Octuplet Births Raise Ethical Dilemmas in IVF

BY BETSY BATES

INDIAN WELLS, CALIF. — Infertility specialists at the annual meeting of the Pacific Coast Reproductive Society expressed dismay and frustration at the circumstances surrounding the in vitro fertilization procedure that led to the birth in January of octuplets to a single, unemployed, 33-year-old California woman who already had six children.

"This is unethical. It violates everything we've worked for for 20 years," said Dr. Robert K. Matteri, a reproductive endocrinologist and infertility specialist in Portland, Ore., during an emotional town hall session during the meeting.

Concerns extended beyond the question of whether six embryos should have been implanted in a woman under the age of 35 years who evidently was not infertile. Reportedly, two of the embryos divided to form homozygous twins, for a total of eight births.

Guidelines of the Society for Assisted Reproductive Technology (SART) and the American Society for Reproductive Medicine (ASRM) call for consideration of transfer of a single embryo in women under 35 with a favorable prognosis. "All others in this age group should have no more than two embryos … transferred, in the absence of extraordinary circumstances."

"There are a lot of reasons this does not reach the standards of care," said Dr. Paul Magarelli, a reproductive endocrinologist and infertility specialist in private practice in Colorado Springs.

"Who is looking out for the rights of these children?" agreed Dr. William G. Kearns, director of a preimplantation genetic testing laboratory in Rockville, Md.

"What society is really mad at us for is not the "octo," it's the "Mom," said Dr. Karen Purcell, a reproductive endocrinologist and infertility specialist in San Jose, Calif.

Despite the violation of voluntary guidelines, the transfer of six embryos "is not really the huge harm," and would have been viewed as a simple error in judgment if a normally conscientious infertility specialist had been desperate to help a woman who had "been trying to get pregnant for years and years and years," Dr. Purcell argued. More salient, she said, is the legal, moral, and ethical question, "Who should not be a mom?"

"Actually, I think the bar should be fairly high," said Dr. Lori Marshall, president of the Pacific Coast Reproductive Society (PCRS) and an infertility specialist in private practice in Seattle.

Some of these quandaries are societal, rather than medical, she stressed.

Indeed, much discussion at the meeting focused on news reports indicating Nadya Suleman had undergone repeated in vitro fertilization (IVF) procedures to have more children despite having no current source of financial support and living in her parents' house, which was in foreclosure. She has indicated in news interviews that three of her older children are disabled.

Some of the ethical issues raised by the Suleman case reminded fertility specialists of dilemmas in their own practices.

Audience members reported struggling with the decision to perform IVF on prospective parents after learning that their previous children had been removed from their homes by Child Protective Services, that prospective parents had criminal records of domestic violence, or that they demonstrated they were not able to reliably keep appointments and follow basic medical advice.

In a newspaper column distributed by the American Forum following the Suleman births, Dr. Marshall wrote that she and her colleagues "cringe" at the glowing publicity given to higher-order multiple births on reality television shows and through "Mother of the Year" contests.

The profound costs and medical risks associated with such gestations deserve a "public outcry," she wrote.

On the other hand, Dr. Marshall cautioned against an overreaction that could lead to hasty, far-reaching legislation that could supplant well-constructed professional guidelines. Instead, consequences should focus on violations of current standards, she argued.

"In response to the birth of the octuplets, we should punish the rogue physician who completely ignored established standards of care in the field of reproductive medicine," she wrote.

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At the meeting, many members expressed support for issuing a strong, PCRS-endorsed statement of condemnation if future well-publicized cases imply professional irresponsibility or ethical laxity.

In the immediate aftermath of the octuplet case, that proved to be a tricky task, explained Dr. Richard Paulson, who sits on the board of the ASRM, which issued a statement that many PCRS members found too mild.

A statement on Feb. 9 by ASRM President R. Dale McClure expressed "heightened … concerns" following news reports about the IVF role in the births of Ms. Suleman's previous six children and noted that the organization was seeking details from her and her physician.

"We are pleased that the California Medical Board has announced they will be investigating this matter, and we are prepared to assist them in any way we can," the statement continued.

Without the power to request medical records, the ASRM and other societies had no facts to go on other than what was being broadcast on often-sensational news shows. The physician's name, the number of embryos transferred, and even details about Ms. Suleman's family and financial circumstances were all purely speculative, Dr. Paulson argued.

"What on earth are you going to say? Whatever it was that they did, we strongly condemn it?" he asked rhetorically.

"Everyone was hoping that the California Medical Board would have some sanctions," said Dr. Russell Foulk, a reproductive endocrinologist and infertility specialist in private practice in Reno, Nev.

However, no specific statutes may have been violated. The Medical Board of California's investigation into the circumstances of the Suleman case is ongoing, according to a spokeswoman at the board's headquarters in Sacramento. The board has not linked a physician's name with the case, although Ms. Suleman has identified Dr. Michael Kamrava of Beverly Hills, Calif. as her infertility specialist for all seven pregnancies.

The presumed facts of the case suggest that Dr. Kamrava, who is not board certified, acted "grossly below the standard of care," but that may not be enough to justify discipline by the board, said Dr. Paulson, chief of the division of reproductive endocrinology and infertility at the University of Southern California in Los Angeles.

The Centers for Disease Control and Prevention's Fertility Clinic Reports Web site for 2006 includes statistics from Dr. Kamrava's clinic and indicates that the average number of embryos transferred in women under 35 was 3.5. Of a total of 52 cycles in women of all ages, two live births resulted, both in women under 35 and one, a twin gestation.

A spokeswoman at Dr. Kamrava's office, the West Coast IVF Clinic Inc., said he would not be interested in doing an interview for this story. ■

FDA Strengthens Syncope Warning for Gardasil Vaccine

BY MICHELE G. SULLIVAN

Patients who receive the Gardasil vaccine should sit or lie down in the office for at least 15 minutes after vaccination to prevent possible injury from falling during syncope, while being observed for paleness, sweating, dizziness, or other signs of a possible vasovagal reaction, the Food and Drug Administration recommended.

Because of continued reports of syncope and related traumatic injury, the FDA requested that Merck & Co., manufacturer of the human papillomavirus vaccine, add this information to the warnings and precautions section of the label.

"The addition of syncope to the [label] emphasizes that health care providers and consumers should be alert that fainting may occur following vaccination with Gardasil, sometimes resulting in falling and injuries," the FDA said in a public information statement.

"These are preventable by having Gardasil recipients remain seated or lying down for 15 minutes following vaccination and closely watching them for the following warning signs and symptoms: paleness, sweating, dizziness, ringing in ears or vision changes, which generally occur before fainting."

Up to 40% of adolescent syncope associated with Gardasil is also accompanied by tonic-clonic seizurelike activity, the FDA said. "If an individual faints and especially if seizurelike activity occurs, the individual should be placed in a position, such as lying down, to help restore blood flow to the brain."

Syncope has been listed on the label as a possible adverse event since October 2007, the statement said. However, the FDA's Vaccine Adverse Event Reporting System (VAERS) continues to receive reports of traumatic injuries related to fainting and falling after vaccination. In light of this, the agency decided to strengthen the label warning.

Fainting doesn't appear to be unique to Gardasil, the statement added. "Syncope has been reported after administration of other adolescent and adult vaccines. … It can also occur with certain medications, after blood donation, or in response to pain."

The fact sheet did not give details of the injuries associated with all these events. However, 70 episodes of syncope in U.S. patients were reported that occurred from January 2005 to July 2007 (MMWR 2008;57;457-60). The reports noted that about 5% of the spells were considered serious; 38 occurred on the same day as vaccination and 37 required hospitalization.

As of May 1, 2009, there were 13,758 VAERS reports of adverse events following more than 24 million Gardasil vaccinations in the United States. Of these reports, 93% were considered nonserious and 7% serious. Nonserious adverse events include fainting, pain and swelling at the injection site, headache, nausea, and fever.

However, the vaccine is still considered a safe and effective one, the FDA said in the public information statement. "Based on all of the information we have today, the Centers for Disease Control and Prevention continues to recommend Gardasil vaccination for the prevention of four types of human papillomavirus. As with all approved vaccines, the CDC and the FDA will continue to closely monitor the safety of Gardasil." ■