The Octuplets: A Medical Mistake Needing More Regulation?

By Bruce Patsner, M.D., J.D.

The spotlight and story line have been shifting continuously since the news of the delivery of octuplets by Nadya Suleman was first announced by Kaiser Permanente Medical Center in California on January 26, 2009.¹ Staged photo shoots of the smiling faces of dozens of physicians and nursing staff involved in the historic Cesarean delivery of the eight premature infants (only the second known living set of octuplets in the U.S.)² were quickly replaced by interviews with family members and efforts to secure multi-million dollar contracts for morning talk show appearances.³ However, public amazement quickly turned to consternation and in some cases outrage when it was revealed that the birth mother was divorced, unemployed, disabled, on food stamps, had a history of psychiatric disease, and already the mother of six other children.⁴ Uncertainty over whether Kaiser Permanente or the citizens of the State of California will end up paying for millions of dollars of medical care for the eight premature infants hasn’t helped the situation.

Infertility specialists almost immediately began to question the rational for implanting eight embryos,⁵ and a noted medical ethicist soon labeled the conduct of all parties concerned “unethical.”⁶ A determined but unsuccessful effort began to keep the identity of the infertility specialist who implanted the eight embryos from becoming known in the face of mounting public and medical criticism. Two weeks after the octuplets’ birth, the California Medical Board announced that it would investigate the infertility specialist for potential violations of the standard of care.⁷ Ms. Suleman may have summed up part of the problem when she asserted in an interview with NBC News that “Those

embryos] are my children, and that’s what was available and I used them. So, I took a risk.”

The octuplets story circles around uncomfortable social issues which run the gamut from parental rights and responsibilities to the obligations of society to support unwed mothers. There is also what is perceived to be a condescending, elitist attitude by some towards women who elect to have large families. The entire spectacle has already taken on a somewhat tawdry air: allegedly incompetent physicians, greedy single mothers on the dole, media hype, and outraged medical ethicists.

Ethical issues aside, there remains the critical question of whether the medical profession is capable of adequately self-regulating infertility specialist conduct or whether the fertility industry curbs require greater government oversight and intervention. The only certainty in all of this is that the road to correcting any alleged flaws in the medical and social system that allowed the current events to transpire will run right through the law.

Medical Standards of Care, but No Federal Rules and Few Laws Governing ART

Although there are laws in some other countries which actually regulate the practice of assisted reproductive technology (ART), of which in-vitro fertilization is just one of several potential routes to achieving pregnancy, there is no over-arching law in the U.S. which places limits on the number of embryos that can be placed in a mother’s womb. In some European countries (Germany, for example) there are federal laws which limit the number of embryos which may be transferred during IVF procedures, and provide robust mechanisms for monitoring such medical treatments. There are monetary fines and in some cases prison terms for knowing violations of such laws. The existence of such legal standards for ART is not at all arbitrary, and represents one of those instances where the law, medical science, and the facts on patient outcomes are all aligned.

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9 Kate Zernike, And Baby Makes How Many? In an era of shrinking broods, larger families can feel under attack, THE NEW YORK TIMES, Sunday February 8, 2009, at 1, “Many mothers, in fact, shared the revulsion and the ethical questions about the in vitro fertilization that led to the birth of the eight babies by the unwed and unemployed California mother. Yet they also say that the reaction to her turned harsh when it was revealed that she had six additional children. Octuplets were amazing; 14 is gross.”


12 Id. The German embryo protection law passed in 1991 stipulates that no more than 3 embryos created per IVF cycle may be transferred.

maternal and fetal) outcomes are generally best when no more than two fertilized eggs are transferred. More importantly, there is no statistically significant increase in the live-born term pregnancy success rate when more than two embryos are transferred.14

In the U.S. what exists on the legislative side is a hodge-podge of different laws in different states regulating this aspect of the medical profession. There is currently only one federal law which explicitly and directly regulates the provision of infertility services: The Fertility Clinic Success Rate and Certification Act of 1992,15 a law designed to prevent consumers from being misled by success claims made by infertility specialists. This law aside, there is no other formal direct federal regulation of ART. At best, some indirect regulation of in-vitro-diagnostic and laboratory tests used in IVF clinics by the Center for Medicare and Medicaid Services (CMS) exists under the 1988 Clinical Laboratory Improvement Amendments (CLIA),16 but it provides no federal oversight of infertility services per se.

The exploding technologies of ART have escaped federal regulation to a large degree because many of the reproductive health issues involve questions which also raise the spectre of termination of pregnancy (i.e. disposal of unused embryos). Individual state efforts to fully regulate ART and pre-implantation gender diagnosis have never been enacted into law in part due to such concerns.

Does the Medical Profession Adequately Self-Regulate?

Even though there is a marked absence of legislative guidelines at the state and federal level for regulation of ART, there are national standards for medical practice in several areas of infertility care which have been published by the American Fertility Society, The American College of Obstetricians and Gynecologists, and the American Society of Reproductive Medicine (ASRM).17 There is also separate oversight of the medical profession at the state level conducted by individual state medical boards.

Medical professional society guidelines are not binding on physicians and do not have the force of law, but they are admissible as evidence in court should a specific infertility practice or outcome allegedly fall below the standard of care. They may be used by state medical boards if they elect to investigate an infertility specialist’s medical practice, and can be used to remove subspecialty society membership from physicians whose practices patterns repetitively fall below medical society standards. In the case at hand, the ASRM guidelines on the appropriate number of embryos which should be transferred in a woman under the age of 35 explicitly state that no more than 2 embryos should be transferred in the absence of extraordinary circumstances.18

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14 Practice Committee of the Society for Assisted Reproductive Technology and the American Society for Reproductive Medicine, Guidelines on the number of embryos transferred, 90 FERTILITY AND STERILITY S163, NOVEMBER 2008 [hereafter ASRM Guidelines].
16 CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA), PUBLIC LAW 100-578 (1988).
17 ASRM Guidelines, supra note 14.
18 Id.
Despite the existence of such medical practice standards, there is a small subset of obstetrician-gynecologists who have tacitly encouraged the practice of multiple-birth pregnancies and have publicly made it a routine part of their medical practice,\(^\text{19}\) even though such medical practices have been criticized by experts in the field of reproductive medicine.\(^\text{20}\) In addition, even though “fetal reductive surgery” has been strongly advocated by many infertility experts to limit the number of pregnancies, and minimize concomitant maternal and fetal medical risks from “super-twin” pregnancies,\(^\text{21}\) the legal reality is that once fetal reductive surgery is offered and refused, there is little to prevent a determined woman or couple from attempting to carry an inordinately large number of fertilized eggs implanted through in vitro fertilization to term. Surgical innovation, as a rule, is not regulated by the federal government, nor is the practice of medicine; state medical boards, and state laws, are the regulatory default in this area.\(^\text{22}\)

Not unexpectedly, there is firm opposition to the imposition of federal laws or guidelines, on the number of fertilized eggs which may be transferred during IVF procedures by infertility specialists. Some of the arguments have been heard before: medicine is an “art;” inflexible rules will not be universally applicable to all infertility patients, and innovation in the field will be stifled. One of the unstated arguments is that ART in general and IVF in particular are big businesses and have enjoyed a very profitable twenty-year run with little formal government intervention.\(^\text{23}\) And there is always the danger that an over-reaction by state and federal regulators to this isolated instance of octuplets will prove worse than the event itself. So the question remains: how well does the medical profession self-regulate, at least as far as the IVF is concerned?

Though no conclusive data is available, there is at least some evidence that professional medical societies such as the ASRM have been somewhat successful in policing its members.\(^\text{24}\) The ASRM has both Quality Assurance and Violation Committees, which routinely investigate infertility practices whose pregnancy rates are more than two standard deviations below the national average for three years in a row or whose higher multiple pregnancy rates are above average.\(^\text{25}\) These Committees formally request clinical information and allow clinicians to implement changes in their practices to self-
correct; they also allow outside investigators to evaluate infertility practices. Failure to self-correct can result in disciplinary actions including loss of ASRM membership, loss of coverage for services by insurance companies (admittedly less of a penalty in what is often a cash business), and notification to state medical boards of loss of professional society status. Since the passage of clinical guidelines and the establishment of a peer-review mechanism by ASRM for IVF clinics to monitor both pregnancy success rates and “super-twin” gestation rates, the number of IVF clinics with poor pregnancy results has declined and the number of multi-fetal pregnancies has declined by 70%.28

Conclusion

Currently there are three meaningful ways to regulate the conduct of IVF physicians in the U.S.: (1) medical malpractice law; (2) professional medical society supervision of clinical activity; and (3) state medical board oversight of physician practice patterns and conduct. The first only applies if patients bring a claim (unlikely in a successful super-twin pregnancy). The second may result in loss of accreditation, membership, income, professional shame, and state medical board action. Even so, state medical board actions against medical licensure status are the only enforcement mechanism with real legal bite. Unfortunately, state medical board actions can be lengthy, time-consuming, and may be contested over years while profitable infertility providers “lawyer-up” and continue to practice. If transferring eight embryos were a felony, for example, the suspension or revocation of a medical license could be carried out by a state medical board almost immediately.29

One advantage of comprehensive government regulation through federal rules would be that definitive and substantive penalties could be imposed immediately in response to medical care which fell below an agreed-upon national standard regardless of how the medical profession itself and state medical boards elect to proceed against an individual physician. A second advantage of one federal law, as opposed to fifty individual state laws regulating IVF and ART, would be consistency and uniformity in application and penalties, and lessening the likelihood that physicians may move to other states with looser regulations or oversight.

This “fourth” approach to regulation of infertility specialists has only been adopted by governments outside the U.S., but federal micro-management of select aspects of medical practice is not without precedent if social and political conditions are right. The U.S. Supreme Court decision in Gonzales v. Carhart30 banning partial-birth abortion in the U.S. demonstrates that the federal government is willing to outlaw specific surgical procedures. No doubt, the spectre of dramatic federal intervention in ART is one reason why ASRM and other professional medical societies have worked so hard to reign in

26 Id.
27 Id.
28 Id.
29 TEXAS OCCUPATIONS CODE §§ 164.001 et seq. a. The board shall suspend a physician’s license on proof that the physician has been initially convicted of: i. a felony.
rogue medical practice, and cooperated so closely with state medical boards. Perhaps, in
select circumstances, the medical profession can adequately self-regulate after all.

*Health Law Perspectives* (March 2009), available at:
http://www.law.uh.edu/healthlaw/perspectives/homepage.asp