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ARTICLE

Application of failure mode and effect analysis in an assisted reproduction technology laboratory

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Abstract Assisted reproduction technology laboratories have a very high degree of complexity. Mismatches of gametes or embryos can occur, with catastrophic consequences for patients. To minimize the risk of error, a multi-institutional working group applied failure mode and effects analysis (FMEA) to each critical activity/step as a method of risk assessment. This analysis led to the identification of the potential failure modes, together with their causes and effects, using the risk priority number (RPN) scoring system. In total, 11 individual steps and 68 different potential failure modes were identified. The highest ranked failure modes, with an RPN score of 25, encompassed 17 failures and pertained to "patient mismatch" and "biological sample mismatch". The maximum reduction in risk, with RPN reduced from 25 to 5, was mostly related to the introduction of witnessing. The critical failure modes in sample processing were improved by 50% in the RPN by focusing on staff training. Three indicators of FMEA success, based on technical skill, competence and traceability, have been evaluated after FMEA implementation. Witnessing by a second human operator should be introduced in the laboratory to avoid sample mix-ups. These findings confirm that FMEA can effectively reduce errors in assisted reproduction technology laboratories.

KEYWORDS: assisted reproduction technology, FMEA, IVF, mismatch, risk assessment

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Introduction

The success in assisted reproduction technology is crucially dependent on carefully controlled conditions in every aspect of the IVF laboratory routine. Good practice in IVF laboratories requires a quality management programme that integrates quality control, quality assurance and quality improvement, and that monitors all procedures and components of the laboratory including not only pregnancy and implantation rates but also a systematic check and survey of all laboratory materials, supplies, equipment and instruments, procedures, protocols and staff performance (Alper, 2013; Magli et al., 2008). In fact, IVF laboratories have a very high degree of complexity in terms of technology/equipment being used and type/number of tasks being carried simultaneously. Possible problems may derive from instrumentation failures, to inaccurate data registration and the unconfirmed identification of gametes and embryos. Significantly, gametes and embryos belonging to a particular couple may be manipulated at different times by different embryologists. Other risk factors, such as very heavy workload and time pressure, might lead to errors or problems with severe or even catastrophic consequences. The "human" factor as a potential source of severe errors is indeed dominant in the IVF laboratory. Over the years, there have been numerous reports of misidentification, resulting at best in a cancelled cycle if the mistake was identified before embryo transfer, or in a tragedy if realized after the embryo transfer. There is therefore a need for approaches that systematically supervise the whole process and identify the causes of all errors, including potential errors (Dyer, 2004; Spriggs, 2003).

Failure modes and effects analysis (FMEA) is a proactive risk evaluation technique used to identify and eliminate known and/or potential failures, problems and errors from a system, design, process and/or service before they actually occur. The method was developed in 1949 by the US military and widely used in industries to predict and evaluate potential failures and unrecognized hazards (Automotive Industry Action Group, 2008; US Department of Defense, 1949). In health care, FMEA focuses on the system of care and uses a multidisciplinary team to evaluate a process from a quality improvement perspective. The proactive methods are more readily accepted by clinicians because they use a positive approach to problems by focusing on examination of the entire process, thus anticipating major adverse events and pre-emptively implementing changes to prevent them from occurring rather than setting up post-error reactive tools (Ashley et al., 2010).

Risk management in assisted reproduction technology laboratories was described by Mortimer and Mortimer in 2005 when, for the first time, FMEA use was promoted in the IVF laboratory. Recently, Rienzi et al. (2015) described an application of FMEA by identifying the possible failure modes associated with sample traceability before and after the introduction of an electronic witnessing system. Thus, the technique was mainly targeted at the analysis of the advantages related to this electronic system. In contrast, our study aimed to apply FMEA to each critical activity/step of an assisted reproduction technology laboratory to systematically assess the risk and to improve the work processes. However, given that the influence of many factors, such as laboratory dimensions, number of embryologists and the number of cycles performed, may cause the same technique to yield different results in different hospitals, the risks associated with the process need to be separately analysed for each IVF laboratory.

Materials and methods

Assembling the team, process mapping and FMEA sessions

The FMEA project was recommended by the Quality and Accreditation Department of the San Raffaele Hospital in Milan in the context of the risk management of the entire hospital. Therefore, the FMEA has been prospectively developed to improve the critical steps of each process in order to minimize the risk of errors, even though a quality system, in terms of procedures, processes and resources needed to implement quality management, had already been set up in the laboratory. The FMEA project was conducted at the laboratory of the Centro Scienze Natalità, an IVF centre that performs more than 1200 "fresh" cycles and about 400 "frozen/thaw" cycles per year (Corti et al., 2013; Papaleo et al., 2014; Restelli et al., 2014; Rubino et al., 2015). The IVF laboratory team is composed of nine embryologists and one technician. Our study was performed between August 2013 and August 2014 and was in line with the FMEA criteria. A team composed of the Laboratory Director, two embryologists and two Quality Managers conducted observations to capture key steps of the process and to ascertain all pertinent roles for inclusion in the FMEA. Any observed failures were also noted and used as prompts during the FMEA sessions. The goal of the team was to participate fully in FMEA implementation and to provide suggestions based on their respective work experience. The team leader ensured that results of the FMEA sessions were recorded accurately. A total of nine sessions of 2 hours were needed for the team to conduct the FMEA. During the sessions, the team created a process map that was reviewed and validated during the FMEA sessions (**Figure 1**). Next, the team identified potential failures associated with each step of the entire laboratory process.

Recognizing the failure modes at each step

A failure mode is any error/problem that might appear during the completion of a process or during the handover procedure. The potential failures have been generated in a systematic manner considering four issues when conceptualizing the failures: how this process step can be (i) done incorrectly, (ii) done incompletely, (iii) omitted or (iv) delayed. Phases considered included oocyte retrieval, sperm preparation, conventional IVF or intracytoplasmic sperm injection (ICSI), embryo culture, embryo transfer, embryo and gamete cryopreservation/thawing and embryo biopsy. Five sources of failure were ultimately identified as patient or sample identification, instruments, reagents, procedures and data reporting.

Ranking the severity, occurrence and detectability of each failure mode

For each identified failure, embryologists were asked to estimate the (i) frequency of the failure, (ii) severity or