

## Minutes of the Scientific and Clinical Advances Advisory Committee meeting 27 February 2013

held at Etc Venues, Bonhill House, 1-3 Bonhill Street, London EC2A4BX

### Members present:

Andy Greenfield  
Alan Thornhill  
Debbie Barber  
Hossam Abdalla

### External advisors present:

Joyce Harper  
Peter Braude  
Robin Lovell-Badge  
Lorraine Young

### Apologies:

David Barlow  
Sue Price  
Melanie Davies

### Staff in attendance

Anna Rajakumar (Secretary)  
Juliet Tizzard  
Chris O'Toole  
Paula Robinson  
Debra Bloor  
Anjeli Kara

### Observers

Lisa Jardine (HFEA Chair)  
Kim Hayes (Department of Health)

## 1. Apologies, welcome and declaration of interests

- 1.1. The Chair conveyed apologies received from Sue Price and Melanie Davies.
- 1.2. The Chair welcomed observer Kim Hayes (Department of Health), new member Sam Abdalla (Authority Member) and informed the Committee that Richard Gardner had stepped down as a Committee Member.
- 1.3. Interests were declared by Sam Abdalla, Daniel Brison, Joyce Harper, Alan Thornhill and Lorraine Young.

## 2. Matters arising and previous actions

- 2.1. The minutes from the Committee's meeting on 14 December 2011 were agreed remotely prior to the meeting and the matters arising from the previous minutes were noted and agreed.

### 2.2. Regulatory recommendations

Anna Rajakumar (AR) informed members that their recommendation to consider the regulation for the use of mitochondria replacement techniques was incorporated into a workshop discussion. The outcomes will be included in a final paper for Authority on 20 March 2013.

A member highlighted that there is a potential inconsistency with how mitochondrial diseases are authorised for preimplantation genetic diagnosis (PGD), whereby the technique can result in mutant mitochondria being present and causing clinical symptoms. The assessment of this is a difficult process and hard to estimate.

The point was made that PGD for mitochondrial disease is therefore defined as a process that reduces the risk of a child being born with mitochondrial disease, not complete avoidance of the disease itself, as may be the case for PNT or MST.

**2.3. Calcium Ionophore**

AR informed members that the use of calcium ionophore for egg activation has been added to licensed activities to be used only for selected patients, such as those with PLCz deficiency.

**2.4. Regulation of animals containing human material**

AR informed the Committee that members' recommendation to draft guidance on the regulation of animals containing human material is yet to be finalised and is in the process of being reviewed and amended.

**3. Chair's business**

**3.1.** Following the resignation of Richard Gardner, the Chair noted the background of any replacement member should be considered carefully to ensure that there is a useful range of specialities sitting on the Committee.

**4. Update on joint working with the MHRA and CE marking**

**4.1.** Members were informed that a guidance document for clinics is currently being developed, detailing the implications of not using CE-marked products and the basics surrounding the use of medical devices. It was highlighted that the next step for the HFEA is to raise these issues with clinics via Clinic Focus.

**4.2.** A member of the Committee also updated the group on the upcoming ACE workshop, on 22 May, addressing best practice when using culture medium in ART.

**4.3.** PB highlighted the potential implications, including patient consent, of conducting a clinical trial assessing the impact of different culture media. Members suggested that if this was run as a randomised patient trial, ethics approval would need to be sought. However, if there is an assumption that both culture media have the same efficacy, there is no requirement to inform the patients involved.

**4.4.** It was suggested that the HFEA should continue to work closely with other regulators with specialist knowledge of this area to demystify CE marking, understand what tests and/or processes are involved, and understand company obligations.

## 5. HFEA organisational update

- 5.1. Paula Robinson presented, for information and discussion, the proposed changes to the Authority membership, HFEA Committee structure and external advisor policy.
- 5.2. PR informed members that the Authority has decreased in size from 19 to 12 members this January as part of an overall organisational governance change. As a result of this organisational change, there is a need to look at committee architecture. This includes a new process for the approval of PGD conditions via a Statutory Approvals Committee, and the new Ethics and Standards Committee. A large part of the change involves the use of external advisors, and the need for consistency and clarity relating to the scope of their roles.
- 5.3. Professor Peter Braude formally announced that he would be resigning from SCAAC after a number of years and that this would be his last meeting.
- 5.4. Members were asked for recommendations on new members to replace Richard Gardner and Peter Braude. All future appointments will be ratified by the Chair.

## 6. Prioritisation of issues identified through the horizon scanning process [SCAAC (02/12)01]

- 6.1. AR introduced a paper on the prioritisation of issues identified through the horizon scanning process. Issues were mostly identified from journal articles, conference attendance and recommendations from experts.
- 6.2. A full list of identified issues (Annex A), which had been categorised as high, medium or low priority were presented. Members were asked to send on any further comments relating to Annex A following the meeting.
- 6.3. The Executive presented the Committee with a summary of the briefing notes on high priority issues (Annex B), which focused on Health outcomes of ART children and Ovarian Tissue Transplantation as highlighted for 2013/14.
  - **Ovarian Tissue Transplantation** - Members were asked whether more extensive research is needed surrounding ovarian tissue transplantation, and how this could affect the HFEA's patient information and current Code of Practice.
  - **Health outcomes of ART children** - Members were asked to consider whether a more detailed literature review of current research is required on ART children born with birth defects, and whether this should affect information that the HFEA gives to patients via its website.

### **Ovarian Tissue Transplantation**

- 6.4. Members discussed Ovarian Tissue Transplantation first. Debra Bloor highlighted some issues surrounding current and future regulation by the HFEA and HTA of ovarian tissue intended for transplantation.
- 6.5. It was suggested that the HFEA should provide more patient information on cryopreservation and egg freezing but that a more detailed consideration of the safety and efficacy of Ovarian Tissue Transplantation was not required by the Committee and not deemed high priority for the 2013/14 workplan.

### **Health outcomes of ART children**

- 6.6. Members discussed the use of ICSI and concerns were raised at the number of ICSI cycles used over IVF questioning the rationale behind conducting this procedure.
- 6.7. The Committee discussed the current statement on the HFEA website outlining the risks of birth defects in children born through assisted conception. Members agreed that the statement remains appropriate. The group felt there is still conflicting evidence surrounding birth defects in ART children and also highlighted that further long-term follow-up is crucial.
- 6.8. The effect of treatment on birth weight was also discussed and members discussed studies that appear to show that:
- Frozen and thawed cycles increase birth weight
  - Altered estradiol reduces birth weight (and has showed signs of an increased risk of pre-eclampsia)

### **Decision**

- 6.9. The Committee agreed the identified topic below should be a high priority for their 2013-14 work plan:
- Health outcomes of ART children
- 6.10. The Committee also agreed that the topics below should remain ongoing issues for 2013-2014:
- In vitro derived gamete research
  - Alternative methods for the creation of ES or ES-like cells
  - Embryo culture media
- 6.11. Members highlighted further key research articles that they felt should be high priority to be added to the horizon scanning spreadsheet. They also suggested a number of useful experts that may be used to consult on/present to the Committee.

## **7. Any other business**

- 7.1. The Committee raised no other business.

**8. Date of next meeting**

8.1. The next meeting will be on 12 June 2013 at 2pm.

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

Chair



Date

20th March 2013