

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

WA Reproductive Technology Council, July 2000

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) may now be approvable under the Act as an innovative practice. The Council also agreed to certain criteria or conditions to be placed on any approvals granted and on what would be required of applications.

A recent review article by A de Vos and A Van Steirteghem (Cells, Tissues, Organs 2000; 166:220-227) (attached) reported five randomised controlled studies which suggested that AH was of no benefit to the overall patient population, but might be of value in increasing embryo implantation rates in selected cases. There was no evidence of benefit for patients simply of advanced maternal age and findings in relation to the use of AH for cases with thicker zonae were contradictory. There was no theoretical cause for concern in relation to increased birth defects, but multiple pregnancy was of major concern.

Standards and conditions for current approval of assisted hatching under the Act

The Council considers that, in its considered opinion, information in the peer reviewed literature suggests AH may now be approvable under the Act as an innovative practice under the following conditions-

- The technique used should be limited to partial zona dissection and zona drilling with acid Tyrode's solution, 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 (ie thick zonae, low developmental rate and/or excessive fragmentation); or women with 3 or more failures of implantation following IVF, 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 AH embryos 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 outcomes of treatments and report on these in the short term (up to birth). At the time of annual reporting (and any other time as requested by the Council) any clinic using AH should notify the Council how many women and treatment cycles it was used for, and what the indications for use were. Clinics should also provide information about any birth outcomes (including monozygosity or otherwise of twins) in these reports
- The Council should ensure that standard reporting requires clinics using AH to provide these short term outcomes for the use of AH, but also allows the Council to monitor and report on the longer 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 may include experience with animal embryos.