

Types and frequency of non-conformances in an IVF laboratory

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STUDY QUESTION: How many non-conformances occur in an ART laboratory and how often do they occur?

SUMMARY ANSWER: The limited data to date demonstrate that IVF laboratories have a very low non-conformance rate compared with reported non-conformances in other medical laboratories, especially when one considers the high-complexity of procedures performed.

WHAT IS KNOWN ALREADY: ART involves a series of very complex patient and laboratory procedures. Although it is assumed that strict measures control ART laboratories, there is very little published data on non-conformances.

STUDY DESIGN, SIZE, DURATION: In accordance with the ISO 9001:2008 standard, Boston IVF has created an electronic database to record non-conformances in the IVF laboratory. We reviewed the non-conformances reported between March 2003 and December 2015. The non-conformances were categorized into four grades largely based upon their impact on the outcome or continuation of an IVF treatment cycle: None/Minimal (not measurably decreasing the likelihood of success), Moderate (a negative impact but not loss of a cycle), Significant (loss of a cycle or majority of gametes or embryos) and Major (infrequent errors that have an extreme impact on a patient or patients such as a confirmed pregnancy or birth involving misidentification of sperm, egg or embryo, or an extreme equipment or documentation failure that affects numerous patients). The category of problem or error associated with the Non-conformance Report was also noted.

PARTICIPANTS/MATERIALS, SETTING, METHOD: Retrospective analysis of an electronic database registering non-conformances at a large IVF laboratory.

MAIN RESULTS AND THE ROLE OF CHANCE: During the study period, a total of 36 654 IVF treatment cycles (fresh and frozen embryo transfer cycles) were conducted which involved a total of 181 899 individual laboratory procedures encompassing egg retrievals, sperm preparations, inseminations, embryo transfers, etc. When combining both moderate and significant non-conformances, 99.96% of procedures and 99.77% of cycles proceeded with no non-conformances. No Major grade non-conformances were reported.

LIMITATIONS, REASONS FOR CAUTION: A comparison of non-conformances between IVF clinics is difficult because of different classifications.

WIDER IMPLICATIONS OF THE FINDINGS: Errors are inevitable and it is incumbent on all IVF centers to be honest and transparent, both within the organization and with patients when errors occur. Robust systems for identifying, documenting, analyzing and implementing improvements should be established and maintained.

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Key words: non-conformances / errors / IVF laboratory / quality control / quality assurance

Introduction

Over the last 40 years, *in vitro* fertilization (IVF) has transformed the treatment of infertility. Concurrently, IVF has also grown to be more complex due to the adoption of highly technological laboratory

procedures, including cryopreservation of eggs and embryos, as well as micromanipulation and pre-implantation genetic testing (PGT). In addition, the patient population being treated has broadened and often includes not only the intended parents but also gametes from egg and sperm donors or the use of a gestational surrogate. These

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