

**MINUTES OF THE FIRST MEETING OF THE SCIENTIFIC AND CLINICAL  
ADVANCES GROUP HELD AT PAXTON HOUSE ON THURSDAY 10  
APRIL 2003 AT 2.30PM**

**Present:**

**Members**

Chris Barratt (Chair)  
Tom Baldwin  
Peter Braude  
Clare Brown  
Jane Denton  
Neva Haites  
May-Beth Jamieson

**Co-opt Members**

Ted Webb (DoH)

**Executive**

Christina Panton  
Chris O'Toole  
Kerri Treston

**1 Apologies for absence**

- 1.1 Apologies were received from David Barlow, Iain Cameron and Sara Nathan.

**2 Minutes of the meeting of 5<sup>th</sup> February 2003**

- 2.1 Members noted that paragraphs 6.3 and 7.1 should be re-worded.
- 2.2 The Members approved the minutes subject to the amendments being made in 2.1.

**3 Matters arising from the last minutes**

- 3.1 It was noted that paragraph 7.3 had not yet been actioned. The Group agreed that a letter should be sent from Suzi Leather to the Department of Health highlighting concerns about unknown risks with culture media used in ART and the need to fund risk assessment as a matter of urgency.

**Action: Executive**

- 3.2 At paragraph 7.4 it was noted that the responsibility of ownership for regulating IVF media still remains unclear.
- 3.3 It was noted that at paragraph 8.5 the Working Group agreed that it would be appropriate to review all research projects before renewal for general information and purposes of horizon scanning. It was brought to the Chair's attention that this would be impractical for regulation purposes as the Group would not meet regularly enough to review applications in a timely manner. It was therefore suggested by Ian Hammond that the Group considers receiving research applications by email for review. It was agreed that it would not be appropriate for SCAG to provide information for

Licence Committee discussions, unless a Licence Committee specifically asked for the Group's advice.

- 3.4 It was noted that an appropriate process should be put into place promptly for considering research applications. Members agreed that the Group's boundaries should be made absolutely clear, as it is not the purpose of SCAG to peer review applications. It was also noted that a peer review system is in operation and is working satisfactorily. It was suggested that the peer review forms should be reviewed by SCAG to ensure that peer reviewers are seeking the correct information on behalf of the Authority.
- 3.5 The Members were informed that Ian Hammond had agreed to provide the Group with a list of all currently licensed research projects and their individual progress to date, for their information.

**Action: Ian Hammond**

- 3.6 The Members were informed that a fax had been received from Professor Ian Wilmut to Suzi Leather on 2 April 2003. The fax asked whether the authority would now be willing to consider applications to produce human embryos by cell nuclear replacement. The Chair was asked by Angela McNab to discuss with the Group the appropriate procedure by which such applications should be received and processed.
- 3.7 It was noted that a paper was being prepared for the members of the Ethics and Law Committee and it would not be appropriate to consider the fax at this stage.
- 3.8 It was agreed that it would be appropriate for the executive to consider any additional licence conditions that would need to be added to the stem cell licence conditions to cover such applications with the Chair's approval.
- 3.9 The Members were informed that further to the information provided in agenda item 5, Christopher Jones (Oxford University) agreed to send advance copies of two papers which are to be published shortly to the HFEA. One will be part of a chapter of a book by Professor Louis Keith entitled 'Triplet pregnancies and their consequences'. The other paper is to be published in the New England Journal, the paper discusses monozygotic splitting.
- 3.10 It was also noted that Christopher Jones had visited the HFEA to discuss his research.

**4 Chairman's Business**

- 4.1 The Chair welcomed Members and executive to the first meeting of the Scientific and Clinical Advances Group (SCAG).

4.2 The Chair asked that the list of up and coming issues as listed in 4.11 of the previous minutes and any other topics of interest for the Group to discuss should be prioritised.

4.3 The following topics were listed as important areas for the Group to discuss:

- MRC (stem cell) update; it was noted this should be discussed as an information process, in that the Members should be made aware of the legal aspects and what research projects have been approved. Chris O'Toole gave a brief update on the new stem cell bank and what the next steps would be.
- CNR; substantial discussions on applications that have been received should take place.
- PGD and associated risks;
- IVM;
- Laser Assisted Hatching;
- Embryo Biopsy;
- Parthenogenesis; it was noted that this issue was no longer a high priority as a legal ruling was passed recently clarifying that embryos created in this way fall under the terms of an embryo as stated in the HF&E Act 1990.
- Artificial creation of gametes
- Follow-up studies

4.4 It was noted that the priority list should be in the Authority's business plan so that the executive has the resources to carry out the necessary detailed work.

4.5 The Chair requested that the executive should provide him with a detailed report of the resources required to carry out the necessary work requested by the Group. Concerns were raised by the Group that it was evident that additional staff would need to be made available to service and provide good quality papers for the SCAG to be effective. It was agreed that strong instruction should be given to the Authority for this matter to be rectified.

4.6 The Executive agreed to detail the resources required, by the Policy Team in particular, to complete work for SCAG to a professional standard and Chris Barratt agreed to raise this issue at the next Authority Meeting.

**Action: Executive**

4.7 Whilst discussing resources, Members asked if the HFEA was required to subscribe to journals. It was noted that the Department of Health already subscribes to journals and it was suggested that the Authority could share that access otherwise the HFEA may be spending unnecessary resources. Ted Webb agreed to determine,

from the Department of Health, whether the HFEA could have access to the journals through the Department of Health subscription charges for journals.

**Action: Department of Health**

**5 Embryo Transfer and the Risks of Multiple Births – SCAG(04/03)01**

- 5.1 This paper was presented by Christina Panton. The Members were asked to consider the literature review and to consider the following issues:
- The methodology to be used in monitoring the new two embryo policy; it was suggested that this include the proposal that embryo transfers and pregnancy outcomes can be recorded through the Registry on the treatment forms. Members were informed that a report could possibly be made available to them towards the end of the year on the data collected.
  - The evidence available for more than two embryos to be transferred in poor prognosis patients;
  - The impact that the new HFEA policy will have on clinics;
  - The evidence for moving towards an elective one embryo transfer policy;
  - Future work for SCAG.
- 5.2 Members were informed that further information would be made available at the Berterelli Foundation Expert Meeting on issues relating to embryo transfer rates.
- 5.3 Concerns were raised about the implementation of the proposed new two embryo transfer policy, in that there had been little evidence to support that it would be best practice in all patients, other than those with good prognosis. It was noted that individuals' human rights' may be affected, as the Authority could be held responsible for patients having unsuccessful treatment.
- 5.4 The Members agreed that a formal procedure should be followed for implementing new policies in the future.
- 5.5 The Members discussed ways in which the Authority could best monitor the proposed two embryo transfer policy. It was noted that the policy should be introduced through a Chairman's letter and that the Authority should monitor data gathered from clinics on triplet rates as well as the number and reasoning for transferring 3 embryos in exceptional circumstances.
- 5.6 The Members were informed that the audit process, which was to incorporate the monitoring of the two embryo transfer policy at centres, was not able to provide SCAG with meaningful data as

figures only covered a small period of time and there was no information collated on triplet rates or the presence foetal sacs.

- 5.7 The Group made a number of suggestions for monitoring and collecting data, such as:
- targeting clinics that have a high number of 3 embryo transfer rates and ask those clinics for their evidence supporting the decision to transfer 3 embryos so that it could be presented to SCAG;
  - arranging unannounced inspections to look at clinics records and to record the exceptional reasons for transferring 3 embryos.
- 5.8 Jane Denton noted the history of the implementation of the two embryo transfer policy. It was noted that no directions had been issued to give the Chairman's letter any weight for collecting data; therefore it was sufficient that centres are only required to detail their exceptional reasons as a matter of good practice.
- 5.9 The Members recommended that while the Code of Practice was delayed for a 12 week consultation process the Authority should take the time to collect information on the reasoning behind replacing 3 embryos and the number of sacs resulting from 3 embryo transfers as a consultative project.
- 5.10 Christina Panton informed the members that a paper had been produced for a previous Senior Manager Team meeting outlining four possible proposals for monitoring the current two embryo transfer policy.
- 5.11 Concerns were raised that a substantial amount of the consultation time would have passed if this course of action needed to be approved by the next Authority. The Members were informed that the collection of information for monitoring purposes could be implemented by liaising with the Regulation and Audit Departments.
- 5.12 It was noted that a small number (6-14) of international fertility units, including a centre in Edinburgh, had applied to the Wellcome Trust for a grant to carry out studies on elective 1 and 2 embryo transfers. If funded, the results of these studies will not be known for at least 4 years.
- 5.13 It was suggested that there would be no beneficial reasons to monitor current 1 embryo transfers as any single embryo transfers were likely to be circumstantial and not elective. Members agreed that ongoing discussion and collection of evidence for moving to a single embryo transfer policy should continue.

- 5.14 The process of managing such a change in policy would need to be handled with care and it was suggested that the initial steps would be to meet with interested groups abroad (such as Sweden and Belgium) and invite the key people as guest speakers in the Summer/Autumn as part of the consultation process. It was agreed that the Authority should look at all perspectives of reducing the embryo transfer rate including psychological input as well as the scientific and clinical view.
- 5.15 The Members suggested a number of contacts who would be useful in the consultative process, including the following:
- Jane Thomas, from NICE who are developing clinical guidelines for fertility treatment; it was also noted that David Barlow is the Chair of the Fertility Guidelines Group.
  - Pharmaceutical companies should be targeted to be more honourable as the cost of drugs for treatment is highly expensive which may encourage patients to have higher number of embryos replaced for assumable better success rates or in case of multiple births a ready made family.
  - Obstetric and paediatric care units to be contacted so that they can reveal the high number of cases referred to them as a result of multiple births.
- 5.16 The Members agreed that research into the best science in this area would be essential and should be ongoing because, as technology and techniques develop, the success rates for 1 embryo transfer should improve.

## **6 Berterelli Foundation Expert Meeting: Controversies about Multiple Gestations – SCAG(04/03)02**

- 6.1 Members noted the discussion papers for the forthcoming Berterelli Foundation Expert meeting on controversies about multiple gestations. The meeting was to take place in New York between April 12<sup>th</sup> and 13<sup>th</sup> 2003.

## **7 Multiple Births Foundation Leaflet – SCAG(04/03)03**

- 7.1 Jane Denton introduced this paper.
- 7.2 The Members were asked to consider the leaflet produced by the Multiple Births Foundation (MBF) with a view to adapting this leaflet for HFEA use. Members were also asked to suggest any amendments.
- 7.3 Jane Denton noted that the leaflet had been targeted towards patients and that it was in need of revision.

- 7.4 Clare Brown suggested that the MBF may wish to adopt an approach used by CHILD and the Miscarriage Association whereby patient quotes had been included within the information, for emotional appeal.
- 7.5 It was agreed that Executive should review and update the leaflet with the assistance of Clare Brown and Jane Denton.

**Action: Executive & Members**

**8 Research Variation Request, Centre [REDACTED] – SCAG(04/03)04**

- 8.1 Christina Panton presented this paper. The Members were asked to consider a request to vary the centre's treatment licence to amend the standard condition regarding the patient selection criteria for PGS to include patients with male factor infertility.
- 8.2 It was noted that male factor infertility had been considered in the past when deciding the criteria for PGS. It was agreed that the executive should go back and review the decision for why it was not included and establish if there have been any further developments which would reverse the Authority's decision.
- 8.3 The Members noted that they would need to see clear advantages for male infertility factors to be included in the criteria, including whether the benefits would justify the cost of treatment as well as the safety and ethical issues involved.
- 8.4 The Members noted that subject to the findings, the additional criteria would need to be incorporated into the PGS guidelines, by developing guidance and conditions which would need to be approved by the Authority. On approval the Licence Committee would be able to consider the centres variation request.
- 8.5 It was noted that this course of action could be a lengthy process and that the applicant should be informed in writing that the Authority requires more time to consider further information in relation to the application for a variation.

**Action: Executive**

**9 Chair's Letter on Imprinting – SCAG(04/03)05**

- 9.1 The tabled paper was introduced by Chris O'Toole.
- 9.2 Members were asked to consider the Chair's letter sent to centres on 28<sup>th</sup> February 2001 and decide whether revised information needed to be sent out to centres on the risks of imprinting disorders associated with assisted conception technologies.

- 9.3 Members were also asked to suggest any amendments.
- 9.4 The Chair noted that the information did require updating and without delay.
- 9.5 It was agreed that Neva Haites would review literature on imprinting and draft revised information as necessary for distribution to clinics.

**Action: Neva Haites**

**10 Any Other Business**

- 10.1 The Chair asked that the executive endeavours to provide the Members of SCAG with papers as early as possible (at least a week) before the meeting so that Members can assimilate all the information that is provided prior to the meeting.
- 10.2 The Chair asked that the executive present 4-6 substantial papers on cloning for discussion at the next meeting, to be sent out in good time.
- 10.3 The Chair reiterated that Keith Campbell would be making a presentation at the next meeting and if members had any questions they would like to ask it was suggested they be sent to Keith Campbell before the presentation.

**11 Date of Next Meeting**

- 11.1 The next meeting was scheduled to take place at 2.30 on Monday 2<sup>nd</sup> June 2003.
- 11.2 The Chair asked that the Members arrive at 1.30 on 2<sup>nd</sup> June in order that more time be made available for discussion before or after the invited speaker, Professor Keith Campbell, makes his presentation.

**Chair..... Date.....**  
**(Professor Chris Barratt)**