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# Reimagining IVF Risk Assessment Through Real-World Data: Lessons from 414,500 Procedures

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## Abstract

Risk assessment in IVF has traditionally relied on theoretical models and isolated adverse event reviews. However, these approaches often miss the broader, recurring patterns of human and procedural error that occur daily in fertility laboratories. This study uses data from 414,500 assisted reproductive technology (ART) procedures across ten clinics to reframe how risk is defined, detected, and addressed. Through barcode-based electronic witnessing, we reveal quantifiable evidence of misidentification, protocol deviations, and staff-related error trends. This article proposes a shift in the IVF safety paradigm from assumption-driven models to measurable, frequency-based frameworks that reflect the real-world complexity of reproductive medicine.

***Keywords:*** *Risk assessment in IVF; Real-world data; IMT Matcher logs*

## 1. Introduction

The assessment of risk in IVF laboratories has long been influenced by subjective judgment, anecdotal reports, and incident-based reviews. Standard models typically rely on severity-probability matrices, with regulatory responses focused on high-impact outcomes. While these tools are useful in managing catastrophic errors, they often fail to account for the cumulative impact of routine deviations and near misses events that are frequent but seldom reported unless harm occurs (1-3).

Advancements in digital witnessing systems such as IMT Matcher offer the opportunity to transition to a more empirical approach. By capturing real-time data on every step of the IVF workflow, these systems allow for quantification of procedural deviations, staff-based trends, and mismatch interception. This dataset enables clinics and regulators to move from traditional compliance-based models to a data-informed culture of risk prediction and mitigation. (4)

## 2. Methods

### 2.1 Data Source

A retrospective analysis was conducted on 414,500 anonymised IVF procedures carried out between 2007 and 2020 at ten fertility clinics. All procedures were monitored using IMT Matcher, a barcode-based witnessing platform that logs each staff action and procedural step. The system enforces correct sequencing and alerts users in real time to any mismatch, skipped step, or identification error.

### 2.2 Error Categories and Analysis

Errors were classified into three primary categories:

- True procedural errors, including misidentification and labware mismatches
- SOP deviations, defined as departures from standard operating protocols not directly resulting in harm
- System errors, which were excluded from analysis due to their technical, rather than clinical, origin

Statistical tools including descriptive analytics, Pearson's Chi-square, and logistic regression models were used to assess error frequency, role-specific patterns, and procedural contexts.

## 3. Results

### 3.1 Prevalence of Errors

The analysis revealed that among the 414,500 procedures:

- 2,404 were true procedural errors (0.58%)
- 718 involved patient or sample misidentification (0.17%)
- 146 were labware mismatches (0.04%)
- 83 errors were due to workspace overcrowding (0.02%)
- 53,719 procedures involved SOP deviations (13%)

These findings indicate that while high-impact errors are relatively rare, low-impact procedural deviations are widespread. This exposes an often-ignored spectrum of IVF risk that traditional frameworks fail to capture.

### 3.2 Role-Based Error Trends

The likelihood of error was not evenly distributed across staff categories. The role-specific error rates recorded were:

- Andrologists: 26.8%
- Embryologists: 1.0%
- Nurses: 0.5%
- System administrators: 0.4%

These disparities highlight the importance of targeted oversight and specialised training for staff in high-risk roles. The elevated rate among andrologists suggests procedural environments with fewer redundancies and less peer oversight (Girnita, 2023).

### 3.3 Procedural Hotspots

Analysis of SOP deviations revealed procedural clustering. Approximately 34% of all SOP deviations occurred during cryopreservation stages. These findings point to systemic vulnerabilities in high-volume or high-complexity processes, where cognitive load and time pressure increase the likelihood of deviation.

## 4. Discussion

### 4.1 Reconstructing the IVF Risk Model

The current model of IVF risk relies heavily on rare-event auditing and theoretical failure modes. This study proposes a revised framework grounded in observed frequency. Rather than rating risk solely on outcome severity, it is essential to consider the regularity of procedural deviation and the circumstances under which errors occur. (1)The following categories emerge as critical:

- High-frequency, low-impact risks (e.g. SOP deviations)
- Low-frequency, high-impact risks (e.g. patient misidentification)

Only the latter tends to be addressed by existing compliance structures. However, the former represents the foundation of a lab's risk environment and warrants equal attention in risk governance.

### 4.2 From Retrospective Audit to Predictive Control

One of the most transformative applications of real-world data is in moving from post-incident auditing to predictive risk modelling. Using IMT Matcher logs, IVF clinics can identify operational zones of heightened vulnerability. For instance, the 26.8% error rate in andrology procedures suggests a need for either structural workflow changes or automation. Similarly, knowing that over one-third of SOP deviations occur during cryopreservation can prompt workload redistribution or enhanced protocol reinforcement during that phase (2).

By continually analysing such patterns, laboratories can anticipate where risk is most likely to materialise and deploy interventions proactively.

### 4.3 Clinical and Regulatory Reform Implications

This model carries significant implications for regulators and quality assurance bodies. Authorities such as the Human Fertilisation and Embryology Authority (HFEA) and the European Society of Human Reproduction and Embryology (ESHRE) currently focus on final outcomes and manual auditing. The findings here suggest that true safety cannot be achieved without continuous, quantifiable monitoring. Regulators should mandate digital witnessing tools in all IVF laboratories and require the submission of monthly or quarterly risk profiles based on procedural frequency data.

At the clinical level, internal quality teams should implement performance thresholds. For example, clinics may establish a target of fewer than 5% SOP deviations or require retraining when any staff member exceeds a predefined error frequency. Real-time dashboards can support this, enabling lab managers to respond immediately to deviation trends. (3,4)

## 5. Conclusion

This study marks a step forward in how risk is conceptualised and addressed in assisted reproduction. Real-world data from over 400,000 procedures demonstrates that IVF risk is not limited to rare catastrophes but includes frequent procedural lapses that accumulate over time. A frequency-based risk assessment model allows for both high-resolution operational insight and long-term performance improvement.

The adoption of barcode-based witnessing systems like IMT Matcher enables this transformation, shifting clinics from a culture of reactive correction to one of predictive governance. Risk in IVF should no longer be assumed. It should be measured, monitored, and mitigated in real time.

## Conflict of Interest

All the author declare no conflict of interest.

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