# Adverse event and ovarian hyperstimulation review

Standard operating procedure (SOP) | FRT-SOP-004

| | |
|---|---|
| Document type | Standard operating procedure (SOP) |
| Title | Adverse event and ovarian hyperstimulation review |
| Document ID | {{facility.code}}-FRT-SOP-004 |
| Version and status | 1.0 \| Issued for use. Pending ASF Expert Committee ratification |
| Prepared by | {{roles.quality_lead.name}}, Quality lead |
| Reviewed by | {{roles.clinical_director.name}}, Clinical director Date: _____ |
| Approver and signature | {{roles.clinical_director.name}}, Clinical director<br>Signature: _____ Date: _____ |
| Effective date | {{document.effective_date}} |
| Next review | {{document.review_date}} (12 months, or sooner after any incident or change) |
| Replaces | None (new document) |
| Standards and criteria supported | Standard 8 (Fertility Clinic), criterion 8.7 |
| Evidence basis | E-006, E-009 |
| Status of this document | Recommended best-practice model. A hospital may adopt, adapt or replace it with an equivalent that meets the same criteria. |

**At a glance: what to do**

1. Each adverse event, including ovarian hyperstimulation and procedure complications, is recorded.
2. Each event is reviewed by a clinician within the set time.
3. Success rates are reported with the basis for the calculation.
4. Events are reviewed each quarter.

Stop and get help straight away if: an adverse event is not recorded or reviewed, or a success rate is published without its basis.

## 1. Purpose

To find and reduce complications, and to report success rates honestly (8.7).

## 2. Scope

| | |
|---|---|
| Applies to | Clinical and support staff in the hospital |
| Locations | All wards, clinics and departments of {{facility.legal_name}} |
| When | Whenever the activity described is carried out |
| Does not apply to | Activities covered by another document listed in section 15 |

## 3. Definitions and abbreviations

| Term | Meaning in this SOP |
|---|---|
| **Clinical lead** | The doctor or nurse in charge of the area at the time |

## 4. Background and rationale

To find and reduce complications, and to report success rates honestly (8.7).

## 5. Responsibilities

| Role | Duties in this SOP | Competence needed |
|---|---|---|
| **Clinical director** | Owns the review and the reports | Clinician |
| **Treating clinician** | Records and reviews each event | Clinician |

## 6. Equipment, materials and resources

| Item | Specification or standard | Check before use |
|---|---|---|
| **Records and forms named in this document** | Current version | Checked before use |

## 7. Safety and infection prevention

- Stop and call for help if a patient is at immediate risk. Do not delay urgent care to complete paperwork.

## 8. Before you start

- Confirm the forms and equipment named in this document are available and current.

## 9. Procedure

*Follow the steps in order. Where a step says "If", take the action for the case that applies. Do not skip a step. If a step cannot be done, use section 11 and section 12.*

| Step | Action | How to do it | Key point |
|---|---|---|---|
| **1** | Record. | • Record the event on FRT-REG-003 with its severity and time. | Every event, however small. |
| **2** | Review. | • Review each event within the set time and record the cause and the action. | A cause and an action. |
| **3** | Report. | • Report success rates each year with the number of cycles and the basis for the calculation. | The basis is always stated. |

### Decision points

- No decision points in this procedure.

## 10. Special situations

| Situation | What to do |
|---|---|
| **Out of hours** | Follow the same steps. Use the on-call contact on the wall of the area. |

## 11. Problems and escalation

- Any serious problem goes to the duty clinical lead at once and to the clinical director the same day.

## 12. Monitoring and compliance

| What is checked | Target | How often | Who | If the target is missed |
|---|---|---|---|---|
| **Adverse events reviewed within the set time** | 100% | Quarterly | Clinical director | Escalate to chief executive |
| **Success rates reported with basis** | 100% | Yearly | Clinical director | Escalate to chief executive |

## 13. Records

| Record | Where it is kept | Kept for |
|---|---|---|
| **Record named in this document** | Patient record or the area file | {{facility.records_retention_years}} years |

## 14. Training and competence

- Staff are trained in this document at induction and refreshed each year, with a recorded competency check.

## 15. Related documents

| ID | Title | Relationship |
|---|---|---|
| **FRT-REG-003** | Adverse event and success rate register | Register |

## 16. Evidence

| ID | Source and status |
|---|---|
| **E-009** | Based on ESHRE revised guidelines for good practice in IVF laboratories (2015). |
| **E-006** | ASF Policy Framework v1.2. Adapted. |
| **E-009** | ASF Expert Committee consensus. |

*EC = ASF Expert Committee consensus. Items marked EC are reviewed by the Committee each year.*

## 17. Change history

| Version | Date | What changed | Approver and signature |
|---|---|---|---|
| **1.0** | {{document.effective_date}} | First version | Pending Expert Committee approval |