

Minutes of the Scientific and Clinical Advances Advisory Committee meeting

30 October 2013

held at Aeonian Centre, 5th Floor, 211 Old Street, London EC1V 9NR

Members present

Sue Price (Chair)
Hossam Abdalla
Andy Greenfield
Alan Thornhill

External advisors present

Daniel Brison
Melanie Davies
Lorraine Young
Robin Lovell-Badge

Apologies

Debbie Barber
Joyce Harper

Staff in attendance

Anna Rajakumar (Secretary)
Nick Jones
Anjeli Kara
Rebecca Lovey
Chris O'Toole
Hannah Verdin

Observers

Lisa Jardine (HFEA Chair)

1. Apologies, welcome and declaration of interests

- 1.1. The Chair conveyed apologies received from Debbie Barber and Joyce Harper.
- 1.2. Interests were declared by Daniel Brison and Alan Thornhill.

2. Matters arising and previous actions

- 2.1. The minutes from the Committee's meeting on 12 June 2013 were agreed remotely prior to the meeting, and the matters arising from the previous minutes were noted and agreed.
- 2.2. Anna Rajakumar (AR) updated members on the progress of matters arising from the June 2013 meeting.

3. Chair's business

- 3.1. The Chair raised no business.
- 3.2.

4. Health outcomes in children conceived using ART

- 4.1. Anna Rajakumar introduced a paper outlining recent research into health outcomes that included work presented at the June 2013 ESHRE meeting, relating to cancer risk in ART children. The Committee was asked to consider the research outlined and identify any further relevant studies of interest. Members were also asked to consider whether the HFEA should review the information (relating to health outcomes following ART) clinics are required to make available to patients, the information the HFEA makes available to patients, and what information they believe would be useful to patients.
- 4.2. The Committee discussed whether information relating to cancer risk should be communicated via the HFEA website, agreeing that it may be useful to outline recent findings (following publication of the relevant studies). They emphasised the need to ensure that figures were communicated in a clear way in order to convey the relative risks.
- 4.3. The Committee also discussed some further identified studies relating to the outcomes of low birth weight and pre-term birth in children conceived using ART. This included a study highlighting that embryo transfer at the blastocyst stage is associated with a higher risk of preterm delivery; however, confounders were not factored out and further randomised trials are needed for conclusive findings. They also highlighted that further information is required on longer term risks of ART.
- 4.4. Additional studies raised at the meeting are appended in the supporting paper titled 'Health outcomes in children conceived using assisted reproductive technologies' (SCAAC(10/13)01).

5. Simplified IVF culture system

- 5.1. Chris O'Toole introduced a paper exploring a simplified IVF culture media system. Chris explained that in a proof of principle study the authors suggest they have identified a simplified culturing system that does not require all of the expensive equipment usually found in IVF laboratories, therefore enabling techniques to be used in developing countries. The group has developed a method which will keep embryos cultured in the acidic environment they require using a simplified technique, without the need for CO₂ chambers. So far the method has given similar success rates as conventional IVF and this has sparked interest from groups wanting to offer cheaper treatment to patients here in the UK.
- 5.2. The Committee was also provided with additional confidential documentation (submitted by an enquiring clinic) relating to the specifics of

the method and equipment involved. Furthermore the Committee was provided with a verbal update on recent, ongoing work in this area.

5.3. The Committee was informed that in terms of a regulatory approach it would seem that this does not fall under the definition of a novel process, as it does not represent a different method for creating embryos. Members were asked to consider the safety and efficacy issues that may arise from such techniques.

5.4. The Committee were not clear that the majority of the cost of IVF necessarily came from the current need for a CO₂ incubator. They also highlighted a recent presentation at the ASRM conference by Prof. Jonathan Van Blerkom and discussed these findings. The Committee raised some concerns regarding the change in culture media and suggested the media proposed would be novel and therefore it would be important to note how this changes embryo development and metabolism. The Committee felt it would be appropriate for any clinics wishing to introduce this system to validate it as a new piece of equipment and a new culture media. Validation should include reference to peer reviewed published studies describing the methodology used, pre-clinical testing and clinical outcomes.

6. Animals containing human material guidance

6.1. Anna Rajakumar explained that the Committee first considered animals containing human material in the context of the Academy of Medical Sciences report in September 2011. Since then the Committee have had sight of the draft versions of the guidance document (produced by the Home Office) to support researchers seeking the appropriate licencing for research projects. The Committee was presented with an almost final version of the guidance document.

6.2. The Committee highlighted that the document needs to reiterate the importance of the HFEA 14-day limit for culturing embryos and specific comments were fed into the draft which will be passed onto the Home Office.

7. Committee review

7.1. The Committee was asked to conduct a review of its effectiveness and activity, which will be reported back to the Authority in January 2014. The Committee highlighted the following areas for consideration:

- circulate an active workplan and draft agenda during meetings in order to plan the next;

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- consider how Committee membership terms should be formalised;
- create an active list of speakers that the Committee would like to invite to present and contribute at SCAAC meetings;
- consider having a wider pool of external advisors who are able to attend relevant meetings; and
- increase the visibility of the Committee through social media and updates to the sector.

8. AOB

8.1. The Committee noted a tabled paper regarding embryoid bodies, suggesting that the article should be included in the Committee's annual update on alternative methods to derive ES and ES-like cells.

8.2. The Committee discussed a study that was raised as part of the health outcomes paper (item 4) and considered the wider topic of freeze-all cycles. The Committee was asked if it felt there are any questions to be answered and further work to be done by the Executive in this area (perhaps in a paper next year). Committee members raised the issue of data recording in relation to "freeze-all cycles". The Executive confirmed that they will consider this as part of the Information for Quality work programme.

8.3. A recent article, published in Science, discussing the HFEA's mitochondria replacement public consultation was considered by the Committee. Members discussed their thoughts on the theories and views raised in the article. The Committee agreed that the findings of this research should be included in any potential future scientific review of mitochondria replacement techniques.

9. Date of next meeting

9.1. The next meeting will be on 5 February 2013.

I confirm this to be a true and accurate record of the meeting.

Chair

Susan H. Price

Date

28/11/13