

## Authority Paper



Committee:	Authority
Meeting Date:	28 March 2007
Agenda Item:	2
Paper Number:	HFEA (21/02/07) 362
Paper Title:	Minutes of the non-confidential Authority meeting held on 21 February 2007
Author:	Committee Secretary
For Information or Decision?	Decision
Resource Implications:	None
Recommendation to the Committee:	The Authority is asked to confirm the minutes as a true and accurate record of the meeting

### **HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY MINUTES OF THE NON-CONFIDENTIAL AUTHORITY MEETING (NON-CONFIDENTIAL - PART 2)**

The meeting was quorate with 10 lay members and 7 professional members attending.

#### **PRESENT**

Shirley Harrison  
(Chair)  
Hossam Abdalla  
David Archard  
Clare Brown  
Anna Carragher  
Sally Cheshire  
Rebekah Dundas  
Ruth Fasht

Emily Jackson  
Maybeth Jamieson  
Bill Ledger  
Walter Merricks  
Roger Neuberg  
Susan Price  
Neva Haites  
Lord Harries  
Jennifer Hunt

#### **APOLOGIES**

Chris Barratt  
Sharmila Nebhrajani

#### **IN ATTENDANCE**

Angela McNab  
Tim Whitaker  
Sally Townsend  
Fran Clift  
David Tellis  
Trish Davies

John-Paul Maytum  
Sarah Marsh (minute taker)  
Hannah Darby  
Diane Malcolm  
Katy Berry  
Chris O'Toole

Charles Lister

#### **OBSERVERS**

Ted Webb - Department of Health  
Gareth Jones - Department of Health  
Ros Gardner - Human Genetics Commissio

**Item 1. Apologies, Welcome & Conflicts of Interest** **Action**

1.0 Apologies were received from:

Chris Barratt  
Sharmila Nebhrajani

1.1 Neva Haites left the meeting at 3pm

1.2 The Chair welcomed new Human Genetics Commission observer, Ros Gardner

1.3 There were no conflicts of interest declared.

**Item 2. Minutes of the meeting held on 10 January 2007  
HFEA ( 10/01/07) 353**

2.0 The Authority approved the minutes of the 10 January 2007 meeting with the following amendments:

2.1 Page 5 paragraph 5.11 - the second sentence should read 'When applying for EU funding it is understood that a maximum of 60% of overall costs are recovered.'

2.2 Page 7 paragraph 6.18 - remove the word 'external'

2.3 Page 10 paragraph 8.12 remove the word 'viable' and replace with ' the embryo does not have the normal potential to develop'

**Item 3 Matters Arising & Previous Actions  
HFEA (10/01/07) 354**

3.0 The Authority noted the matters arising.

**Item 4. Chair's Report  
(verbal)**

**4.0 Select Committee**

The Chair informed the Authority that the Science and Technology Select Committee had requested that the HFEA attend its enquiry into Hybrids. The Chair had attended together with the Chief Executive and Professor Neva Haites on 31 January. The Select Committee had been robust in its questioning and the Chair of the Committee had reported that the HFEA representatives were excellent witnesses.

4.1 **Joint HFEA/HTA RATE Meeting**

The Chair reported that the first joint RATE meeting for members had been held on 26 January. The meeting was useful to both the HFEA and the HTA and the Chair asked members to volunteer to join a joint RATE Steering Group. The aim of the group will be to look at strategic issues, to monitor progress and to act as an information channel between the organisations. The Chair requested anyone interested in joining the group to contact her via e-mail. It is expected that membership will consist of the Chair plus one lay member and one professional member from both the HFEA and HTA

**Item 5. Chief Executive's Report (verbal)**

5.0 **Meeting of Competent Authorities - EU Commission**

The Chief Executive informed the Authority that the first meeting of the Competent Authorities for the Tissues and Cells Directive had been held last week. In preparation for the meeting a questionnaire had been sent out to all member states to find out how they are progressing with the transposition of the Directive into law. The questionnaire revealed that reproductive medicine was not well-reflected in the response and it showed that most representatives of the Competent Authorities meeting were from a tissue background. The Commission recognised that more work needs to be done on the complex issues of the Directive with regard to Assisted Reproductive Technologies (ART).

5.1 Compensatory payments were discussed at the meeting and it was agreed to work towards establishing some guidelines on compensatory payments. The HFEA has been asked to submit its own guidelines and to sit as part of a small working group to look at this issue. The HFEA has also been asked to submit its report framework on adverse incident reporting to assist the Commission in developing standards.

5.2 The Chief Executive continued that there was considerable discussion on the subject of import and export of gametes. Within the EU, provision of material from one member state to another is viewed as distribution or transfer between premises and it is specifically permitted for competent authorities to give individual clinics authorisation to agree to receiving material from other member states. In addition to this, if one member state approved an import from a non-EU

country subsequent distribution from there can be done as a transfer. This would mean that the HFEA would not be able to deal with these cases on a case-by-case basis and further thought may need to be given on how the HFEA operates. However, individual clinics would need to ensure they reach the standards required of any material transferred in.

5.3 The Chief Executive also advised the Authority that member states that have higher standards than the Directive may refuse to accept material from member states not meeting those standards. The Regulation Committee will consider the impact of the EU Tissue Directive on these issues and report to the Authority in June. Also, more consideration will be given on how best to inform patients of the new regulations under the Directive.

5.4 **European Assisted Conception Consortium Meeting (EACC), Brussels**

The Chief Executive informed the Authority that concern was expressed that member states are not fully addressing ART issues. The EACC agreed to write to the European Commission Officers highlighting areas where potential inconsistencies could result.

**European Union Standards and Training for the Inspection of Tissues Establishments Project (EUSTITE)**

5.5 The Chief Executive advised the Authority that, as mentioned in the 10 January 2007 Authority meeting, more thought has been given to the European funded EUSTITE project. The project is to look at inspection frameworks and adverse incident reporting in terms of the Directive across member states. The HFEA have now assessed time commitments and believes that, with care, it can meet these demands.

**Arms Length Bodies (ALB) Financial Team**

5.6 The Chief Executive reported to the Authority that the ALB Finance Team had looked at the 2007/08 Business Plan and were content with the document with a small number of amendments.

5.7 **Regulatory Issues**

The Chief Executive updated the Authority on current regulatory action with respect to two London clinics. She noted that a Judicial Review is underway which the Authority will vigorously defend. It was noted that further information about the regulatory action could not be provided due to the legal action.

**Item 6. Regulation, Finance and HR Report  
HFEA (21/02/07) 355**

6.0 **Regulation**

Trish Davies, Deputy Chief Executive and Director of Regulation, introduced this report.

6.1 The Authority heard that most of the renewal inspections had been carried out with half of the interim inspections due completed and the rest scheduled. Ms Davies highlighted the large number of additional inspections on page 2 of the report which impact on the Regulation Department. Report production has been consistent and 100% of reports have been produced within 28 days exceeding all performance targets.

6.2 Ms Davies continued that import and export of sperm remains quite high as the deadline for import/export approaches but no bulk applications were received this month. With regard to the regular export of sperm to Cyprus, the HFEA now has written assurance from the PR of the exporting centre that treatment carried out in Cyprus does meet UK standards.

6.3 The Authority was informed that two alerts are still being prepared but due to a staff family emergency, this has meant a short delay.

6.4 **Finance**

Sally Townsend, Director of Resources & Corporate Development, introduced this report.

6.5 Ms Townsend informed the Authority that this report presents the December management accounts showing results for the first 9 months of the year. Some amendments have been made to the full year forecasts based on extrapolation of year-to-date fee income, recruitment and central maternity costs and current levels of applications for centres newly regulated under the EUTCD regulations. The revised forecast continues to show a break-even position.

- 6.6 The risks to overall financial outturn for the financial year are in respect of income from EUTCD licensing and additional legal costs associated with regulatory action as well as the inherent uncertainties over fee invoicing for the last quarter. The impact of the ongoing regulatory action will be reflected in the January management accounts. Evaluation of the implications for financial resources and the business plan of this action is underway. A high level review of all forecasts indicated that the Authority should still achieve break even for this financial Year. This will continue to be closely monitored.
- 6.7 A member asked why there was such a large increase in IVF cycles reported in October 2006 (graph 3 of the report 'IVF Treatment Cycles Reported and Billed Monthly'. It was explained that this resulted from delays in reporting that occurred when the electronic data interchange system was rolled out.
- HR**
- 6.8 Sally Townsend, Director of Resources & Corporate Development, introduced this report.
- 6.9 The Authority heard that staff turnover had stabilised following a peak in November and it is anticipated to remain low between now and the year end. However the overall rate remains high because of the high levels of turnover earlier in the year. Sickness absence remains low.
- 6.10 The HR Department have commenced roll out of the Diversity Awareness training. Four sessions have been held to date and feedback from staff on these has been positive.
- 6.11 The Authority was informed that recent activity within the HR department has included a significant amount of work supporting HTA recruitment. Work has commenced in conjunction with the HTA on HR issues for the RATE subgroup (such as relocation and common processes to ensure smooth transition into RATE).
- 6.12 Ms Townsend continued that the HFEA had observed the Samaritans National Stress Down Day on February 1st. Ten minute massages had been provided for staff as well as lifestyle advice. This was a great success.

**Item 7. Witnessing Procedures  
HFEA (21/02/07) 356**

- 7.0 Hannah Darby, Policy Officer, introduced this report.
- 7.1 Ms Darby introduced the proposed new standard, guidance and model protocols for witnessing. It was explained to the Authority that these new requirements aim to reduce the risk of mix ups and misidentification of gametes and embryos as far as possible, however, the risk of human error cannot be completely eradicated. The standard which requires clinics to have a witnessing protocol is the only mandatory part of these new requirements. The guidance supports this and the model protocols are intended to help clinics comply with the standards.
- 7.2 The Authority heard that the draft standard, guidance and protocol have been written after consultation with experts and the sector and the Regulation Committee approved the final draft in January. It has also been seen and commented on by the Licensed Centres Panel.
- 7.3 Ms Darby continued that it is estimated that the regulatory burden for centres carrying out manual witnessing will be slightly reduced. The regulatory burden for centres which use electronic witnessing will be reduced even further as the number of manual witnessing steps required is reduced. The new protocols will address incidents such as those mentioned in Annex A of the report. Following Authority approval the new standard and guidance will amend the new Code of Practice and will be sent out to centres in April or May. It was proposed that centres should be given three months to implement these requirements.
- 7.4 Discussion
- A member thought the best approach would be for inspectors to ask whether the clinic has considered seriously moving towards electronic witnessing and if not, to have good reasons as to why. It would also be sensible to write to clinics highlighting the advantages and disadvantages of the new system as laid out in page 7 of the report.
- 7.5 A member commented that the guidance was very useful and recognised that the protocols can be adapted to suit all clinics. The member thought that it was too soon to enforce electronic witnessing as currently there has been little incentive to buy the equipment. It is expensive and

current protocols require manual witnesses. The evidence the HFEA currently have on electronic witnessing is not from IVF laboratories (current evidence is from blood transfusions and medicine administration) but there are barcoding system trials currently taking place in Liverpool.

- 7.6 A member raised the point that some parts of the new system may increase errors in the laboratory as ART is more complicated than blood transfusion and further thought should be given about how the processes fit in ART.
- 7.7 A member raised the issue of non-compliance (mentioned in Annex D as a major source of error) and whether the HFEA has considered ways to pick up non-compliance?
- 7.8 It was explained to members that electronic systems would give you a read-out of the detail of all processes that had taken place and the staff involved. In some cases it may be necessary for staff to use fingerprint identification to start the process.
- 7.9 A member raised the issue of the 'appropriate person' (page 21 and 28 of the report) and the suggestion that the patient may act as a witness. The member felt very strongly that it was not appropriate at egg collection and embryo transfer and that both the embryologist and clinician should be present. For clarity the Chair asked when it would be satisfactory for a patient to act as the 'appropriate person' and was told that it may happen in small clinics with a small number of cycles but the sample would have already been prepared.

#### Decision

- 7.10 The Authority approved the standard, guidance and model protocols and these will replace the current Direction on witnessing within the suggested timeframe. They should amend the Code of Practice in April/May and centres should be given three months to implement the new requirements.
- 7.11 The Authority recommended that all clinics complete a risk assessment or review of the type of system used for witnessing to see whether they should move towards electronic witnessing. This review should be carried out within the next 6 months.
- 7.12 The Authority is not ready to recommend that all clinics

move to electronic witnessing but will wait until laboratory testing is carried out and consider the subject again at a later date when it has clear evidence

**Item 8. Eggs for Research - policy decisions**  
**HFEA (21/02/07) 357**

8.0 Katy Berry, Policy Manager, introduced this report.

8.1 Dr Berry informed the Authority that this paper provides further information to help form a policy on the donation of eggs for research. An earlier version of the paper has been seen by the Ethics and Law Committee and following the Authority decision, new Guidance for research donation will be produced.

8.2 The Authority heard that the public consultation 'Donating eggs to research: safeguarding donors' ran between September and December 2006. The responses to the consultation did not provide a clear consensus but a wide-ranging collection of views.

8.3 Other work included in the review were:

- A literature review on donor information
- Results of an Infertility Network UK survey on egg sharing
- Consideration of the Helsinki declaration
- Notes from a discussion meeting on egg donation for research hosted by a research group in Edinburgh

8.4 The Authority heard that there had also been a meeting held with researchers and scientists working in the field to gauge their opinion and again, the views were varied. The views of the scientists at this meeting were noted by the Ethics and Law Committee and were considered at their meeting in January. The Committee concluded that the caution shown by scientists was not necessarily enough reason to prohibit the use of human eggs in research. The views of the Ethics and Law Committee are detailed on pages 8 and 9 of the report.

Discussion

- 8.5 A member raised the issue of the media. It was felt that the HFEA could be doing more work to ensure that incorrect stories were not reported in the media.
- 8.6 Tim Whitaker, Director of Communications and Policy, responded that a great deal of work had been done with the media and briefings had been held but there was very little that could be done about inaccurate reporting and media speculation.
- 8.7 A member raised the issue of risk given that the medical risks for donating for research are no higher than for treatment. However other risks such as coercion or donating eggs for money would be covered by the additional safeguards listed on page 9 of the report. Payments to the donor are compensatory only and only apply to receiptable expenses and in some cases, loss of earnings equivalent for that received for Jury Service (a maximum of £250). A further member felt content that there was a 'cooling-off' period for donors (page 5 paragraph 4.10).
- 8.8 A member asked whether eggs donated to research would reduce the number of eggs available for treatment? The member was informed that women should be under 36 to donate eggs for treatment but potentially donors can be over 35 years of age when donating for research.
- 8.9 One member felt it important to point out that the HFEA remit only covers the egg donation process when it results in an embryo.

Decision

- 8.10 The Authority agreed to allow the donation of eggs for research both through non-patient donation and egg-sharing arrangements. Where egg sharing for treatment and research take place at one centre, equal benefits-in-kind should apply to both.
- 8.11 The Authority accepted that the measures recommended by ELC on page 9 are introduced and requested more clarity that these safeguards are in addition to current existing safeguards
- 8.12 The Authority requested a good statement for the media should be prepared that cannot be misconstrued

- 8.13 The Authority will review the egg-sharing policy in general (for treatment and research) when there has been a chance to further review the practice and in light of any decision made by the EU.

**Item 9. New Register Forms  
HFEA (21/02/07) 358**

- 9.0 David Tellis, Director of Information Management, introduced this report.
- 9.1 The Authority heard that in October, the Information Programme Management Board delegated the review of the existing register forms to a small workshop of clinicians with the final format to be approved by the Authority.
- 9.2 Mr Tellis continued that at the IMPB meeting of 6 February, members discussed the sequence and timing of events required to allow the new forms/transactions to be introduced both by the HFEA and by 3rd party supplier of Electronic Patient Records suppliers to clinics. The deadline of 30 September 2007 was agreed.
- 9.3 A member requested a box added to the 'IVF Treatment & Embryo Creation/Use Form' under section 15A stating the 'Number of Normally Fertilised EGGS'.
- 9.4 The question was also raised as to why disability and ethnicity questions have been added to the registration forms. The Authority was informed that the HFEA is subject to new diversity rules and is now required to collect this information from its stakeholders.

Decision

- 9.5 The Authority agreed the new forms with the amendment:
- 9.6 Add 'Number of Normally Fertilised Eggs' to section 15 A of the 'IVF Treatment & Embryo Creation/use Form'
- 9.7 The forms will now be sent to all clinics and will become mandatory, through Directions from September 2007.

**Item 10. Publication of PGS Cycle Data  
HFEA (21/02/07) 359**

- 10.0 David Tellis introduced this paper.
- 10.1 The Authority heard that at the February 2007 IMPB meeting, a proposal was made to report Pre-implantation Genetic Screening (PGS) cycles as part of the 'normal' IVF cycles data from the next 'Find a Clinic' (Patients Guide) which will be published in April 2007. PGS cycles have previously been treated in the same way as Pre-implantation Genetic Diagnosis (PGD) cycles and excluded from Patient Guides and the Authority is asked to ratify the IMPB proposal of reporting PGS and PGD cycles separately.
- 10.2 The Authority ratified the decision made by the IMPB to publish PGS and PGD data separately and clinics will be written to verify their PGD/PGS data.

**Item 11. Communications Update Report  
HFEA (21/02/07) 360**

- 11.0 Tim Whitaker, Director of Communications & Policy, introduced the report.
- 11.1 Mr Whitaker drew the attention of the Authority to the latest survey results from Fertility Views, the HFEA's on-line patients' panel.
- 11.2 The Authority was informed that the panel consists of about 800 patients both past and present and the panel is very useful to the HFEA in gauging patient opinion on issues and therefore helping improve practice.
- 11.3 A member pointed out that the survey results showed that only 55% of patients found counselling helpful or very helpful. The member has knowledge of individual clinics where well above 90% of patients found counselling helpful and the discrepancy could be due to variations in quality and standards across the sector and should be explored further by the Regulation Committee.
- 11.4 The Chair informed the Authority that the issue of counselling will be one of the sessions in the HFEA's Annual Conference in June 2007 and these issues can be looked at in detail at that time.
- 11.5 A member asked for more information on the range of clinics that Fertility Views members have experience of.

TW

**Item 12. Multiple Births Consultation Process and Timelines  
HFEA (21/02/07) 361**

- 12.0 Charles Lister, Head of Policy, introduced the report.
- 12.1 The Authority approved the timeline for the consultation with the following changes:
  - The patient meeting will be held in London during the weekend (not a weekday as stated)
  - The professional meeting will be held in Manchester
- 12.2 A member raised the point that the HFEA could begin work on model options during the consultation process.
- 12.3 The Chief Executive agreed and options on each of the outcomes would be discussed with the British Fertility Society and the Provider Panel. **CL**
- 12.4 Mr Lister also stated that initial discussions had been had with stakeholders on the subject at a meeting in January,

**Item AOB**

**13.0**  
13.0 There was no other business to discuss.

**Item Date of Next Meeting**

**14.0**  
The next Authority meeting will be held on 28 March 2007

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

.....  
**Chair**

Date .....