# Introduction: Risk and safety management in infertility and assisted reproductive technology

David R. Meldrum, M.D.,[a] and Dominique de Ziegler, M.D.[b]

[a] Reproductive Partners Medical Group, Redondo Beach, California; and [b] Université Paris Descartes, Paris Sorbonne Cité - Assistance Publique Hôpitaux de Paris, CHU Cochin, Dept of Ob Gyn and Reproductive Medicine, Paris, France

Drs. Meldrum and de Ziegler contrast medicine with the ultra-safe industry of aviation. Analogous to the "right patient, right side, and right organ" procedures already instituted widely throughout medicine, they emphasize the extreme importance and methods for identification and tracking of specimens and recipients for assisted reproductive technology (ART) procedures. One of the authors describes his experience with a formal "ISO" accreditation process that standardizes most aspects of risk and safety management. Because risk and safety management has yet to be commonly extended into physicians' offices and that is where ART procedures are usually recommended and carried out, detailed suggestions are offered regarding ways to reduce risk and maximize safety in that environment. Finally, a suggestion is made for establishment of a Clinical Safety Board for ART so adverse events are reported and investigated, promoting educative efforts and preventive strategies to enhance future patient safety. (Fertil Steril® 2013;100:1497–8. ©2013 by American Society for Reproductive Medicine.)

**Discuss:** You can discuss this article with its authors and with other ASRM members at http://fertstertforum.com/meldrumd-risk-safety-management-infertility-art/

Use your smartphone to scan this QR code and connect to the discussion forum for this article now.*

* Download a free QR code scanner by searching for "QR scanner" in your smartphone's app store or app marketplace.

It is not by accident that six pilots are included in the authorship of this series of reviews. As pilots, we take for granted that when incidents or accidents occur, they are fully investigated to determine contributing causes and the results are widely available so we have opportunities to learn from others' errors. Hopefully, that avoids repeating them to the peril of ourselves and our passengers. Unfortunately, medical care stands in sharp contrast to aviation. Although some of the more serious errors are probed within a hospital department or among physicians in a group practice, there are limited mechanisms for widespread sharing of this information.

To the credit of the American Society for Reproductive Medicine, the Society for Assisted Reproductive Technology, and *Fertility and Sterility*, a major effort has been successfully carried out to reduce the incidence of high-order multiple births resulting from IVF, which has led to a fourfold reduction during the past decade. In a recent issue of this Journal, a series of articles and reviews suggested how using comprehensive chromosome screening can be used in the women at greatest risk for multiple pregnancies to allow a high rate of success with transfer of a single, chromosomally normal embryo (1). In this series we have argued that assisted reproductive technology (ART) is an ideal field to continue exploring ways to enhance safety for our infertile couples. Assisted reproductive technology has increased the reliability and safety of so many aspects of infertility care that it is especially fitting for our subspecialty to take the lead in improving the safety of all aspects of our practice.

Perhaps the most egregious error is mix-up of specimens (gametes and embryos), which has resulted in a small number of accidents worldwide, with catastrophic consequences for the couple and the IVF program. De los Santos and Ruiz have discussed in detail the protocols that can be used to track specimens throughout the IVF procedure. We and most other practitioners also have rigid, redundant identification and tracking of specimens and recipients for IUI. For example, one never asks "are you Mrs. Smith", but always "please say your name". Prevention of cross-contamination of

Received October 3, 2013; accepted October 3, 2013; published online November 4, 2013.
D.R.M. has nothing to disclose. D.d.Z. has nothing to disclose.
Reprint requests: David R. Meldrum, M.D., Reproductive Partners Medical Group, 510 North Prospect Avenue, Redondo Beach, California 90277 (E-mail: drmeldrum@gmail.com).

Fertility and Sterility® Vol. 100, No. 6, December 2013 0015-0282/$36.00

http://dx.doi.org/10.1016/j.fertnstert.2013.10.003

sperm for IUI and IVF also requires rigid fail-safe procedures. Disasters have occurred in all of these examples worldwide since the inception of ART. For any program not having these protocols in place, we strongly recommend a site visit by someone experienced in this facet of ART. And, as our authors point out, aspects of program organization beyond such protocols can also mitigate risks. Just as in aviation, fatigue, conscious and involuntary automaticity, ambiguous accountability, stress, and fatigue can act as "latent failures" that may confound the most carefully constructed standard operating procedures.

Michael Alper has described how a thorough process of outlining and documenting all procedures, risks, incidents, and outcomes (including by individuals) will provide a structure that mitigates risk and optimizes results ("say what you do and do what you say"). Whether this takes the form of ISO accreditation or ART programs are stimulated to include these protocols outside of a formal certification process, the benefits that will accrue are considerable.

De Ziegler et al. have emphasized that many risks must be identified in the physician's office. As examples, if a predisposition to thromboembolism is not identified and changes to IVF protocols are therefore not made; if the presence of an endometrioma does not lead to modifying the protocol for vaginal preparation or antibiotic prophylaxis; or if a high antral follicle count or level of antimüllerian hormone fails to lead to changes of ovarian stimulation and perhaps deferred transfer, these risks can lead to severe or even fatal accidents. Perhaps most important, the current high rate of twin pregnancies must be reduced by identifying the patients at greatest risk and strongly encouraging elective single ET, with or without comprehensive chromosome screening.

Finally, Richard Scott and Nathalie de Ziegler have made the most provocative proposal that there should be a Clinical Safety Board for ART analogous to our National Transportation Safety Board to investigate reported accidents, resulting in recommendations to mitigate risks before they become incidents (e.g., infected endometrioma) or accidents (e.g., oophorectomy). As they aptly point out, medicine is more akin to rescue helicopter operations where interventions must proceed with known risks and sometimes under less than ideal circumstances without the luxury of deferring operations until conditions improve. The actor Dennis Quaid, who is also a pilot, co-authored a plea for medical safety boards ("An NTSB [National Transportation Safety Board] for Health Care") (2). In that piece he describes not only the agony of having his newly born twins receive an inadvertent 1,000-fold overdose of heparin (fortunately without serious consequences), but also his later disconcerting realization that the same error had led to infant deaths a year earlier and subsequently as well. To anyone outside of medicine, and particularly to pilots, it seems inexcusable that accidents occur without at least some benefit to the care of other patients.

Joe Gambone, a former naval pilot and reproductive endocrinologist who has contributed to this series, has been involved in a major effort by the American College of Obstetricians and Gynecologists aimed at exactly what we are proposing for our subspecialty. As in all walks of life, it is easier and more comfortable to follow, and much more difficult to lead. We hope that our specialty and subspecialty will be examples of the latter rather than the former, and that this series of reviews will serve as a further catalyst.

## REFERENCES

1. Meldrum DR. Introduction: preimplantation genetic screening is alive and very well. Fertil Steril 2013;100:593–4.
2. Denham CR, Sullenberger CB 3rd, Quaid DW, Nance JJ. An NTSB for health care: learning from innovation: debate and innovate or capitulate. J Patient Safety 2012;8:3–14.