

## Human Fertilisation and Embryology Authority Scientific and Clinical Advances Group

<b>Committee:</b>	Scientific and Clinical Advances Group
<b>Meeting Date:</b>	24 <sup>th</sup> November 2005
<b>Agenda Item:</b>	5
<b>Paper Number:</b>	SCAG (11/05)01
<b>Paper Title:</b>	<b>Horizon scanning work plan for SCAG</b>
<b>Author:</b>	Katy Berry
<b>For Information or Decision?</b>	Information and decision
<b>Resource Implications:</b>	Taken into account in the business planning
<b>Recommendation to the Committee:</b>	<ul style="list-style-type: none"> <li>• Note the recommendations made and approve the proposed work plan.</li> </ul>

### 1. Background

1.1 Issues identified by the horizon scanning process were discussed at the last SCAG meeting in September. Members of the committee made comments about how these issues could be taken forward and with what priority. Bearing in mind the comments made at the previous meeting, the Executive have produced a proposal on how to take the issues forward in the SCAG plan and the business plan for 2006-2007.

1.2 As suggested at the last meeting, many of the issues can be dealt with before the next business year. The issues that can be dealt with more immediately are those that do not require many resources. If any of the issues require more work it will be necessary to take this into account in the business planning for 2006/2007.

### 2. Topics that require further work

2.1 From the horizon scanning process and subsequent discussions at SCAG meetings the following topics were identified as requiring further consideration by SCAG:

- *In vitro* derived gametes
- Germinal vesicle transfer

- Deriving stem cell lines from individual blastomeres
- *In vitro* maturation
- Vitrification
- PGD and microarrays
- Sex selection using sperm sorting
- 'Stembrids'

2.2 The amount of work that would be required to further consider each of the issues will affect when the issues will be looked at. Those that require significant work will have to be taken into account for the next business year (2006/2007). We recommend that *in vitro* derived gametes are considered in more detail in the next business year along with some of the less urgent issues (PGD and microarrays, stem cell lines from individual blastomeres and sperm sorting for sex selection). Some issues that are more urgent and require less work will be considered sooner (stembrids, *in vitro* maturation, germinal vesicle transfer and vitrification).

## **Issues for consideration in 2006/7**

### **3. *In vitro* derived gametes**

3.1 At the last meeting it was decided that SCAG will have to look at which techniques will be most important commercially and which are most likely to have an impact in the press.

3.2 In the Department of Health consultation on the Review of the Act the government proposes that the use of artificial gametes in assisted reproduction should not be permitted but that the Act should contain regulation-making power giving flexibility to parliament to introduce it in the future. The earliest that a new Act could be introduced is late 2007. This means that if an application is received before the introduction of any new legislation, it would fall to the Authority to consider it.

3.3 Any work undertaken on this issue would have to be sensitive to the views of the Government whilst at the same time considering the safety and the potential use of *in vitro* derived gametes. Before any decisions about the safety of this technique were taken there would have to be extensive review of the safety, efficacy and ethical issues around the use of gametes derived artificially.

3.4 Prior to any application for clinical use of *in vitro* derived gametes it is likely that an application would be received for a research licence to create an embryo using *in vitro* derived gametes. This would be required to verify that the *in vitro* derived gametes were actually able to produce an embryo.

### 3.5 Recommendations for artificial gametes:

- This work will be carried out in the next business year (2006/2007). Provisionally the first paper will go to SCAG and ELC in June and again in September. It is unlikely that this will need to be considered prior to that because it is unlikely that we would receive any application for use of *in vitro* derived gametes either in research or treatment before that date.
- A literature review will be undertaken and research into the development of techniques to derive them will be undertaken in 2006
- There will be consideration of the ethical issues surrounding various uses of *in vitro* derived gametes in research and treatment by the Ethics and Law committee in June 2006
- If development of the technique is rapid and it seems likely that the HFEA will receive an application for treatment prior to any new legislation being announced, some form of public consultation would be required.

## 4. PGD and microarrays

4.1 At the last meeting some members thought that the technology was not likely to be useful to detect mutations i.e. single gene disorders. However it is more likely that it could be used to detect viability of embryos. There was some data on this presented at the ASRM meeting. One group has shown that they are able to detect viability genes (specific genes that are more likely to lead to the embryo implanting) on a microchip from both the secreted transcriptome and from a number of trophoblast cells (ref).

4.2 If this technique were to be introduced it could improve embryo selection and therefore success rates with minimal disruption to the embryo (especially if it were possible to obtain the information from the secreted transcriptome).

### 4.3 Recommendations for PGD and microarrays:

- This issue is still in early stages of research and therefore should be considered in the next business year (2006/7)
- The literature will be monitored for all uses of microarrays and PGD and the issue will be reconsidered at the June SCAG meeting.

## 5. Stem cell lines from individual blastomeres

5.1 A recent publication demonstrated that in mouse it is possible to derive a embryonic stem cell line from an individual blastomere (this required the presence of other embryonic stem cells though). If this technology was

developed for human embryos it would be possible for each individual to have a stem cell line derived and banked from the embryo for potential future therapeutic use. At the previous meeting it was noted that this should be considered to be a priority issue and the HFEA should come to a view on this technique.

5.2 This research to date has only been carried out in mouse and is therefore not a high priority issue. However, it is possible that this could be achieved relatively soon in humans so we should be aware of this issue.

5.3 Recommendations for stem cells from individual blastomeres:

- As this issue is not immediate this will be considered in the next business year (2006/7) provisionally at the April meeting
- Literature will be reviewed and a paper will be produced discussing deriving individual stem cell lines from a biopsied blastomere
- In discussion with the Ethics and Law committee members will come to a view on the use of this technology.

## **6. Sperm sorting for sex selection**

6.1 This issue was raised at the last meeting. There will be some new data on the effectiveness of sperm sorting that will require consideration by SCAG. At the last meeting it was suggested that the HFEA should be prepared for this new data. When this data becomes available this issue will be considered. Unless this data becomes available by the next meeting, it is likely that this issue will not be considered until 2006/7.

6.2 Sex selection is permitted for medical purposes. Previously the HFEA has not considered sperm sorting effective enough for sex selection. If the new data demonstrates that sperm sorting is effective and reliable, the HFEA may have to reconsider its use. The use of sperm sorting would remove the need for embryo biopsy which is currently used to determine the sex of embryos.

6.3 Recommendations for sperm sorting:

- Consideration of this issue as soon as the data is available (not likely to be until 2006/7) this has been provisionally been put on the agenda for the September meeting but could be considered sooner if data becomes available
- If the data demonstrates that the technique is safe and effective, the HFEA may wish to make a statement on the use of sperm sorting for sex selection.

## **Issues for earlier consideration**

### **7. *In vitro* maturation**

7.1 This was considered to be a high priority issue and a decision should be made about this at the November meeting. There is a paper included in this set of papers on this issue.

### **8. Germinal vesicle transfer**

8.1 This issue was discussed at the last meeting and Justin St John kindly agreed to write a paper on this issue for further consideration. This paper is included in this set of papers.

### **9. Vitrification**

9.1 At the last meeting Maureen Wood gave a presentation on this issue. It was suggested that following further consideration, SCAG should decide whether they feel a statement should be produced on this issue. There is a paper on vitrification in this set of papers.

### **10. 'Stembrids'**

10.1 Stembrids are a way of producing embryonic stem cell lines without the use of embryos. In this technique somatic cells with the required genetic make up for the stem cell line are fused to other embryonic stem cells. The presence of components in the embryonic stem cell line is sufficient to cause the somatic cell to dedifferentiate.

10.2 Although this technique does not involve the use of embryos and therefore does not fall under the remit of the HFEA, it would be useful for members of SCAG to consider the issue and form a view on the technique. A paper on stembrids will be presented at the February meeting of SCAG.

## **11. Conclusions**

11.1 Members are asked to:

- Note the recommendations for all of the issues
- Approve the future work plan for SCAG