

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

MINUTES OF THE SCIENTIFIC AND CLINICAL ADVANCES ADVISORY COMMITTEE MEETING

held at Etc Venues, Bonhill House, 1-3 Bonhill Street, London EC2A4BX $4^{\rm th}$ June 2014

COMMITTEE	MEMBERS	PRESENT:
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Sue Price (Chair) Andy Greenfield Alan Thornhill Joyce Harper (external advisor) Daniel Brison (external advisor) Robin Lovell-Badge (external advisor) Lorraine Young (external advisor)

COMMITTEE	MEMBERS APOLO	 Melanie Davies Debbie Barber Sam Abdulla
		Sam Abuulla

MEMBERS OF THE EXECUTIVE:

Anna Rajakumar (Secretary) Hannah Verdin Danielle Vincent Kemi George Anjeli Kara

OBSERVERS:

Glyn Stacey (UK Stem Cell Bank)

1. Apologies, welcome and declaration of interests

- **1.1.** The Chair conveyed apologies received from Debbie Barber, Melanie Davies and Sam Abdulla.
- **1.2.** The Chair welcomed observer, Glyn Stacey from the UK Stem Cell Bank as an observer to the meeting.
- **1.3.** Interests were declared by Daniel Brison, Alan Thornhill, Joyce Harper, Lorraine Young and Robin Lovell-Badge.

2. Matters arising and previous actions

2.1. The minutes from the Committee's meeting on 5th February 2014 were agreed remotely prior to the meeting and the matters arising from the previous minutes were noted and agreed.

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- **2.2.** The Committee discussed its forward workplan in order to identify future priorities. The following topics were identified as a priority for upcoming meetings and invited speakers.
 - Next Generation Sequencing
 - Fertility preservation and IVM procedures
 - Time-lapse imaging
 - Freeze-all cycles and simplified IVF systems
- **2.3.** Glyn Stacey informed members that a SABTO report will be released shortly, detailing some guidance on next generation sequencing, which that may be of interest to the Committee.
- **2.4.** The Committee discussed the speakers required for these items and members agreed they are happy to have longer meetings if it means covering more topics per meeting.

3. Overview of Information for Quality – update

- **3.1.** Kemi George (Stakeholder Engagement Officer) presented an overview of the Information for Quality (IfQ) Programme, which is a current HFEA programme of work. The work is considering the way information is collected, presented and published through the website, Choose a Fertility Clinic, EDI and Clinic Portal. The IfQ Advisory Group and four Expert Groups are currently working on proposals to develop this work and considering approaches for consultation with the sector.
- **3.2.** The Committee discussed the usefulness of this work and highlighted the importance of having expert groups with a diverse representation of clinic staff.

4. Getting started guide – information update

- **4.1.** Danielle Vincent (Communications Manager) introduced this item. The Committee was provided with draft wording which is to be subsumed within an HFEA publication called "getting started", that is currently being updated. The aim of publication is to provide a useful starting point to those seeking treatment. There are some areas that the Executive identified for review by SCAAC and these sections were considered enclosed with some amendments/additions highlighted in red for your review. The Committee discussed the areas identified by the Executive and noted the following general points:
 - The guide should have a section that discusses additional services that patients may be offered by clinics and guidance on the types of questions patients should be asking their clinicians. This section may include detail of new technologies, in relation to PGD and PGS.

- The option of consenting to donating to research should be included within the guide.
- **4.2.** Further detailed comments on wording and placement of advice were also fed back to the Executive.

Decision

4.3. The Executive explained the review process (consulting with BFS and AFPO) and members were asked to feedback any further comments by email in the coming weeks.

5. Update on alternative methods to derive ES and ES-like cells [SCAAC (06/14)01]

- **5.1.** 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 regarding iPS (induced pluripotent stem) cells, highlighted articles on developments regarding cells derived from amniotic sources and recent developments in somatic cell nuclear transfer (SCNT) ES cells.
- **5.2.** 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.
- **5.3.** Members were asked to:
 - consider the progress of research since June 2013, into alternative methods to derive embryonic or embryonic-like stem cells;
 - advise the Executive if they are aware of any other recent developments; and reflect on whether their views have changed in the light of recent research.
- **5.4.** The Committee discussed the studies identified through horizon scanning and concluded that studies show the technical ability to carry out procedures, rather than successful findings. The Committee noted that the quality of stem cell lines derived from IPS cells are improving but further experiments are required to fully characterise these. A member also noted that the Rodin et al., study identified in the update, should be recategorised under another heading (making clinical grade stem cell lines without destroying an embryo), rather than SCNT.
- **5.5.** The Committee further noted a number of key papers to be added to the paper, the Executive will update these papers into the final version of the update.

Decision

5.6. 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 Committee agreed to continue to review research on an annual basis.

6. Reproductive Immunology update [SCAAC (06/14)02]

- **6.1.** Anna Rajakumar introduced a paper updating the Committee on developments regarding reproductive immunology identified through the prioritisation of issues conducted in February 2014. The Committee considered the area of reproductive immunology in the context of patient information, in 2010. This is also a topic that SCAAC revisits annually as part of their horizon scanning function.
- **6.2.** Members were asked to:
 - Review the recent literature in this area and consider the safety and efficacy issues that may arise from such techniques.
 - Review the HFEA website text (provided at Annex A to the paper) and provide comments to the Executive, relating to possible updates and changes including any studies they feel should be added to the website text as highlighted articles.
- **6.3.** The Executive drew the Committee's attention to a recent study conducted in the UK, (Tang et al, 2013) which explored the feasibility of screening women with idiopathic recurrent miscarriage for high uterine natural killer cell density and randomising to prednisolone or placebo when pregnant. The paper demonstrated that it was feasible to recruit women with idiopathic recurrent miscarriage into a 'screen and treat' trial despite their desire for active medication.
- **6.4.** The Committee noted two key points in their discussion:
 - Whether patients should be given steroids in the first trimester, as a safety concern.
 - Whether blood tests predict miscarriage or the population of uterine natural killer cells (Katano et al., - who started the field – have carried out a large cohort study and decided blood tests may no longer be effective)

Decision

6.5. The Committee agreed that a further discussion on reproductive immunology with attendance of identified speaker should be conducted by the group and consultation with the British Fertility Society's Policy and Practice Forum should be carried out. Based on this further update the Committee can evaluate the patient advice that should be disseminated.

7. Any other business

7.1. The Chair introduced a number of AOB items including:

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• The Chair updated the Committee on the recent publication of the Mitochondria replacement scientific review and informed the Committee that the recommendations for critical and desirable research outlined in 2013 remain, however the Committee noted good progress had been made in this area.

Date of next meeting: 22 October 2014 at 2pm.

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

Committee Chair Name: Dr Susan Price

Committee Chair Signature: Sum 1 thice

Date: 18/06/14