

Review of novel processes – intrauterine culture

Strategic delivery: Safe, ethical, effective treatment Consistent outcomes and support Improving standards through intelligence

Details:

Meeting Scientific and Clinical Advances Advisory Committee (SCAAC)

Agenda item 5

Paper number SCAAC(05/02/2018)02

Meeting date 05 February 2018

Author Anna Quinn, Scientific Policy Manager

Output:

For information or decision? For decision

Recommendation The Committee is asked to:

- consider the outcomes report provided by the clinic; and
- advise if this raises any concerns which might lead them to recommend that intrauterine culture should be removed from the authorised processes list.

Resource implications Possible paper to the Statutory Approvals Committee if SCAAC recommend that the device is de-authorised

Implementation date N/A

Communication(s) N/A

Organisational risk Low Medium High

Annexes Annex 1: Intrauterine device outcomes report

1. Introduction

- 1.1. As the UK regulator of fertility clinics, the HFEA maintains a list of authorised processes, which are arranged under each of the licensable activities permitted by the Human Fertilisation and Embryology Act 1990 (as amended). If a centre wishes to carry out a process which does not appear on the list, it must apply to the Authority for permission. The Authority delegates the authorisation of novel process to the Statutory Approvals Committee (SAC), who are advised on the matter by the Scientific and Clinical Advances Advisory Committee (SCAAC).
- 1.2. As part of considering a novel process application, SCAAC should agree that the process is sufficiently different from the processes currently authorised as to be considered 'novel'. The Committee should also provide a view on whether the process is effective and whether there is any evidence to indicate that it is unsafe.
- 1.3. According to the Standard Operative Procedure (SOP) for considering novel process applications, SCAAC should receive an outcomes report two years after a process is approved. This report should cover the safety and efficacy of the process such that the Committee can discuss any concerns about the process being either unsafe or ineffective. If concerns are raised the Committee may consider recommending that the process is removed from the authorised processes list. This decision would have to be agreed by SAC.
- 1.4. This paper provides an outcomes report on the intrauterine culture novel process, which was authorised in 2015.

2. Intrauterine culture

Background

- 2.1. The Anecova AneVivo intrauterine device is an *in vivo* embryo culture device for use during IVF treatment that allows fertilisation and embryo development to occur in the patient's uterus within the natural tubal and uterine fluids, rather than in the incubator and an artificial medium.
- 2.2. The intended use of the device is the placement and retrieval of gametes or embryos into and from the uterine cavity, with the objective of their culture within the device whilst in the uterine cavity. This enables fertilisation and early embryo development to take place *in vivo*, reducing the exposure of embryos to synthetic *in vitro* conditions during this crucial early phase of development, but also exposing the endometrium to any compounds produced by the embryo.
- 2.3. The Committee first considered the Anecova AneVivo intrauterine culture device in June 2015. During this meeting the Committee commented that the description of the device could be misleading when it states that it allows the

embryo to develop in a more natural environment. The Committee stated that naturally the embryo would be in the fallopian tube at this stage of development and not in the uterine cavity.

- 2.4.** In June 2015 the Committee concluded that it had not been provided with sufficient information to determine the safety and efficacy of the device and requested further information from the applying clinic.
- 2.5.** In July 2015 the Committee held a further meeting by teleconference to consider additional evidence provided by the applying clinic. Following this meeting, SCAAC was of the view that:
- the device is not unsafe; and
 - the clinical data on the device was limited and therefore does not demonstrate its efficacy, although there is not evidence to indicate that the process would not be effective.
- 2.6.** At its meeting in August 2015 SAC formally considered the novel process application and agreed to add intrauterine culture to the Authority's list of authorised processes, noting that it is possible that the process might offer no improvement in efficacy and might add an unnecessary cost to patients.

Outcomes report

- 2.7.** An outcomes report has been provided by the original applying centre on their use of the Anecova Anevivo intrauterine culture device between August 2015 and December 2017. The report and table of patients treated can be found at Annex 1.
- 2.8.** The outcomes report notes that ten patients received an empty device as part of the training process and 12 patients were recruited for a clinical pilot study (although in four of these patients the device was not used *in vivo* culture for clinical reasons).
- 2.9.** Two patients from the *in vivo* cohort had embryo transfer and one became pregnant, but unfortunately had an early miscarriage.
- 2.10.** The clinic notes that none of the patients who used the device had any adverse reactions or complications, however some concerns were raised regarding temperature maintenance and increased manipulation of eggs during a period when they would otherwise be in undisturbed culture.

3. Recommendations

- 3.1.** The Committee is asked to:
- consider the outcomes report provided by the clinic; and
 - advise if this raises any concerns which might lead them to recommend that intrauterine culture should be removed from the authorised processes list.

Annex 1: Intrauterine device outcomes report

Content redacted for confidentiality