Statutory Approvals Committee - minutes

Authorisation of novel process – Anecova AneVivo device

Thursday, 27 August 2015

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Committee members	David Archard (Chair, lay) Rebekah Dundas (Deputy Chair, lay) Margaret Gilmore (lay) Anthony Rutherford (professional)	
Members of the Executive	Jo McAlpine	Secretary
External advisor	None	
Legal Advisor	Tom Rider	Fieldfisher
Observers	None	

Declarations of interest

- Members of the committee declared that they had no conflicts of interest in relation to this item.

The committee had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- Authorisation for a novel process paper and annexures

1. Consideration of application

1.1. The committee had regard to its Decision Tree. The committee noted that the application was for a novel process to be added to the HFEA's authorised processes. The novel process is the intrauterine culture of gametes/embryos (including insertion and removal of device, followed by transfer of embryo(s) to the same woman), using the Anecova AneVivo device.

1.2. The committee noted that Anecova AneVivo intrauterine device is an in vivo embryo culture device for use during IVF treatment that allows fertilisation and initial embryo development to occur in the patient's uterus within the natural uterine fluids, rather than in an incubator and artificial medium.

1.3. 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 while inside 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 the development, but also exposing the endometrium to biochemicals produced by the developing embryos.

1.4. The committee had regard to the advice of the HFEA's Scientific and Clinical Advances Advisory Committee (SCAAC), which had made an initial assessment of the application. The committee noted that SCAAC's consideration was as follows:

- The use of intrauterine culture devices did constitute a novel process;
- The process applied for falls within two licensable activities: processing gametes and processing embryos;
- The evidence provided gave no indication that the process is unsafe;
- SCACC did not see any evidence to suggest that intrauterine culture of gametes/embryos using a device such as the Anecova AneVivo would not be effective. However it did not feel that there was sufficient clinical data to say whether the process has a greater or lesser efficacy than that of traditional IVF methods.

1.5. The committee sought the advice of the legal adviser on the questions that it had to address. It noted that the questions considered by SCAAC were: (a) is there evidence to suggest the process is not safe; and (b) is there evidence to suggest that the process is not effective. In contrast, the decision tree states that the questions for the committee to consider are: (a) is the process safe; and (b) is the process effective. The committee did not feel that these questions were the same. The legal adviser advised that the novel process in this case involves processing gametes and embryos in the course of providing treatment services. Thus, it relates to licences granted under section 11(1)(a) and paragraph 1 of schedule 2 to the Human Fertilisation and Embryology Act 1990, to which, by virtue of section 14A(2), the conditions required by schedule 3A must apply. By paragraph 11(b) of schedule 3A, one of the requirements is that the processing of gametes and embryos must comply with Annex II, Part B, of Directive 2006/86 EC, and paragraph 1 of part B of Annex II states that the processing procedures "must not render the tissues or cells clinically ineffective or harmful to the recipient". Therefore, the questions to be considered by this committee are essentially the same as those that had been considered by SCAAC.

1.6. The committee noted the opinion of SCAAC, and the supporting evidence provided. It concurred that there was nothing in the evidence to indicate that the process is not safe, and noted and accepted SCAAC's opinion that this was a novel process, and if approved it would fall under the licensable activities of processing gametes and processing embryos.

1.7. In respect of the efficacy of the process, the committee noted in particular that the sample size of people included in the clinical studies was very small and that because of this it was not possible to make an objective assessment of efficacy of the process, nor to say whether it is more or less effective that current IVF techniques. However, the Committee noted that Anecova AneVivo

intrauterine device has been used for treatment in three European countries resulting in a number of live births, suggesting that it is sufficiently effective to give successful IVF outcomes some of the time.

2. Decision

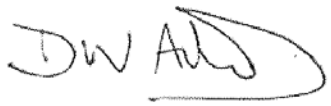
2.1. The Committee approved the decision by majority with one member expressing concerns about the lack of evidence that the process was safe or effective. The process would be added to the HFEA's list of approved processes under the licensable activities of processing gametes and processing embryos.

2.2. In agreeing to authorise the novel process, the committee agreed with SCAAC's observation that, as it is possible that the process might offer no improvement in efficacy and might add an unnecessary cost to patients, any patient information provided by clinics should highlight this. In addition, information on the HFEA website should draw attention to the fact that the process has not yet been subject to a clinical trial, and its efficacy is therefore not known.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature



Name

David Archard

Date

10 September 2015