

## Minutes of the Scientific and Clinical Advances

### Advisory Committee meeting

12 June 2013

held at Auditorium 1, 1st floor, Finsbury Tower, Bunhill Row

#### Members present:

Sue Price  
Andy Greenfield  
Alan Thornhill  
Debbie Barber  
Hossam Abdalla

#### External advisors present:

Joyce Harper  
Daniel Brison  
Melanie Davies

#### Apologies:

David Barlow  
Robin Lovell Badge  
Lorraine Young  
Kim Hayes

#### Staff in attendance

Anna Rajakumar (Secretary)  
Juliet Tizzard  
Nick Jones  
Suzanne Hodgson  
Anjeli Kara

#### Observers

Lisa Jardine (HFEA Chair)  
John Keen (Health Research Authority Ethics Committee)

### 1. Apologies, welcome and declaration of interests

1.1. The Chair conveyed apologies received from Lorraine Young, David Barlow, Robin Lovell Badge and Kim Hayes.

1.2. Interests were declared by Daniel Brison, Debbie Barber and Alan Thornhill.

### 2. Matters arising and previous actions

2.1. The minutes from the Committee's meeting on 27 February 2013 were agreed remotely prior to the meeting and the matters arising from the previous minutes were noted and agreed.

#### 2.2. CE marking guidance

Anna Rajakumar (AR) updated members on the progress of a CE marking guidance document, informing them that this had been finalised and circulated to the sector in May 2013.

### 3. Chair's business

3.1. The Chair raised for discussion the new contracts proposed for all external advisors. Members were asked to feed back any comments and consider the renewal of their terms of appointment as expert advisors. The new agreements will be in place by the October meeting.

- 3.2. The group was also asked to consider if there were any gaps in specialty expertise that may need to be addressed with new expert advisors.

#### 4. **Time-lapse imaging to assess outcomes of IVF**

- 4.1. Dr Simon Fishel (Managing Director of CARE Fertility) presented research recently published in Reproductive Biomedicine Online regarding time-lapse imaging to assess embryos in IVF. The Committee was asked to consider the progress of research and the potential for this technology to predict the most viable embryos. The group was also asked to consider the patient information implications and to consider the recommendations surrounding the use of this technique.

- 4.2. The Committee emphasised that the research presented was a small-scale study conducted retrospectively. They highlighted that while this was an interesting exploratory piece of research there remained the need for significant further work to show if there are any conclusive benefits to predicting the viability of an embryo. It was also noted that defined algorithms would need to be configured for each clinic. The group suggested that a prospective randomised control trial should be conducted in order to further research in this area.

- 4.3. The Committee also noted that time-lapse imaging remains a promising technology that could prove to provide useful research information for embryo development. Research and progress in this area should be monitored by the Executive.

#### 5. **Multiple births and blastocyst transfer outcome data**

- 5.1. Suzanne Hodgson (SH) presented an analysis of data regarding the outcomes of fresh blastocyst transfer versus cleavage stage transfer. She also reported on outcomes related to pregnancy and birth rates, twinning, gestation and birth weight, congenital abnormality and the sex ratio.

- 5.2. SH concluded that:

- The proportion of embryos transferred at blastocyst stage continues to increase, now approaching half.

- 5.3. The data now suggests that there is evidence that:

- success rates are higher for blastocyst transfers than cleavage transfers, though it was noted that women suitable to receive blastocyst transfer may have a better prognosis anyway.
- blastocysts may result in more monozygotic twins; double blastocyst transfer has a very high multiple birth rate
- the sex ratio of children born following blastocyst transfer (particularly elective single blastocyst transfer) no longer appears



to be skewed in favour of males now that more data has been collected.

SH concluded that there does **not** seem to be evidence that there is either:

- a difference in birthweight; or
- a difference in gestation period

in babies born following blastocyst transfer compared with those born following cleaving stage transfer.

The Committee advised that a paper had been published recently linking blastocyst transfer with low birthweight for gestational age. The Executive will look at this when a more detailed analysis is performed.

## **6. Update on alternative methods to derive ES and ES-like cells [SCAAC (06/13)01]**

- 6.1. Anna Rajakumar introduced a paper updating the Committee on alternative methods to derive embryonic stem (ES) cells and ES-like cells. This included potential new developments to iPS (induced pluripotent stem) cells and recent developments in somatic cell nuclear transfer (SCNT) ES cells.
- 6.2. The HFE Act requires embryo research to be "necessary or desirable" for defined purposes. If alternative methods of deriving ES or ES-like cells are developed, it may not be necessary for research groups to destroy viable embryos. It is, therefore, important for the Authority to keep up to date with developments regarding these alternative methods.
- 6.3. The Chair outlined comments from members who were not able to attend the meeting, stating that members felt good progress has been made into the methods for the derivation of ES cells via SCNT. The Committee discussed specific research by Tachibana et al (2013) which has shown for the first time that ES cells can be derived from embryos generated from adult cell nuclei reprogrammed via SCNT into oocytes. This provides the opportunity to compare iPS and ES cells from an individual. The group suggested that SCNT ES cells could potentially provide a more clinically relevant source of cells, however further work is required to assess both iPS and SCNT ES cell safety and therapeutic potential.
- 6.4. The group agreed that ES cells are still the "gold standard", and while iPS cells are extremely useful for studying diseases, their variability and genetic instability (increased chance of carrying mutations and uncertain epigenetic status) is higher due to the way they are derived. This may make them unsuitable for clinical use. Further research needs to be conducted exploring this instability and potential epigenetic effects.

- 6.5. Some Committee members also brought other key pieces of research to the attention of the Executive to be added to the annual review.

**Decision**

- 6.6. The Committee concluded that, despite promising developments in the iPS cell creation process there is still no viable equivalent to embryonic stem cells and therefore the creation of stem cells from embryos may still be considered "necessary or desirable" for defined purposes. The Committee noted that it has been shown that it may be possible to develop SCNT embryos for the derivation of patient-matched ES cells. The group agreed to continue to review research on an annual basis.

**7. Animals containing human material guidance**

- 7.1. AR updated the Committee on the progress of a draft guidance document produced by the Home Office. The Committee provided the Executive with minor suggestions for revision and also highlighted that the limitations of embryo research need to be highlighted (14 day limit on research conducted using human embryos).

**8. AOB**

- 8.1. AR informed the Committee that, as per the workplan, SCAAC will consider papers on health outcomes for ART children and developments in culture media at its next meeting.

**9. Date of next meeting**

- 9.1. The next meeting will be on 30 October 2013 at 2pm.

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

**Chair**

Susan A. Brown

**Date**

27/6/13