

The Case of the Embryo Mix-up: A Briefing for IVF Inc.

To the Board of IVF, Inc.:

Our group was charged with examining the issues that your patients and the clinic face following the embryo mix-up. We do not attempt in these briefings to give you direction on how to resolve these problems and, indeed, given the short lead time for this examination, you will understand that the briefings to follow will necessarily lack the depth and comprehensiveness of an internal review you are likely to conduct yourselves. We seek to highlight this issues that, in our judgment, pose the gravest problems in this scenario.

The issues fall into two basic categories: 1) what went wrong? and 2) what can be done now?

This briefing will be restricted to the first category by looking at the problems you face from the perspectives of the standards, policies, and procedures that should have been in place at the clinic; and secondarily at what can be learned from previous unfortunate cases of embryo mix-up. Briefings from my colleagues will undoubtedly cover issues in the second category.

A. Applicable standards that may cover your clinic

1. Clinical Laboratories Improvement Act (CLIA)

As you are no doubt aware, CLIA covers *diagnostic* tests done in your laboratory (such as analysis of blood or semen). If the techniques conducted in your clinic with regard to the Remus' and the Fosters' were for procedures of assisted reproduction rather than diagnostic tests, then further laboratory certification requirements may not apply.¹ You may gain breathing space in terms of whether and to what extent CLIA does or should apply to embryology laboratories performing ART-related tests and procedures because it is currently a matter of debate.²

What can you do? *Obtain legal counsel as to whether the procedures taken with the two couples can be construed to fall under CLIA regulations.*

If, however, CLIA is found to apply to ART clinics, then you will be required to establish and follow written quality control procedures described in a procedures manual, and maintain records of all quality control activities. Your laboratory's manual must also include *remedial action* policies and procedures. CLIA regulations also provide for federal officials to perform announced or unannounced inspections and employee interviews. In addition, the regulations contain provisions for enforcement and permit the imposition of sanctions on non-complying laboratories.

What can you do? *Produce your written procedures manual that complies with all requirements of the CLIA regulations OR, if no manual exists, be prepared to state and document the quality control procedures that are in use in the clinic.*

2. American Society for Reproductive Medicine (ASRM) Guidelines and Minimum Standards

Although voluntary, embryology laboratories should have knowledge of and abide by the professional guidelines issued by the ASRM. You are referred to “Revised Minimum Standards for Practices Offering Assisted Reproductive Technologies.”³

As detailed in the above standards, your laboratory should be certified by the College of American Pathologists (CAP) and should report data to the Society of Assisted Reproductive Technology (SART). SART works in conjunction with the Centers for Disease Control to collect and validate outcome data and to require accreditation of embryology laboratories. Submitting data and allowing validation of this data is a requirement for membership in SART. In addition, all SART members must have their embryology laboratories accredited by CAP/ASRM, JCHO, or NYSTB.

In 1999, the CDC published a notice that sets forth a [model certification program](#)⁴ that includes definitions, administrative requirements, and embryo laboratory standards. Under the program, embryo laboratories may apply to their respective states for certification. Those laboratories that choose to do so are inspected and certified by states or approved accreditation organizations. Certification is valid for a two-year period. The CDC has authority to inspect any laboratory that has been certified by a state to ensure compliance with the standards. The penalty for noncompliance under the model program is revocation of certification.

What can you do? *Find out whether your state has adopted the model program advocated by the CDC. The program is voluntary and some states have used it to develop their own regulations or guideline.*

3. 1992 Fertility Clinic Success Rate and Certification Act⁵

This is a federal law stating that all clinics performing ART should report data annually to the CDC for every ART procedure initiated. The standard definition of ART used by the CDC is: “ART includes all fertility treatments in which both eggs and sperm are handled. In general, ART procedures involve surgically removing eggs from a woman’s ovaries, combining them with sperm in the laboratory, and returning them to the woman’s body or donating them to another woman.” Clinics submit their data to CDC through the Society for Assisted Reproductive Technology (SART) reporting system.

What can you do? *Check that IVF, Inc. has sent data to the CDC of all treatments provided. Please note that the annual Assisted Reproductive Technology (ART) Report by the CDC contains a list of non-reporting clinics, by state on a [publicly accessible web site](#).*

In summary, the actions IVF Clinic, Inc. can take to prepare for the meeting with the Fosters and Remus’ is to offer documentation on compliance with the above standards (and other applicable state guidelines, if any). If not in compliance, IVF, Inc. is urged to take swift steps to remedy the situation and prepare for adverse publicity and possibly actions for negligence.

B. What can be learned from previous cases of embryo mix-ups.

A. Fasano-Rogers case of 1998

In this case Donna Fasano of New York, gave birth to another couple's baby in 1998. Ms Fasano, who is white, gave birth to a black child and a judge ordered that she should hand the infant over to his biological parents. According to court papers, it was the result of an embryo mixup at Central Park Medical Services, a fertility clinic on W. 57th St. owned by Dr. Lillian Nash, an obstetrician-gynecologist who was treating both couples. Nash said at the time she informed both families of the mistake when Fasano reported she was pregnant about a month later. Deborah Perry-Rogers, 40, and her husband, Robert, an African-American couple from Teaneck, N.J., failed to conceive. When the Rogerses learned of their genetic son, they sued the doctors for custody of the boy in a bitter court fight against the Fasanos that they eventually won. The Fasanos gave up Akeil and lost a bid for visitation.^{6,7}

Outcome: *Both parties successfully sued the Nash, the owner and OB/GYN and Obasaju, the embryologist.*

B. British case of 2002

English law does not allow the parties to be named in this dispute. According to newspaper reports, the couple went to the fertility clinic for IVF treatment after trying unsuccessfully for years to have a child. When the babies were born, the couple noticed that they were clearly dark-skinned, and suspected that something had gone wrong. Human errors and "systems failures" were blamed for the mix-up at the Leeds hospital, the commissioned report investigating the incident found two years later. The [report](#)⁸ made a number of recommendations; of special note are Recommendations 78 – 81.

Outcome: *In 2003, the High Court ruling potentially gave Mr B (the black man whose sperm was mistakenly used) rights over how the children were to be brought up; however, he was not awarded custody. A previous ruling had already declared that the twins should continue to live with the white couple, known only as Mr and Mrs A. Mr. A would have to adopt the twins if he wished to become their legal parent. The As are believed to have brought a compensation claim for negligence against the NHS.*

C. Opinion from Edwards, R. G. and Bennett, F. G. A. Source: Reproductive BioMedicine Online

Obviously, the strictest guidelines are essential, yet they can have weaknesses somewhere between the patient arriving for oocyte aspiration, collection of the sperm sample and every successive stage of embryo care and transfer. The majority of responsibility in these cases falls on embryologists and technicians, although the immediate responses and care of patients must be met by nurses and counseling staff. Physicians are responsible for ensuring the right person is brought to the collection theatre, and then for transfer, and that her name is confirmed with embryologists on both occasions. These responsibilities, and many others, also lie in the laboratory. Not only this, but embryologists also have to perform increasingly complex embryological procedures, so adding yet further responsibilities with fresh prospects of making simple errors with tragic consequences.⁹

In summary, based on the experience of the two cases cited above, it is likely that IVF Clinic, Inc. will face legal action brought by both parties. IVF Clinic, Inc. is advised to retain legal counsel. IVF Clinic, Inc. is also advised to institute a program of Quality Assurance that will look at the laboratory as a whole and identify problems or potential sources of error. Specific indicators should include, but not be limited to: oocyte collection, sperm collection, gamete preparation, specimen identification, fertilization, cleavage, cryopreservation, embryo transfer, laboratory reporting, laboratory safety, and outcomes.¹⁰

References

1. *Executive Summary of Assisted Reproductive Technologies: Analysis and Recommendations for Public Policy*. New York State. Dept of Health. Retrieved on 4 Feb. 2006 from <http://www.health.state.ny.us/nysdoh/taskfce/execsum.htm>
2. *Regulatory environment for assisted reproductive technology*. Genetics and Public Policy Center. Retrieved on 2 Feb. 2006 from <http://www.dnapolicy.org/policy/art.jhtml.html>
3. [Revised Minimum Standards for Practices Offering Assisted Reproductive Technologies](#). 2003. *Fertility and Sterility*,(80): 1556-1559.
4. *Implementation of the Fertility Clinic Success Rate and Certification Act of 1992: A Model Program for the Certification of Embryo Laboratories*. CDC. Retrieved 11 Feb. 2006 from http://www.phppo.cdc.gov/dls/art/fcsrca_9907.aspx
5. *The Fertility Clinic Success Rate and Certification Act of 1992* (Pub. L. 102-493), 42 U.S.C. 263a-1 et seq. Retrieved on 11 Feb. 2006 from <http://www.phppo.cdc.gov/dls/pdf/art/fcsrca.pdf>
6. IVF mix-up heads for court. *BBC News Online*. 8 July, 2002, Retrieved on 2 Feb. 2006 from <http://news.bbc.co.uk/2/hi/health/2115522.stm>
7. Start today for embryo mixup trial. *New York Daily News*. September 13, 2004. Retrieved on 2 Feb. 2006 from <http://www.nydailynews.com/news/local/story/231501p%2D198804c.html>
8. Toft, Brian. *Independent review of the circumstances surrounding four adverse events that occurred in the Reproductive Medicine Units at The Leeds Teaching Hospitals NHS Trust, West Yorkshire*. Retrieved on 3 Feb., 2006 from <http://www.dh.gov.uk/assetRoot/04/08/43/58/04084358.pdf>
9. Edwards, R. G. and Bennett, F. G. A. Two immensely complex and difficult ethical cases of IVF. (2002) *Reproductive BioMedicine Online*, 5 (2): 219.

10. Mayer, Jacob F. Jones, Dowling-Lacey E.L., Nehchiri, D., et.al. (2003). Total quality improvement in the IVF laboratory: choosing indicators of quality. *Reproductive BioMedicine Online*, 7(6): 695-699.