Royal Hospital for Women (RHW)
BUSINESS RULE
COVER SHEET

Ref: T24/82460

NAME OF DOCUMENT	Invitro-fertilisation (IVF) Reporting of Adverse events
TYPE OF DOCUMENT	Clinical Business Rule
DOCUMENT NUMBER	RHW CLIN107
DATE OF PUBLICATION	16.12.24
RISK RATING	Low
REVIEW DATE	December 2029
FORMER REFERENCE(S)	Nil
EXECUTIVE SPONSOR	Dr Rachael Rodgers – Clinical Director, Fertility & Research Centre – Royal Hospital for Women
AUTHOR	Ashlee Rea – Clinical Nurse Consultant, Fertility & Research Centre – Royal Hospital for Women
SUMMARY	The aim of this clinical business rule is to provide framework and guidance for mandatory reporting of adverse events in IVF at the fertility & research centre, Royal Hospital for Women.
Key Words	In vitro fertilization (IVF), intracytoplasmic sperm injection (ICSI), ART (Assisted reproductive technology)

This Clinical Business Rule (CBR) is developed to guide safe clinical practice at the Royal Hospital for Women (RHW). Individual patient circumstances may mean that practice diverges from this Clinical Business Rule. Using this document outside RHW or its reproduction in whole or part, is subject to acknowledgement that it is the property of RHW and is valid and applicable for use at the time of publication. RHW is not responsible for consequences that may develop from the use of this document outside RHW.

Within this document we will use the term woman, this is not to exclude those who give birth and do not identify as female. It is crucial to use the preferred language and terminology as described and guided by each individual person when providing care.

1 BACKGROUND

Adverse events are defined as an unplanned event that results in, or has the potential for: harm, injury, damage or loss, inclusive of near misses. NSW health require all clinical incidents and near misses to be reported via IMS+. In addition to IMS+, facilities providing Assistive Reproductive Technology (ART) treatments, are also required to disclose serious reportable adverse events to their governing body, known as the Reproductive Technology Accreditation Committee (RTAC). The disclosure of serious reportable adverse events to RTAC ensure ART units identify issues around patient safety including, causative factors and provide evidence for the corrective actions taken to prevent future adverse events.

The Royal Hospital for Women currently offers Assisted Reproductive Technology (ART) procedures at the Fertility and Research Centre (FRC). Incident and near-miss reporting is managed via an internal incident management system referred to as IMS+. In addition to IMS+ notifications, the RTAC code of practice requires ART units to provide evidence of serious notifiable events (defined in **Appendix A**) that assist in identifying trends and underlying causes for adverse events. RTAC utilises information provided to assist ART units in enhancing quality improvement processes via technical bulletins and during yearly accreditation.

1.1 Definition of Key terms

ARTEMIS	Computer program which stores data for all patients at FRC undergoing ART procedures
Adverse event	Any unplanned outcome that may result in harm or near miss directly impacting the patient
ART procedures	Assisted reproductive technology which refers to clinical treatments and procedures that include handling of human oocytes, sperm or embryos. Inclusive of invitro fertilisation, intracytoplasmic sperm injection, gamete

	cryopreservation, preimplantation genetic testing, intrauterine insemination and invitro maturation.
ART organisation	An entity accountable for the delivery of ART services
Certifying body (CB)	Independent auditing company used to accredit ART unit – currently Global Mark
FRC	Fertility & research centre
FSANZ	Fertility Society of Australia and New Zealand
Harm	As per NSW Health - Incident Management PD2020_047 is any unintended and unnecessary harm resulting from or contributed to, by healthcare. This includes an absence of medical treatment. Harm may include staff (workers), visitors and family (relatives) or damage to property or the environment.
RTAC	Reproductive Technology Accreditation Committee under FSANZ is the governance body maintaining the ART code of conduct to which ART organisations are reportable too
Serious adverse event (as per RTAC)	Harmful or negative outcome that occurs as a result of ART treatment and involves hospitalisation
Serious reportable adverse event (as per RTAC)	Is defined by RTAC as an abnormal outcome associated with ART treatment which results in the following: - Transmission of communicable disease - Results in mortality or morbidity - Arises from a gamete or embryo identification error/mix up

2 RESPONSIBILITIES

2.1 Fertility & Research Centre staff (medical, nursing/midwifery and allied health)

- All FRC staff are responsible for recognising, and reporting adverse patient events/outcomes via the internal incident management system (IIMS +) and undertake training in incident notification
- Nurse unit manager (NUM) must undertake incident management training, monitor notifications in IMS+, complete investigations and ensure appropriate notification to the certifying body & RTAC for additional reporting.
- Head of department must assist managers with incident management as needed, assist in undertaking open disclosure, support staff involved in incidents, support staff participation in incident review and analyse and discuss incident trends.

3 PROCEDURE

3.1 Clinical Practice

IMS+ incident management

- Report all near miss & adverse events, on the same day as they occur or as practicable, into NSW Health IMS+ for internal investigation in accordance with NSW Health - Incident Management PD2020_047 policy.
- Internal IMS+ notifications should be utilised to identify causation of factors contributing to the event and escalation of process based on level of severity or harm score
- Identify the event as either a serious adverse event or a serious reportable adverse event as defined by the RTAC code of practice refer to **Appendix A** and follow pathway for additional notification (if applicable)

Reproductive Technology Accreditation Committee (RTAC) incident reporting

- Serious reportable adverse events are to be submitted to RTAC & the certifying body (CB) as soon as practical as defined in **Appendix A & Appendix B**
    - No longer than 6 weeks after the provider becomes aware of the incident
    - Within 2 weeks for a potential breach or actual breach of legislation
    - Within 48 hours in the event of death
- Complete the template attached to the RTAC code of practice for submission of serious reportable adverse events to RTAC secretariat and certifying body
- Nurse Unit Manager and Clinical Director to review and implement corrective action into relevant policies & protocols (if applicable)
- IMS + and serious reportable adverse events to be discussed during the FRC departmental meeting
- Education to be provided to FRC staff (by Clinical Nurse Consultant/Nurse Unit Manager) surrounding updates to policies & protocols based on outcomes of both serious adverse events and serious reportable adverse events
- Maintain internal record of both serious adverse events and serious reportable adverse events and the corrective actions implemented.
- Submit evidence of this record during the annual RTAC certifying body audit

3.2 Documentation

- IMS+

- EMR
- Patients fertility file

3.3 Education Notes

- ART organisations must provide evidence of the implementation of incident management systems to allow accountability for adverse events that may occur within the unit.
- Serious notifiable adverse events must be reported to RTAC through the secretariat and to the appropriate Certifying Body (CB) to facilitate audit responses and appropriate action
- Reporting adverse events within the ART organisation assists in identifying trends in adverse outcomes, opportunities for increased staff education and/or updates in policy and procedures.

3.4 Related Policies/procedures

NSW Health Incident Management PD2020_047

Ovarian Hyperstimulation (OHSS) LOP

3.5 References

1. Fertility Society of Australia and New Zealand (2024). Code of Practice for assisted reproductive technology units. Reproductive technology accreditation committee. Retrieved on November 4th 2024, https://www.fertilitysociety.com.au/wp-content/uploads/20241030-RTAC-ANZ-COP-pdf
2. Fertility Society of Australia and New Zealand. (2021). *RTAC Scheme*. Retrieved March 30, 2023, from https://www.fertilitysociety.com.au/wp-content/uploads/RTAC-Scheme-20-December-2021.pdf
3. Fertility Society of Australia and New Zealand. (2014). RTAC Technical Bulletin 5; Serious Notifiable Adverse Events. In *https://www.fertilitysociety.com.au/wp-content/uploads/20150211-RTAC-Technical-Bulletin-Number-5.pdf*. Retrieved March 30, 2023, from https://www.fertilitysociety.com.au/wp-content/uploads/20150211-RTAC-Technical-Bulletin-Number-5.pdf
4. Royal College of Obstetricians and Gynaecologists. (2016). *The Management of Ovarian Hyperstimulation Syndrome (Green-top Guideline No. 5)*. Retrieved March 31, 2023, from https://www.rcog.org.uk/guidance/browse-all-guidance/green-top-guidelines/the-management-of-ovarian-hyperstimulation-syndrome-green-top-guideline-no-5/

4 ABORIGINAL HEALTH IMPACT STATEMENT DOCUMENTATION

Considerations for culturally safe and appropriate care provision have been made in the development of this Business Rule and will be accounted for in its implementation.

When clinical risks are identified for an Aboriginal and/or Torres Strait Islander woman or family, they may require additional supports. This may include Aboriginal health professionals such as Aboriginal Liaison Officers, health workers or other culturally specific services

5 CULTURAL SUPPORT

For a Culturally and Linguistically Diverse CALD woman, notify the nominated cross-cultural health worker during Monday to Friday business hours

If the woman is from a non-English speaking background, call the interpreter service: NSW Ministry of Health Policy Directive PD2017_044-Interpreters Standard Procedures for Working with Health Care Interpreters.

6 REVISION AND APPROVAL HISTORY

Date	Version No.	Author and Approval
25/11/2024	1	Ashlea Rea, Fertility
2.12.24	2	RHW BRGC

Appendix A

Guideline for RTAC incident reporting

Scenario	Serious Reportable Adverse Event	Serious adverse Event
Ovarian Hyperstimulation Syndrome (OHSS)		
Hospitalisation for observation and fluids after symptoms of OHSS	**No**	**Yes**
Hospitalisation for OHSS that included paracentesis or draining of pleural effusions	**Yes**	**No**
Hospitalisation for OHSS with permanent disability	**Yes**	**No**
Mild OHSS symptoms- pain, bloating, nausea	**No**	**No**
Hospitalisation <24 hrs – where ovarian torsion, infection and severe OHSS are excluded	**No**	**No**
Infection		
Hospitalisation for suspected infection after Oocyte pick up or Embryo transfer which required intravenous antibiotics	**Yes**	**No**
Hospitalisation for suspected infection after OPU or ET which required surgery	**Yes**	**No**
Ovarian Torsion		
Hospitalisation after IVF treatment for ovarian torsion with no permanent consequences	**No**	**Yes**
Hospitalisation after IVF treatment for ovarian torsion which required surgical intervention	**Yes**	**No**
Blood Loss		
Hospitalisation after OPU for suspected blood loss	**No**	**Yes**

Drug Reaction		
Hospitalisation for unexpected drug reaction	**Yes**	**No**
Needle-Stick Injury		
Needle-stick injury involving a patient screened negative for HIV, Hep B, Hep C, with no infection	**No**	**Yes**
Needle-stick injury involving a patient screened positive for HIV, Hep B, Hep C whether cross-infection occurs	**Yes**	**No**
Incorrect Gametes or Embryos		
Potential use of incorrect gametes or embryos detected before use by the clinic's identification procedures	**No**	**Yes**
Actual use of incorrect gametes or embryos, no matter what the consequence (i.e., pregnant, or not)	**Yes**	**No**
Pregnancy complications		
Ectopic pregnancy	**No**	**No**
Complications arising from a miscarriage	**No**	**No**

Appendix B

Serious Adverse Event Definitions as per RTAC code of conduct

A serious adverse event (which is notifiable) includes any event which:

- Causes a significant medical or surgical condition that occurs as a result of the ART treatment defined below
- Results in the hospitalisation of the patient due to a complication of ART treatment
- Results or may result in the transmission of a communicable disease
- Results in a breach or potential breach of legislation
- Arises from a gamete or embryo identification mix up
- Causes a loss of viability of gametes or embryos or suspected deterioration (beyond accepted laboratory standards) that renders them unsuitable for use.

- Arises from a systematic failure in the validation/verification of a diagnostic test and/or technology that has resulted in misdiagnosis and/or significant potential harm or loss to patients, their gametes or embryos
- Specific medical or surgical conditions that define a serious adverse event

1. OHSS (Ovarian Hyperstimulation Syndrome)

- Any one of the severe or critical OHSS features as defined by RCOG guidelines (see table included below) and/or
- Where hospitalisation occurred for >24 hours and/or
- Where paracentesis or chest drain occurred (either inpatient or outpatient) and/or
- Where thrombosis occurred

Category of OHSS as defined by RCOG 'green top' guideline	
Severe	Clinical ascites (± hydrothorax) Oliguria (< 300 ml/day or < 30 ml/hour) Haematocrit > 0.45 Hyponatraemia (sodium < 135 mmol/l) Hypo-osmolality (osmolality < 282 mOsm/kg) Hyperkalaemia (potassium > 5 mmol/l) Hypoproteinaemia (serum albumin < 35 g/l) Ovarian size usually > 12 cm
Critical	Tense ascites/large hydrothorax Haematocrit > 0.55 White cell count > 25 000/ml Oliguria/anuria Thromboembolism Acute respiratory distress syndrome

2. Confirmed pelvic infection

That occurred as a direct result of ART treatment (oocyte retrieval, embryo transfer or intrauterine insemination) which resulted in admission to hospital, treatment with

IV antibiotics and/or surgical intervention. The initial patient presentation was within the first 4 weeks of the procedure.

3. **Complication at oocyte retrieval**
   Where injury to a pelvic structure occurred requiring admission to hospital and/or IV antibiotics (not prophylactic) and/or blood transfusion.

4. **Ovarian torsion**
   Which occurred during stimulation or within 4 weeks of oocyte retrieval and required hospital admission for > 24 hours

5. **Complication of a sperm retrieval procedure**
   Requiring hospital admission

6. **A serious medical or surgical condition**
   That resulted directly from the ART treatment and required hospitalisation that is not covered by the above 5 events. May involve admission to hospital for > 48 hours for pain, bloating, nausea where OHSS, torsion, infection has been excluded.

7. **Severe mental health event**
   Requiring hospitalisation in which ART was a major contributing factor and which occurred during or within 2 weeks of the completion of the treatment cycle.
8. **Death**
   Direct Death - a death that is directly caused by ART treatment
   Indirect Death - a death for which the direct cause of death was not due to ART treatment, but the ART treatment had a contributing effect
   Coincidental Death – Deaths from unrelated causes that happen during an IVF treatment cycle
   Note: Maternal death in an IVF patient is not included as this will be captured in obstetric reporting