicians or patients.

Social justice requires a response to this event. ASRM and SART have called for a comprehensive evaluation of the medical practice in question. Appropriate actions then can be taken in this particular situation. The Society for Assisted Reproductive Technology also is reevaluating its guidelines regarding the number of embryos to transfer based on the most recent clinical data submitted by SART programs and is making its internal quality assurance and validation policies and procedures more stringent. We also call for more support for research in IVF and

for better insurance coverage for infertility care to help reduce patient motivation to transfer too many embryos. Physicians' compliance with practice standards could be helped by legal protection from unreasonable patient requests. The Medical Board of California, as well as those of other states, has the right to levy sanctions, including loss of medical licensure, for care that does not follow national standards. As professional societies, SART and ASRM can develop guidelines for standards, but they have the power only to revoke membership.

In summary, this tragic situation has focused our attention on the problem of multiple births from IVF. ASRM, SART, and their members have made much progress with this issue. Application of currently available regulations, guidelines, and professional organization procedures will protect the health, safety, and rights of women, children, and our society. The Society for Assisted Reproductive Technology and ASRM, as well as other stakeholders in reproductive medicine, are actively evaluating changes in the current system that can be made to reduce the risk further and hopefully to prevent another tragedy in the future.

REFERENCES

1. The Ethics Committee of the American Society for Reproductive Medicine. Child-rearing ability and the provision of fertility services. *Fertil Steril* 2004;82:564-7.
2. The Practice Committee of the American Society for Reproductive Medicine. Multiple pregnancy associated with infertility therapy. *Fertil Steril* 2006;86:S106-10.
3. The Practice Committee of the Society for Assisted Reproductive Technology; Practice Committee of the American Society for Reproductive Medicine. Guidelines on number of embryos transferred. *Fertil Steril* 2008;90:S163-4.
4. Assisted Reproductive Technology Success Rates, National Summary and Fertility Clinic Reports. Centers for Disease Control. 2005. Available at: <http://www.cdc.gov/ART/ART2005/index.htm>. Retrieved March 19, 2009.
5. The Practice Committee of the American Society for Reproductive Medicine; Practice Committee of the Society for Assisted Reproductive Technology. Revised guidelines for human embryology and andrology laboratories. *Fertil Steril* 2008;90:S45-59.
6. The Practice Committee of the Society for Assisted Reproductive Technology; The Practice Committee of the American Society for Reproductive Medicine. Revised minimum standards for practices offering assisted reproductive technologies. *Fertil Steril* 2008;90:S165-8.

