Assisted Reproductive Technology (ART) Adverse event notification guidelines

The *Human Reproductive Technology Directions 2021* ("the Directions") introduced new adverse event notification requirements for licensed fertility providers.

When to submit a notification

Section 2.14 of the Directions requires that Licensees:

- notify the Chief Executive Officer of the Department of Health ("the CEO") of a ***serious adverse event:***
    - within 7 days of the event occurrence OR
    - within 7 days of becoming aware of the event occurrence;

AND

- provide the CEO with information on investigations and corrective actions undertaken within 6 weeks of the occurrence of the event.

It is important that Licensees have procedures in place to ensure that adverse events are identified as quickly as possible. However sometimes it may not be immediately apparent that an adverse event has occurred. For example, patients may not report incidents until their next follow up visit, some medical or surgical incidents may take some time to present, or regulatory breaches may only be identified through annual reporting or auditing. In this instance, Licensees should ensure that a notification is submitted within 7 days of becoming aware of the event occurrence.

Notification obligations established under the Directions are in addition to other adverse event reporting requirements where applicable including:

- Reproductive Technology Accreditation Committee (RTAC)
- Licensing and Accreditation Regulatory Unit (LARU)
- Therapeutic Goods Administration (TGA) adverse event
- Communicable Disease Notification.

Submitting an adverse event notification does not negate the need to submit data to the Reproductive Technology Registers.

What is a "serious adverse event"?

The definition of a "serious adverse event" under the Directions aligns with the definition in the RTAC *Code of Practice for Assisted Reproductive Technology Units.*

1. Causes a ***significant medical or surgical condition*** that occurs as a result of the ART treatment
   1.1. ***Ovarian hyperstimulation syndrome (OHSS)***:
      - Severe as per Royal College of Obstetricians and Gynaecologists (RCOG) guidelines
      - Critical as per RCOG guidelines
      - Hospitalisation > 24 hours
      - With paracentesis or chest drain
      - With thrombosis
   1.2. ***Pelvic infection*** that occurred as a direct result of ART treatment, with patient presentation within four weeks of the procedure, that resulted in:
      - admission to hospital and/or
      - treatment with IV antibiotics and/or
      - surgical intervention.
   1.3. ***Oocyte retrieval complication*** with injury to a pelvic structure requiring:
      - Admission to hospital and/or
      - IV antibiotics (not prophylactic) and/or
      - Blood transfusion.
   1.4. ***Ovarian torsion***:
      - which occurred during stimulation or within 4 weeks of oocyte retrieval and
      - required hospital admission for >24 hours.
   1.5. ***Sperm retrieval procedure complication*** requiring hospital admission.
   1.6. ***Other serious medical or surgical condition*** that resulted directly from the ART treatment and required hospitalisation >24 hours.
   1.7. ***Severe mental health event*** in which ART was a major contributing factor:
      - requiring hospitalisation; and
      - which occurred during or within 2 weeks of the completion of the treatment cycle.
   1.8. ***Death***:
      - Direct: direct cause by the ART treatment
      - Indirect: direct cause not ART but the ART treatment had a contributing effect
      - Coincidental: unrelated to ART but occurred during the ART cycle.
2. Results in the ***hospitalisation of the patient*** due to:
      - OHSS
      - Pelvic infection with patient presentation within 4 weeks of procedure
      - Injury to pelvic structure from oocyte retrieval complication
      - Ovarian torsion
      - Sperm retrieval procedure complication
      - Other >48 hours
3. Results or may result in the ***transmission of a communicable disease***
4. Results in a ***breach or potential breach of legislation***
5. Arises from a ***gamete or embryo identification mix up***
6. Causes a ***loss of viability of gametes or embryos or suspected deterioration*** (beyond accepted laboratory standards) that renders them unsuitable for use.
7. 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.

How to report

Reports can be made via: https://redcap.link/ART_AdverseEvents

Reports are in two parts:

- Part 1: Adverse event details. Must be submitted within 7 days.
- Part 2: Investigation outcomes: recommendations and corrective actions. Must be submitted within 6 weeks.

Licensees will receive an email with a PDF copy of their responses each time part the survey is submitted. The PDF report can be sent to the RTAC to meet adverse event reporting requirements under the RTAC *Code of Practice for Assisted Reproductive Technology Units*.

Reviewing incidents

The Licensee or a senior staff member should be assigned to investigate and review the incident. Details of the investigation undertaken should be provided in Part 2 of the notification.

Contributory and/or causative factors should be identified, and corrective actions should be developed to prevent future adverse events. Corrective actions should be listed in Part 2 of the notification.

Further information

If you are unsure if an incident requires reporting, please contact the RTU to discuss.

Phone: 6373 2312

Email: rtu@health.wa.gov.au

Licensees may be contacted by the RTU for further information. Licensees are required under the Directions to provide information in the specified timeframe.

This document can be made available in alternative formats on request for a person with disability.

health.wa.gov.au

OHSS Categorisation

A woman with a symptom in a category must be recorded in that category.

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)

Critical

- Tense ascites/large hydrothorax
- Haematocrit > 0.55
- White cell count > 25 000/ml
- Oliguria/anuria
- Thromboembolism
- Acute respiratory distress syndrome

Data dictionary

Variable	Section	Field Type	Field Label	Choices	Notes	Validation	Required?
record_id	Part_1	text	Record ID				
clinic_name	Part_1	dropdown	ART unit name	1, Adora Fertility 2, Concept Fertility Centre 3, Fertility North 4, Fertility Specialists of WA - Claremont 5, Fertility Specialists of WA - Applecross 6, Genea Hollywood Fertility 7, PIVET Medical Centre			y
rtac_number	Part_1	text	RTAC license number				y
artref_number	Part_1	text	Report reference number (ART Unit)		Enter a reference that will assist you if you need to come back and edit this report or submit updated information once investigations have been completed. Please ensure that this reference number does not contain identifying information (patient full names etc).		y
auth_notified	Part_1	checkbox	Authorities who will be notified of this event:	1, WA Department of Health 2, RTAC 3, Certifying body 4, Other			

Variable	Section	Field Type	Field Label	Choices	Notes	Validation	Required?
event_type	Part_1	dropdown	Type of event	1, Clinical 2, Laboratory 3, Regulatory 4, Compliance 5, Patient 6, Other		autocomplete	
criteria	Part_1	checkbox	Criteria for notification	1, Medical or surgical condition (please specify below) 2, Patient hospitalisation > 24 hours 3, Communicable disease transmission 4, Legislative breach 5, Gamete or embryo mix up 6, Loss of viability or gametes or embryos 7, Systemic failure of a diagnostic test			y
diagnosis	Part_1	text	Incident description				
med_surg_cond	Part_1	checkbox	Please select all medical or surgical conditions that apply	1, OHSS (see OHSS Categorisation) 2, Pelvic infection 3, Oocyte retrieval complication 4, Ovarian torsion 5, Sperm retrieval complication 6, Other condition not covered above requiring hospitalisation 7, Severe mental health event 8, Death			y
ohss_stimulation	Part_1	text	Type of stimulation				y
ohss_drug	Part_1	text	Drug and dose used to induce ovulation				y
ohss_e2	Part_1	text	E2 level before trigger				y
ohss_para	Part_1	yesno	Paracentesis				y
ohss_embryo	Part_1	yesno	Embryo transfer				y
ohss_preg	Part_1	yesno	Pregnancy				y

Variable	Section	Field Type	Field Label	Choices	Notes	Validation	Required?
incident_date	Part_1	text	Date the incident became apparent or the patient was first re-admitted to hospital (for re-hospitalisation events)			date_dmy	y
proc_date	Part_1	text	Procedure date: - date of OPU - date of ET (if FET) or - ANZARD start date if no OPU or FET			date_dmy	
procedure	Part_1	text	ART procedure (as per ANZARD)				
lic_name	Part_1	text	Name of person completing this notification				y
position_1	Part_1	text	Position of the person completing this notification				y
lic_email	Part_1	text	Email of the person completing this notification			email	y
notif_date	Part_1	text	Date of notification			date_dmy	y
docs1	Part_1	file	Upload any additional documents here				
analysis	Part 2	notes	Investigation and analysis of incident				y
conclusion_date	Part 2	text	Event conclusion date			date_dmy	
eggs	Part 2	text	Number of eggs collected			number	
preg_outcome	Part 2	text	Pregnancy outcome				
patient_outcome	Part 2	text	Patient outcome				
hospdays_count	Part 2	text	Hospitalisation days				
actions	Part 2	notes	Recommendations and corrective				y

Variable	Section	Field Type	Field Label	Choices	Notes	Validation	Required?
			actions				
documents	Part 2	file	Additional documentation				
reviewer_name	Part 2	text	Name of the person completing the review				
review_date	Part 2	text	Review date			date_dmy	
lic_name_2	Part 2	text	Name of the person completing this form				y
position_2	Part 2	text	Position of the person completing this form				y
lic_email_2	Part 2	text	Email of the person completing this form			email	y