



## Reproductive Technology Council

### **ASSISTED HATCHING: Standards and conditions for approval as an innovative or routine practice under the *Human Reproductive Technology Act 1991 (Act)*.**

#### **Background**

At its meeting of 27 June 2000 the Reproductive Technology Council (Council) agreed to recommendations of its Scientific Advisory Committee that, based on available information in the peer reviewed literature, assisted hatching (AH) might be approvable under the Act as an innovative practice. At its meeting of 21 September 2010, Council reviewed the use of AH in the practice of assisted reproductive technology. Minor changes to the standards and conditions for approval and use of assisted hatching have been implemented as below.

AH can be offered under prescribed conditions. A meta-analysis of twenty-eight selected studies on assisted hatching (Das et al., 2009) concluded that there was *some evidence that AH improves the chance of pregnancy in women for whom IVF has been repeatedly unsuccessful*. However, the review also highlighted that many issues around AH were unresolved. This includes the risk of adverse outcomes, in particular multiple births including monozygotic twinning. Until further peer-reviewed international research improves understanding of outcomes associated with AH, the criteria and conditions limiting the patient profile to whom the procedure can be offered will remain.

#### **Standards and conditions for current approval of AH under the Act**

The Council considers that AH may be approvable under the Act as an innovative or routine practice under the following conditions-

- The technique used should be limited to partial zona pellucida dissection and zona drilling, unless adequate justification can be given for the use of other methods;
- AH should only be offered to
  - women aged 38 or older, with elevated basal FSH (>12 iu/l) and poor prognosis embryos (i.e., thick zonae, slow developmental rate and/or excessive fragmentation); or
  - women with three or more failures of implantation following in vitro fertilization (IVF); or
  - as required for pre-implantation genetic diagnosis or screening,—unless adequate justification can be given for extension of these criteria.
- Clinics should carefully consider the risk of multiple births in decisions about the numbers of embryos submitted to AH to be implanted, and to include information about these risks in their patient information;
- Patient information should also include specific information from the literature about the likely safety and effectiveness of the procedure and what is known about birth outcomes;
- Clinics using AH should monitor the outcomes of treatments—including monozygosity or otherwise of any twins—and report on these as required by the Schedule 2, Part 2 and Schedule 3, Part 2 of the Directions under the HRT Act. Reporting should allow monitoring of long-term outcomes of treatments using AH.
- Any clinic proposing to carry out AH must provide evidence that their staff have suitable experience and expertise to perform AH effectively, which might include experience with animal embryos.
- Clinics are able to seek Council approval to perform AH as a routine procedure. Reporting requirements under Schedule 2, Part 2 and Schedule 3, Part 2 will still apply.

#### **WA Reproductive Technology Council, November 2010**

Das S, Blake D, Farquhar C, Seif MMW. Assisted hatching on assisted conception (IVF and ICSI). Cochrane Database of Systematic Reviews 2009, Issue 2. Art. No.: CD001894. DOI: 10.1002/14651858.CD001894.pub4