



Octuplets case sparks ethics uproar over IVF excess and patient screening

Fertility groups want a closer look at the doctor's actions, but oppose more regulation of the reproductive technology.

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AMNEWS STAFF

What began in late January as a feel-good story of a California medical team's Herculean efforts to deliver octuplets after a 31-week pregnancy quickly morphed into a controversy over the medical ethics of fertility practices.

The octuplets' mother, 33-year-old Nadya Suleman, said in an interview on NBC's "Today" that her physician transferred six embryos and two split. Suleman is single, unemployed and has six other young children. All were conceived through in vitro fertilization at the same clinic, she said. For each pregnancy, her doctor transferred six embryos, Suleman said.

If that is true, the physician's actions went well beyond American Society for Reproductive Medicine guidelines, society president R. Dale McClure, MD, said in a statement. The Medical Board of California is investigating, and the ASRM has offered to aid the inquiry. The AMA referred requests for comment to the ASRM.

"What was done is clear-

ly irresponsible, clearly unethical, and it placed the life and health of the mother as well as the fetuses at great risk," said Samuel H. Wood, MD, PhD, a La Jolla, Calif., reproductive endocrinologist. "It's simply the wrong thing to do."

For a woman younger than 35 with a previous successful IVF cycle, the ASRM recommends transferring one embryo — two at most. The society says pregnancies with four fetuses or more pose huge risks, including a 95% chance of pre-term labor and delivery, and a greater than 60% chance of

preeclampsia. One in 10 such pregnancies results in gestational diabetes mellitus.

Pasquale Patrizio, MD, director of the Yale Fertility Center in Connecticut, said he would not have transferred so many embryos in a patient "for any reason. I don't understand why such a decision was made. No matter how much a patient may insist on a transfer of such a large number of embryos, it is out of the question and the request should not be honored at all."

Suleman, who said she has occluded fallopian tubes, told "Today" she dreamed of having a "huge family" and her goal with this pregnancy was to have one more child. She refused to selectively reduce the embryos when she learned six had been implanted successfully.

As of early February, the eight low-birth-weight babies were being tube fed donated pasteurized breast milk and monitored in the Kaiser Permanente Medical Center in Bellflower, Calif., where they were born. The hospital said the babies were expected to remain for several more weeks.

Regulation the answer?

The fertility practice Suleman named in her interview, West Coast IVF Clinic Inc. in Beverly Hills, Calif., is a member of the Society for Assisted Reproductive Technology. SART is an ASRM affiliate that represents more than 85% of U.S. fertility clinics and describes itself as a "governmental watchdog for ART" with quality-assurance expertise.

HOW MANY EMBRYOS?

Fertility specialists have devised guidelines on the optimal number of embryos to transfer, depending on a patient's age and circumstances.

CLEAVAGE-STAGE EMBRYOS 2 OR 3 DAYS AFTER FERTILIZATION

Prognosis	Younger than 35	35-37	38-40	Older than 40
Favorable	1-2	2	3	5
All others	2	3	4	5

BLASTOCYSTS 5 OR 6 DAYS AFTER FERTILIZATION

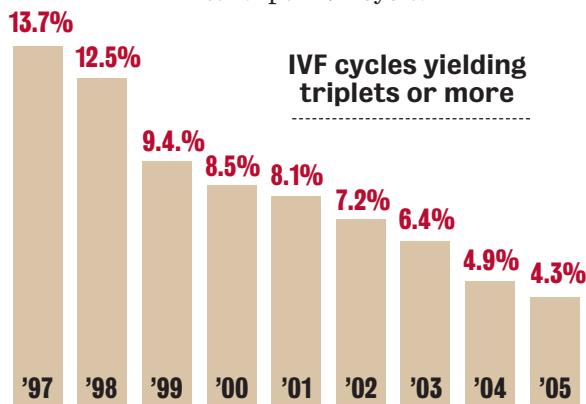
Favorable	1	2	2	3
All others	2	2	3	3

NOTE: INDICATIONS OF FAVORABLE DIAGNOSIS INCLUDE IT BEING THE FIRST CYCLE OF IVF, GOOD EMBRYO QUALITY, EXCESS EMBRYOS AVAILABLE FOR CRYOPRESERVATION OR PREVIOUS SUCCESSFUL IVF CYCLE.

SOURCE: AMERICAN SOCIETY OF REPRODUCTIVE MEDICINE PRACTICE COMMITTEE GUIDELINES, PUBLISHED IN FERTILITY AND STERILITY, NOVEMBER 2008

FEWER MULTIPLES

Aside from the California octuplets, the rate of high-order multiple births resulting from IVF has been declining. Better IVF techniques also have helped reduce the average number of embryos transferred by 38%, to 2.4 per IVF cycle.



SOURCE: "A 47-YEAR-OLD WOMAN WITH FERTILITY PROBLEMS WHO DESIRES A MULTIPLE PREGNANCY," JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, FEB. 28, 2007

SART has contacted the clinic's medical director, Michael M. Kamrava, MD, to learn more about the medical circumstances of the case before taking any action, which could include revoking the clinic's society membership. Dr. Kamrava, an ob-gyn who was shown treating Suleman in a 2006 Los Angeles TV news show, declined requests from *AMNews* for an interview.

The Suleman case shows the fertility industry's self-regulation is insufficient, said Debora L. Spar, PhD, author of *The Baby Business: How Money, Science, and Politics Drive the Commerce of Conception*, which examined the market for reproductive technology. She said government should set rules on how many embryos can be transferred.

"Most people are agreeing this was an extreme case," Spar said. "That is exactly what regulation is best suited for. It defines the extreme and unacceptable behavior. Even if you took the ASRM guidelines, I think what this case shows is that even reasonable guidelines are not necessarily followed by unreasonable practitioners, and it is those unreasonable practitioners that you have to worry about."

The California medical board's decision to investigate may not prevent similar cases, Spar said. "We don't want regulation after the fact. We want regulation beforehand."

Fertility doctors said the proportion of high-order multiple births has dropped, thanks to better methods of culturing embryos and ASRM guidelines on transfers. The percentage of IVF cycles resulting in triplets or more fell 69%, to 4.3%, from 1997 to 2005, the last year for which data are available

from SART and the Centers for Disease Control and Prevention.

"This particular case is a big problem, but I don't think we have a big problem generally," said James A. Grifo, MD, PhD, program director of the New York University Fertility Center. He said regulation could have unintended consequences, contending that a 1992 law requiring the CDC to publicly track clinics' success rates perversely encouraged physicians to increase the number of embryos they transferred to improve the odds.

"We passed the guidelines and made recommendations for what doctors should do, adjusting for the fact that not all patients are the same," said Dr. Grifo, a past president of SART. "Medicine is not formulaic. If it were, then why do we need doctors? We should just go to a computer."

Screening patients

Others said the case — Suleman now is the sole parent to 14 children younger than 8 — highlighted the need for more screening of prospective parents seeking reproductive technology services.

"I would like to see a mandatory psy-

chological evaluation," said Arthur L. Caplan, PhD, director of the University of Pennsylvania Center for Bioethics. Caplan noted that such screening is standard for living organ donors and patients seeking bariatric surgery. "We need to look at what steps we can take to ensure they will be competent parents."

The ASRM published guidelines in 2004 saying fertility clinics could "withhold services from prospective patients on the basis of well-substantiated judgments that

those patients will be unable to provide or have others provide adequate child rearing for offspring." The guidelines do not call for routine screening or home studies.

Fertility specialist Dr. Wood said he has referred a number of prospective parents for psychological counseling. At the same time, some doctors fear trampling on their patients' autonomy.

"I don't feel comfortable being in a position to tell a couple, or a woman, 'You're not going to do any more, because you have enough kids,'" said Yale's Dr. Patrizio. "It's not morally correct because it's not my reproductive right; it's her reproductive right. If she wants to have a large family — do it one at a time or, at the max, two at a time. But it's her choice." ♦