Reproductive Technology Accreditation Committee (RTAC)

TECHNICAL BULLETIN 9

DISASTER MANAGEMENT

November 2016

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 normally enforceable unless also incorporated into the Code of Practice.

Background

Given that an underlying principle to the RTAC Codes of Practice is "that patients and their offspring remain the most important consideration in all decisions", Assisted Reproductive Technology (ART) Units have a duty of care to ensure the safety and well-being of patients during their treatment, and of gametes and embryos whilst in culture or storage. Unfortunately, disasters can occur beyond the control of the ART Unit that requires action to be taken to limit damage or loss. Examples have been seen in recent years, in ART Units located in Australia and New Zealand, of earthquakes, storms, floods and fire.

Such disasters can affect Units in a number of ways including the interruption of clinical procedures, the loss of temperature control in the storage of medications and reagents, and the disruption of the culture and storage of gametes and embryos. Furthermore, the disaster may have unforeseen consequences which compound the problem. These can be direct such as power loss resulting in electronic security doors in the Unit being unable to be opened and access to the Unit being prevented, or indirect as when electric fuel pumps do not work and prevent the supply of fuel for a generator. Instances have also been reported of generators failing despite assurances from hospitals or private building owners.

In order to minimise the risk of serious adverse events, the RTAC Codes of Practice require a risk assessment programme and risk management strategies to be in place in certified and accredited ART Units.

Requirements

ART Units should comply with the appropriate RTAC Code of Practice at all times. This is monitored by approved Certifying Bodies who take snapshots of the performance of a Unit by conducting an annual audit. The Unit is audited against the Critical Criteria of the Code every year whilst the Good Practice Criteria are reviewed on a 3-year cycle. Compliance with the Code during the audit results in Certification by the Certifying Body, and a recommendation for the issuing by RTAC of a licence (Australia and New Zealand) or Certification in International Units.

Both the Australian and New Zealand Code of Practice (August 2015) and the International Code of Practice (March 2014) address the need for ART Units to ensure that the care of patients and their gametes and embryos within the Unit is maintained at all times. This is covered in the Good Practice Criterion 1.9 (Buildings and Facilities) and 1.10 (Risk Management) where Units are required to provide evidence of implementation and review of aspects of the quality management system. These include an assessment of the buildings, facilities and equipment to meet the goals and objectives of the Unit, and ensuring management of risks. e.g. emergency equipment, power, gas.

Should this level of care not be maintained because of an adverse, unplanned and untoward event, then the Unit is required by the Critical Criterion 4 to provide evidence during the audit of implementation and review of policies/procedures to systematically collect, analyse causal factors, review and act on all such events. Technical Bulletin 5 outlines the process for reporting adverse events.

Recommendations

In order to minimise the risk of serious adverse outcomes following a disaster, RTAC and the Fertility Society of Australia recommends that:

a) ART Units certified and accredited against the respective RTAC Codes of Practice should have contingency plans that address potential disaster scenarios including those unique to their location.
b) The Unit should show evidence of working through scenarios, identify the principle components of the plans, and show them to be feasible and to work.
c) These contingency plans should consider scenarios including but not limited to:
    a. power loss to the laboratory and during a clinical procedure, and the capacity of back-up systems.
    b. power loss outside of clinic opening hours, and for longer than 1 day, including the function of remote alarm systems.
    c. key equipment malfunction (eg. Gas changeover malfunction or gas pipe fracture so the contents of all the gas cylinders connected to the incubators are lost, and integrity of liquid nitrogen dewars is compromised)
    d. non-delivery of key reagents (eg. culture medium), consumables (eg. liquid nitrogen, embryo transfer catheters), and medications for longer than stores will last.
    e. air conditioning failure in locations with a high ambient temperature
    f. physical stability of equipment in earthquake prone locations.
    g. fire, floods and water damage.

d) The ART unit should have a policy of open disclosure concerning adverse events. In line with the document Australian Open Disclosure Framework produced by the Australian Commission on Safety and Quality in Health Care, the elements of open disclosure should include:
    a. an apology or expression of regret.
    b. a factual explanation of what happened.
    c. an opportunity for the patient and their family to relate their experience (eg with the clinic's counsellor).
    d. a discussion of the potential consequences of the adverse event.
    e. an explanation of the steps being taken to manage the adverse event and prevent recurrence.