Reproductive Technology Accreditation Committee (RTAC)

TECHNICAL BULLETIN 5

Serious Notifiable Adverse Events

November 2014

From time to time RTAC will become aware of issues, questions or comments where it may consider assisting units enhance the quality of their service to patients. A Technical Bulletin is an educational communication to all units, and Bodies certifying units to the RTAC Code of Practice, offering advice and guidance. It is not enforceable.

The 2014 version of the RTAC Code of Practice requires, under Critical Criterion 4, that an Organisation must acknowledge and investigate adverse events.

ART Organisations must provide evidence of implementation and review of:

- *policies/procedures to systematically collect, analyse causal factors, review and act on all adverse, unplanned and untoward events.*
- *Adverse events, including serious adverse events and serious notifiable adverse events are defined in Attachment 2 to the COP.*
- *Serious Notifiable Adverse Events, as defined in Attachment 2 to the COP, must be reported to RTAC through its secretariat and to the appropriate Certifying Body to facilitate audit of responses to the Adverse Event.*

A **Serious Adverse Event** is any event associated with ART treatment:

- which causes or potentially causes harm, loss or damage to patients or their reproductive tissues - which results in hospitalisation following, and as a result of, the treatment.

Serious adverse events must be investigated, fully documented, and corrective actions put in place for review by the Certifying Body at the next scheduled inspection

A **Serious Notifiable Adverse Event** is an abnormal unintended outcome associated with ART treatment which:

- might result in the transmission of a communicable disease
- might result in death or a life-threatening, disabling, or incapacitating condition
- arises from a gamete or embryo identification error or mix-up.

Serious Reportable Adverse Events must be reported immediately to RTAC and the Certifying Body, along with a summary of investigation of the event and any actions taken. This report should be in the format of the Organisation's investigation of non-conformances, including details of the event and its outcome, analysis of potential causes, and corrective and preventive actions put in place.

RTAC and the RTAC Technical Committee will collate and analyse reported serious adverse events in a de-identified state. Should trends in the causes underlying the notifications be detected RTAC will use the information to assess the need for future Technical Bulletins

On the following page is a table with suggested reporting management of the most common adverse events associated with ART treatment.

RTAC is grateful to Dr. John Peek for assistance in the development of this Technical Bulletin.

Keith Harrison
RTAC Chair

Scenario	**Serious Reportable Adverse Event** Document, analyse and report to RTAC and CB	**Serious Adverse Event** Document, analyse and retain for CB
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
Infection		
Hospitalisation for suspected infection after OPU or ET which required IV 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
Hospitalisation after OPU for blood loss requiring blood transfusion	Yes	No
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 or not 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