Guidance Note – Reporting Adverse Incidents (June 2021)

The Victorian Assisted Reproductive Treatment Authority (the Authority) imposes general conditions on all registered Victorian ART providers in the public interest.

This Guidance Note is intended to help registered ART providers comply with Condition 2.6 of the Authority's *Conditions for Registration (Effective 1 February 2020)* (the Conditions for Registration) by providing additional information about the types of incidents that should be reported to the Authority. It does not act to limit the scope of Condition 2.6.

Condition 2.6(a) says:

> *An ART provider must give the Authority written notice of:*
>
> *i) any actual or potential contravention of the [Assisted Reproductive Treatment Authority Act 2008 (the Act)] or [the Assisted Reproductive Treatment Regulations 2019 (the Regulations)];*
>
> *ii) any actual or potential breach of its [Conditions for Registration] or conditions attached to any approval granted by the Authority;*
>
> *iii) any incident that is reported to [the Reproductive Technology Accreditation Committee (RTAC)] as part of accreditation requirements; and*
>
> *iv) any contravention of the guiding principles of the Act in carrying out activities regulated by the Act, including any incident which is or is likely to be harmful to the health or wellbeing of patients, donors, gametes or embryos –*
>
> *by the ART provider or by a doctor carrying out treatment procedures on its behalf.*

Under Condition 2.6(c), registered ART providers are generally required to report incidents as soon as practicable but no later than **six weeks** after becoming aware of the incident. However, where the incident:

i) is a sentinel event, involves an error in identification/traceability of genetic material, poses an immediate risk to patient safety or could otherwise result in severe consequences, notification must be made within **48 hours** of the ART provider becoming aware of the incident;

ii) involves an actual or potential legislative breach, notification must be made within **two weeks** of the ART provider becoming aware of the incident.

If you are uncertain about reporting an incident, please contact the Authority for guidance.

The Authority may consider it necessary to investigate some incidents. For the Authority to decide whether it should commence an investigation, registered ART providers are requested to provide as much detail as possible in the adverse incident notification form.

Please refer to the Victorian Department of Health's clinical risk management policy[1] if you require general guidance about how to complete an adverse incident notification form.

[1] https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/clinical-risk-management

If an incident requires investigation, the Authority will generally provide a written request for further information. Additional information requests may be made as the Authority considers the facts and determines appropriate actions.

Actual or potential contraventions of the *Assisted Reproductive Treatment Act 2008* (VIC) (the Act), *Assisted Reproductive Treatment Regulations 2019* (VIC) (the Regulations), Conditions for Registration, and/or conditions attached to any approval granted by the Authority (Condition 2.6(a)(i)-(ii))

While actual contraventions of the Act and/or the Regulations will generally be more readily identifiable, potential contraventions may be more difficult to detect and evidence.

Where possible, please identify the relevant section of the Act, Regulations, Conditions for Registration, and/or condition of approval that may have been breached in the adverse incident notification form.

Incidents required to be reported to RTAC as part of accreditation (Condition 2.6(a)(iii))

Under Section 3.2(c) of the RTAC *Code of Practice for Assisted Reproductive Technology Units (Revised October 2017)*, 'Serious Notifiable Adverse Events' must be reported to RTAC and the appropriate certifying body. A 'Serious Notifiable Adverse Event' is defined as:

an abnormal unintended outcome associated with ART operations which:

- *might result in the transmission of a communicable disease*
- *might result in the death or a life-threatening, disabling, or incapacitating condition*
- *arises from a gamete or embryo identification error or mix-up*
- *might impact safety of people, gametes, embryos, equipment or facilities as a result of a disaster*
- *results in a potential or actual breach of legislation.*

The Authority may communicate with RTAC regarding an incident if it has been reported to both bodies.

Incident which is or is likely to be harmful to the health or wellbeing of patients or donors (Condition 2.6(a)(iv))

The following is a non-exhaustive list of the types of incidents that should be reported to the Authority:

- ovarian hyperstimulation syndrome (OHSS) that results in an overnight hospital admission or longer;
- OHSS which has a severity classification of severe or critical (see **Appendix 1**)[2]; or
- other clinical complications arising from egg collection procedures such as ovarian torsions, significant delays in, or cessation of, treatment that affects the wellbeing of patients due to failure to follow legislated processes.

No reporting is required in cases of ectopic pregnancies.

Incident which is or is likely to be harmful to, or affect the viability of, or cause the destruction of, gametes or embryos (Condition 2.6(a)(iv))

The following examples are types of incidents that should be reported to the Authority:

[2] Royal College of Obstetricians and Gynaecologists: Ovarian Hyperstimulation Syndrome Management (Green-top Guideline No. 5) (2016).

- incorrect gametes used in an artificial insemination procedure or to form an embryo;
- gametes and/or embryos lost through incorrect disposal, freezing unit or dry shipper failure, or another scientific/laboratory error;
- the transfer of an incorrect/non-viable embryo or unfertilised egg in a treatment procedure.

Appendix 1

ROCG classification for the severity of OHSS

Category	Features
Mild OHSS	Abdominal bloating Mild abdominal pain Ovarian size usually < 8 cm³
Moderate OHSS	Moderate abdominal pain Nausea ± vomiting Ultrasound evidence of ascites Ovarian size usually 8–12 cm³
Severe OHSS	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 cm³
Critical OHSS	Tense ascites/large hydrothorax Haematocrit > 0.55 White cell count > 25 000/ml Oliguria/anuria Thromboembolism Acute respiratory distress syndrome