

**MINUTES OF THE THIRD MEETING OF THE SCIENTIFIC AND  
CLINICAL ADVANCES GROUP HELD ON WEDNESDAY 23<sup>RD</sup> JULY  
2003 AT PAXTON HOUSE**

**PRESENT:**

**Members**

Chris Barratt – Chair  
Tom Baldwin  
David Barlow  
Peter Braude  
Iain Cameron  
Jane Denton  
Maybeth Jamieson  
Suzi Leather  
Sara Nathan

**Executive**

Chris O’Toole – Secretary  
Alison Cook  
Ian Hammond  
Peter Mills  
Jo Rippington  
Kerri Treston  
Tim Whitaker

**Observers**

Kim Hayes – DH

**1. APOLOGIES**

- 1.1 Apologies were received from Clare Brown and Neva Haites.
- 1.2 The Chairman welcomed Roger Pederson, co-opted Member, to the Scientific and Clinical Advances Group.
- 1.3 The Chairman invited Members to declare any conflict of interest they had with any of the papers for discussion.
- 1.4 A number of Members and an individual from the Executive who had acted in an advisory capacity, declared that they had a conflict of interest in relation to the Matters Arising item on MRC/HFEA follow-up in children at paragraph 3.19. It was noted that as the Member of the Executive had acted in an advisory capacity on behalf of the HFEA that this did not constitute a conflict of interest.

**2. MINUTES OF THE PREVIOUS MEETING OF JUNE 2003**

- 2.1 The Members approved the minutes of 2<sup>nd</sup> June 2003 subject to the following changes:
  - that paragraph 2.12 be removed as it was a duplication of paragraph 2.11.
  - that ‘Berterelli’ is replaced with the correct spelling ‘Bertarelli’ throughout the minutes.
  - that ‘obsession’ in paragraph 8.6 is replaced with ‘possession’.

**3. MATTERS ARISING**

**Imprinting [SCAG (04/03)05]**

- 3.1 At its meeting on 10<sup>th</sup> April 2003 SCAG considered information that had been sent to centres on the risks of imprinting disorders associated with assisted conception technologies. Literature on imprinting had been reviewed and the information for centres revised for distribution.

- 3.2 Members were asked to review the draft letter attached at Annex 1 in order to advise the Authority that the revised information should be sent to all centres.
- 3.3 The Chair of SCAG noted that he would provide the executive with further information from a French Publication that may be used as a reference in the letter.
- Action:** Chris Barratt
- 3.4 The Members made a number of suggested amendments to both the text and font, specifically:
- that the abbreviation 'GP' in the first paragraph should be expanded to 'General Population'
  - that the fourth paragraph should be reworded to state ' ...there remains a far greater risk to the offspring from multiple pregnancies associated with ART'.
  - that the title for the paper listed in the reference section be included for Kurinczuk JJ (2003).
- 3.5 The Members queried whether risks associated with ICSI treatment should be included, however, it was agreed that it would be more appropriate to make reference to the ICSI leaflet in the letter, to remind centres that the ICSI information had also been updated.
- 3.6 The executive informed the Members that amendments would be made to the letter and that SCAG would be informed of any developments at the next meeting.
- Action:** Chris O'Toole

**Access to Irreversibly Anonymised Data for Research [SCAG (06/03) 01]**

- 3.7 At its meeting on 2<sup>nd</sup> June 2003 SCAG considered the release of anonymised data from the HFEA Register for research. SCAG proposed a process for managing research requests. It was noted that a moratorium had been called for on all requests for the next 3-4 months to allow for the development of the Register and to agree and pilot the proposed process.
- 3.8 The Members were reminded that the Authority had agreed that proposed work must be an area of priority for the HFEA and Members were asked to consider whether they wished to propose criteria that research requests would be judged against.
- 3.9 The Members noted that the data fields that would be released from the Register to researchers should be fully explained to reduce ambiguity and misinterpretation of the data.
- 3.10 Some Members raised concerns about the necessity for the Authority to restrict the provision of data for research to HFEA priorities, as the Authority may be construed as being bias or preventing valuable

research being carried out. However, it was agreed that whilst the system is established data sets should be provided only to researchers who fulfil the criteria.

- 3.11 It was suggested that once the Register had been developed and the Authority was confident with the data, the criteria could be reviewed.
- 3.12 The Members discussed the meeting of the first pilot Writing Group and how practical the process was. The Members noted that there were a number of issues that needed to be developed to encourage the good work that could result and to enhance the Authority's reputation in providing a fair and level playing ground for all applicants. David Barlow agreed to lead on the development of the Writing Group.  
**Action:** David Barlow

**Journals – [Chairman's Business from SCAG 2<sup>nd</sup> June 2003]**

- 3.13 The Members asked if the Department of Health had determined if the Authority could share access to the journals that the Department of Health subscribes to. It was noted that there had not been any definitive view from the Department of Health. It was agreed that the Observer from the Department of Health would ascertain if the Authority could have access to the journals through the Department of Health.  
**Action:** Kim Hayes
- 3.14 The Members were informed that the Policy Department was in the process of creating a catalogue of resources currently used by the Authority, such as journals. It was noted that this issue inter-linked with SCAG's concerns for the need for the Policy Department to have additional resources in order to support SCAG appropriately. The Members were informed that the Policy Department had arranged an 'away day' specifically to identify the Department's priorities and the requirement for further support or resources. The Members of SCAG welcomed the initiative.

**Research Strategy Group**

- 3.15 An update was given on the progress of the Research Strategy Group (RSG). Members were informed that the RSG was primarily formed to support SCAG and report issues raised through this group would be fed back to SCAG for consideration.
- 3.16 The executive informed the Members that the RSG met on a monthly basis but it was thought that in future these meetings would be held every two months.
- 3.17 It was suggested that the RSG should collate and validate information and data that is held by the Authority on particular techniques, for example, Laser Assisted Hatching, for SCAG to consider and recommend whether HFEA policies, in relation to techniques used in ART, are reviewed.

- 3.18 It was agreed that any considerations or recommendations by SCAG are fed back to the Regulation Department to ensure policies are current. It was also agreed that the Secretary of SCAG and the Chair of the RSG should work together to summarise data for SCAG.

**Action:** Ian Hammond/Chris O'Toole

**MRC/HFEA Working Group – Follow-up of Children born through ART**

- 3.19 A number of Members had noted that they had been approached by a prospective applicant wishing to carry out research in this area who was extremely frustrated with the process in which the application had been through.
- 3.20 The executive noted that a format for agreeing research proposals had been introduced.
- 3.21 The Members questioned if the application had been handled appropriately. The executive noted that all appropriate steps had been taken by the HFEA, however, the pace by which the application was handled was largely dependent on issues being resolved by the MRC, particularly, the MRC agreeing the funding of the research project. The Members raised concerns that the Authority's reputation could be tarnished if it was not seen to be communicating effectively.
- 3.22 It was suggested that in order to rectify this situation and to avoid similar situations arising in the future a member of the executive should be identified as a first point of contact. It was further suggested that this person should be able to report to the CEO and possess the ability to impart information with confidence.
- 3.23 Furthermore, to ensure that the format for research proposals is appropriately communicated to all relevant people, it was agreed that all Members should be made aware of the process in place for requests for data from the Register. It was agreed that the executive should produce a draft of the process for research proposals and that Members of SCAG should view the document for information purposes.

**Action:** Chris O'Toole

- 3.24 The executive informed the Members that the MRC/HFEA Working Group had established two sub-committees to meet in September 2003. The first to look at access to databases and the second to consider practice for clinical research. The Members were informed of the membership of the sub-committees and the observers expected to attend from the HFEA executive.

- 3.25 It was noted that the Chief Medical Officer is keen for the work on follow-up studies to commence. The Members were informed that a brief was scheduled to be given to the Chief Medical Officer providing an update of the progress made so far. It was noted that the brief

would be copied to the Department of Trade and Industry for its information. It was agreed that a formal letter should be sent to the Chief Medical Officer from the Chief Executive to provide information on the progress made by the HFEA.

**Action:** Chris O'Toole

#### **4. CHAIRMAN'S BUSINESS**

4.2 The Chairman had no additional business for SCAG.

#### **5. SECRETARY'S BUSINESS**

5.1 The Secretary reported orally on the forthcoming Patients' Guide and Equipment Failure at licensed clinics.

##### **Patients' Guide [SCAG (07/03) Tabled Paper 01]**

5.2 The Secretary informed SCAG that the Chair of the Authority had asked that SCAG discuss the applicability of four methods proposed by the Clinic Information Working Group to ensure that information provided would be statistically significant, biologically relevant easy to access and in a format that would be understood by patients.

5.3 The Members discussed the four proposed methods and agreed that the chosen method would need to ensure that meaningful results were published and that centres would be unable to distort their figures. The Members were confident that any centre wishing to distort their figures would be identified at HFEA inspection and audit visits.

5.4 The Members considered that the forthcoming Patients' Guide would be a comparative document for patients and it should reflect clinical practice in the data.

5.5 In discussing the four proposals the Members agreed that the following method would be the most biologically/clinically relevant:

- Live birth event per cycle registered for the first three cycles, over a 3 year period in 5 year age bands.

5.6 In addition, it was suggested that it would be informative to separately list statistics on treatments involving donated eggs. It was also suggested that information relating to one, two and three embryo transfers to encompass the effects of the embryo transfer policy would be informative for patients, especially to highlight the number of babies lost through multiple pregnancies, when transferring two or three embryos.

5.7 The Members were asked to submit any further comments in relation to the biological/clinical relevance of methods.

**Safety of Equipment used in ART Laboratories [SCAG (07/03)  
Tabled Paper 02]**

- 5.8 The Secretary informed SCAG that a centre had reported an incident whereby sperm samples stored for patients perished as the dewar storing the samples failed to fill with liquid nitrogen. The Members were also informed that there had been at least two previous incidents of this nature where sperm samples had perished due to failures in the storage dewars.
- 5.9 The Secretary asked SCAG to discuss whether the HFEA should include advice on safety of equipment used in ART laboratories as part of its Code of Practice and to agree the Secretary's suggested action for the HFEA in order to ensure incidents such as that detailed above did not reoccur.
- 5.10 The Members discussed the importance of introducing systems within the laboratories, particularly on health and safety grounds to avoid critical incidents occurring in the future. The Committee further discussed what initiatives and procedures centres would need to introduce in order to ensure the safety of equipment in their laboratories.
- 5.11 The Members suggested that the professional organisations should be contacted for their opinions and recommendations on procedures that should be in place as suitable practice and to comment on the sixth edition of the Code of Practice to ensure that it provides suitable information and guidance.
- 5.12 It was agreed that until a Laboratory Accreditation agency had been established the incident should be recorded on the alert system. The alert would be able to advise centres what a centre should consider under these circumstances, for example to provide patients with immediate advice and counselling, and what systems should be in place as a preventative measure. Specifically, Members agreed that centre staff should visually confirm liquid nitrogen levels rather than rely on automatic external readings; centres should be working towards 24-hour technical cover with low level alarms fitted to all dewars and suggested that best practice would be to split samples between dewars particularly where further samples could not be produced .
- 5.13 The Members suggested that the Authority's Legal Advisor should be approached to ascertain what a centre would be liable for if it did not take on board guidance provided by the Authority.
- Action:** Chris O'Toole
- 5.14 The Members agreed that, once comments have been received from the professional bodies and the Regulation department have been contacted to establish what current guidance is given out to centres at inspections, a Chair's letter should be drafted for the September Authority meeting, outlining recommendations for all centres.

**Action:** Chris O'Toole

**6. PAPER ON EGG GIVING – SCAG(07/03)01**

- 6.1 The Secretary introduced this paper. She informed SCAG that a number of enquiries and expressions of concern from patients and licensed centres in relation to an arrangement known as egg giving had been received.
- 6.2 Members were asked to decide whether egg giving could in any circumstances be regarded as a safe and suitable practice. If so, Members were asked to:
- decide whether egg giving should only be carried out under strict guidelines;
  - propose guidelines under which egg giving could be carried out at licensed centres; and
  - agree for the executive to seek the opinion of the RCOG, RCNFG, BICA and BFS.
- 6.3 The Members noted that a Chair's letter had been sent to all clinics informing them that the HFEA was currently reviewing gamete donation and that guidance to clinics on egg giving, produced as a consequence, would be completed and made available by the end of 2003. The wider review of gamete donation would continue into 2004.
- 6.4 The Members decided for clarification to classify egg giving into two sub groups:
- Primary egg giving – an arrangement whereby a woman seeking IVF treatment goes through one cycle in which all the eggs recovered are donated to a second woman followed by a further cycle of IVF for her own treatment at reduced cost.
  - Secondary egg giving – an arrangement whereby a woman consents to enter an egg sharing arrangement but because fewer eggs are collected than the number required to share, the egg provider decides to donate all the eggs to the recipient and return for a second cycle in which she would keep all the eggs for her own use.
- 6.5 The Members discussed both the safety and suitability of egg giving. Although Members conceded that as egg donation as a whole is considered safe, as is egg sharing, then egg giving could also be considered safe. However, it was noted that the risk of patients suffering OHSS is estimated at 1%, although considered low risk, patients participating in egg giving programmes would be twice at risk given that these patients would undergo two stimulatory cycles. It was also suggested that it was not a choice driven procedure unlike egg sharing and 'secondary' egg giving.

- 6.6 In conclusion the view of SCAG was that primary egg giving is not a safe and suitable practice mainly due to the fact that a woman would have to undergo an unnecessary procedure that has potential health risks. It was the opinion of SCAG that secondary egg giving could be permitted but that the guidelines on egg sharing would need to be amended.
- 6.6 The Members asked that the executive should seek the views of the professional bodies and patient groups before the Authority would issue any advice to centres or attempted to revise guidelines relating to egg giving.
- 6.7 It was agreed that the executive should draft a letter to be sent to the RCOG (President and the Chair of the Scientific Advisory Group), BFS, Royal College of Nursing Fertility Nurses Group, BICA, CHILD and ISSUE for their opinion on egg giving.

**Action:** Chris O'Toole

- 6.8 The Secretary suggested the following approximate timetable for issuing guidance to licensed centres, should it be considered necessary:
- That received responses should be collated and viewed by a Members Sub-Working Group in mid August.
  - A policy paper should be drafted and presented to the Senior Management Team at the end of August.
  - An update of developments should be presented to the Authority in September.
  - Recommended policy on egg giving should be considered by SCAG, the Ethics & Law Committee and the Licensing and Regulation Committee in October.
  - A final decision by the Authority should be made in November.
  - Agreed advice and guidelines should be sent to centres by the end of 2003.

## **7. PAPER ON MONITORING TWO AND THREE EMBRYO TRANSFER POLICY – SCAG (07/03)02**

- 7.1 This paper was introduced by Jo Rippington. The paper asked Members to consider the information required to monitor the implementation by clinics of the two embryo transfer policy, the 'exceptional circumstances' in which three embryo transfer would be carried out and the impact of the two embryo policy on outcomes.
- 7.2 The Members were verbally provided with the history of the introduction of the two embryo transfer policy for continuity purposes. The Members noted that to incorporate the policy within the Code of Practice would cause implications with enforcing the policy and monitoring its effectiveness, as there is currently no sanction against non-implementation. Additionally, Members noted that it had been suggested in the past that Directions could be issued requiring centres to record information.

7.3 The Members were informed that through the Authority's audit process information had been collated in connection with the monitoring of the embryo transfer policy, however, this information had yet to be put into context. Members requested to be informed of what information had been collected and what that data indicates.

7.4 It was noted by a Member that the data within the Patients' Guide provides an insight to the number of multiple births, particularly the triplet birth rate, in relation to two and three embryo transfers. A Member agreed to provide the executive with a summary analysis of this data.

**Action:** Peter Braude

7.5 Individual Members of SCAG were identified to provide advice on specific questions that the HFEA data set could answer, if interrogated by a statistician or epidemiologist.

**Action:** Jane Denton/Iain Cameron

7.6 The Members discussed the need for comparative data in order to identify evidence of effects of moving from three to two embryo transfers. It was agreed that in order to compare cycles in which two embryos were transferred with cycles in which three cycles were transferred the following information should be collected:

- the number of sacs;
- the outcome, including:
  - o live births
  - o number of babies born
  - o neonatal deaths
  - o gestational term

7.7 The Members suggested that the data may be most informative and manageable if broken down into 5 year age bands of:

- Below 30
- 30-34
- 35-38
- 39-40
- Above 40

7.8 The Members also suggested that the above data could be broken down further to take into account the cycle number and, although not a priority, it would be useful to note the number of embryos collected.

7.9 The Members agreed that other issues related to this item would be considered at a later date once the above data had been collected and analysed.

## **8. REPORT FROM ESHRE CONFERENCE 2003 – SCAG (07/03)03**

8.1 The Secretary introduced the reports by executive who attended sessions at the ESHRE conference. The Secretary asked Members to note that the summary of reports was not complete.

8.2 Due to time constraints the Chairman asked Members to provide reports on key points that were raised at ESHRE to be discussed at the next meeting.

## **9. PAPER ON FUTURE WORK – SCAG (07/03)04**

9.1 The Chair of SCAG informed Members that the Authority would probably be receiving an application to carry out Cell Nuclear Transfer (CNR) research in the near future. Following a presentation given by Professor Campbell, the Chair suggested that SCAG should consider, as a priority, the conditions that would apply to such a research licence.

9.2 Some Members commented that it would be prudent for the Authority to expect an applicant to have an appropriate amount of experience using animal cells with this technique before applying research to human cells.

9.3 The Members agreed that it would be important to have a process in place before an application was received and that this should be included in the issues that should be considered at a future meeting.

**Action:** Chris O'Toole

9.4 The Members noted issue one, which invites SCAG to recommend whether the Authority should review current policy following a request from a licensed centre asking for a view on whether it would be acceptable to use sperm from donors who are serologically positive for CMV in the treatment of women who are serologically negative for CMV if semen samples were tested and found to be negative.

9.5 The Members agreed that it would be more appropriate for the British Andrology Society to consider whether its current guidance should be reviewed in light of the enquiry, to overcome considerable pressure on supplies of semen from which to select suitable donors for couples.

**Action:** Chris O'Toole

9.6 The Members noted issue two and the suggestion that a paper be considered to discuss embryo biopsy procedures and associated risks.

9.7 The Members agreed that it would be particularly useful to consider information on the associated risks with embryo biopsy in order to discover if the removal of cells during PGD or PGS affects the development of the embryo and if the technique increases the risk of twinning.

9.8 The Members agreed that issue three – Artificial creation of Gametes was no longer a high priority. The Members were informed that

currently there had not been any oocytes derived from mouse embryonic stem cells. It was agreed that it would be more appropriate for SCAG to consider the issues along with legal advice once oocytes had been derived. It was agreed that the concept of licensing and developing a policy for the use of artificial gametes in treatment services should be referred to the Ethics and Law Committee for consideration.

**Action:** ELC

- 9.9 Under issue 4 – Introduction of new technologies into clinical practice, Members felt that SCAG should consider the licensing of IVF culture media. Concerns were raised that currently there is not an organisation in the UK that has the responsibility to regulate the production and use of media. It was agreed that this issue should be brought to the attention of the Department of Health for consideration.

**Action:** Chris O'Toole

**10. Any Other Business**

- 10.1 No other business was raised at this meeting.

**11. Date of Next Meeting**

- 11.1 The date of the next meeting is to be held on 12<sup>th</sup> November 2003 at 11am.