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Mini-Review

# Standard Operating Procedure Deviations in IVF: A Hidden Epidemic in Reproductive Medicine

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## Abstract

While catastrophic IVF errors like sample mix-ups attract public and legal scrutiny, smaller deviations from Standard Operating Procedures (SOPs) often escape attention despite being frequent and indicative of systemic weakness. This study reveals that 13% of IVF procedures analysed using the IMT Matcher system involved SOP deviations. These findings suggest that routine non-conformance is a critical but neglected aspect of reproductive medicine safety. By quantifying these silent failures across 414,500 procedures, this paper advocates for enhanced digital oversight and targeted staff training.

*Keywords: SOP deviations; IVF procedures; Reproductive Medicine*

## 1. Introduction

Standard Operating Procedures (SOPs) are foundational to clinical consistency in ART labs. Institutions such as the Human Fertilisation and Embryology Authority (HFEA) mandate strict procedural adherence, yet real-world environments often depart from these ideals due to staff workload, system fatigue, or complacency (1, 2). Unlike gross misidentifications, which are rare and easily categorized, SOP deviations are harder to detect, record, or address. This study leverages digital witnessing data to systematically uncover the frequency and nature of SOP lapses in IVF clinics. (3.4)

## 2. Methods

A total of 414,500 anonymized ART procedures across ten clinics were analysed using data from IMT Matcher, a barcode-based electronic witnessing system. SOP deviation was defined as any action performed out of regulatory order, skipped without authorization, or conducted with unvalidated tools.

### 2.1 Deviation Categories Included:

- Skipped witnessing steps
- Use of uncalibrated or incorrect equipment
- Procedural shortcuts
- Errors during thawing, biopsy, or cryopreservation

Chi-square analysis and logistic regression were used to explore deviation patterns by staff role and procedural step.

## 3. Results

### 3.1 Overall Deviation Frequency

Of 414,500 total procedures:

53,719 included SOP deviations, amounting to 13% of all cycles.

**Table 1. Deviation Type Breakdown.**

| Deviation Type | % of Deviations |
|---|---|
| Cryopreservation protocol errors | 34% |
| Missed witnessing steps | 28% |
| Biopsy/PGT protocol lapses | 16% |
| Equipment misconfiguration | 12% |
| Miscellaneous | 10% |

**Table 2.** Deviation by Role.

| Role | Procedures | Deviations | Rate (%) |
|---|---|---|---|
| Embryologists | 233,676 | 27,899 | 11.9 |
| Andrologists | 1,028 | 210 | 20.4 |
| Nurses | 17,549 | 1,294 | 7.4 |
| System Admins | 98,379 | 4,285 | 4.4 |

## Discussion

This study reveals that SOP deviations occur in roughly one out of every eight IVF procedures, making them a major, underrecognized form of procedural risk. These are not isolated incidents but recurring, systemic breakdowns in clinical discipline.

### 4.1 Causes and Risk Amplifiers

Key drivers include shift fatigue, unclear protocol documentation, time pressure, and variation in staff training (1,2). These deviations, while often unnoticed by patients or supervisors, compromise safety and erode quality benchmarks.

### 4.2 Literature Comparison

Previous RFID-based systems have estimated deviation rates as low as 0.1% (Thornhill and Brunetti, 2012). Our independently verified figure of 13% challenges those assumptions and highlights the value of real-time, role-linked error tracking.

### 4.3 The Case for Digital Oversight

Manual SOP enforcement fails when teams are overburdened. Barcode-based tracking provides not just alerting but audit trails and user-specific accountability—features critical for modern IVF governance. (3,4)

## 5. Conclusion

SOP deviations are not rare exceptions but routine events in many IVF labs. The reproductive medicine field must recognize that true safety comes not only from preventing catastrophic mistakes but from addressing systemic drift. Enhanced oversight, automation, and uniform staff training protocols are urgently needed.

## Conflict of Interest

All the author declare no conflict of interest.

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