

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

MINUTES OF THE 139th OPEN AUTHORITY COMMITTEE MEETING

held at the Royal College of Obstetricians and Gynaecologists
held at the New Connaught Rooms
on 18 February 2004

The Authority meeting was quorate with 16 Members attending, 9 lay members and 7 professional members.

PRESENT

Suzi Leather [*Chair*]
Tom Baldwin [*Deputy Chair*]
David Barlow
Chris Barratt
Peter Braude
Ivor Brecker
Clare Brown
Jane Denton

Neva Haites
Richard Douglas Harries
Jennifer Hunt
Emily Jackson
Maybeth Jamieson
Simon Jenkins
Walter Merricks
Sara Nathan

IN ATTENDANCE

Angela McNab [*Chief Executive*]
Barry MacDonald [*Director of Resources & Corporate Development*]
Jackie Hammond [*Director of Regulation*]
David Tellis [*Director of Information Management*]
Tim Whitaker [*Director of Policy & Communications*]
Frances Clift [*Legal Advisor*]
Heidi Homar [*Committee Secretary*]

OBSERVERS

Kim Hayes [*Department of Health*]

Hilary Harris [*Human Genetics Commission*]

ACTION

Item 1 Apologies

1. Apologies for absence were received from Iain Cameron, and Sharmila Nebhrajani and Liz Woodeson. Kim Hayes from DH was welcomed to the meeting.

The Authority introduced themselves to the guests and no conflicts of interest were raised.

**Item 2 Minutes of the meeting held on 14 January 2004
[Paper HFEA (18/02/04) 131 attached]**

2. The minutes of the previous meeting held on 14 January were accepted subject to the following changes:
- Item 2 Para 4 5th bullet point change the of the word ‘abortion’ to ‘ending of life’.
 - Item 6 Para 20 2nd bullet point change to ‘The main cost to HFEA will be in the process rather than the start up costs.’
 - Item 7 Para 22 add further bullet point ‘the options are not mutually incompatible – you could have any of 1, 2 or 3 plus option 4.’
 - Item 7 Para 26 add ‘clinics and research’ before community

**Item 3 Matters Arising & Previous Actions
[Paper HFEA (18/02/04) 132 attached]**

3. The Authority noted that actions taken have been included in the Matters arising.

Item 3 para 6 about division of labour between HFEA and HGC, it was reported that HGC will exclude PGD/HLA however, further discussions have taken place to make division of labour long term rather than short term. HGC will include PGD/HLA in their long term review.

Item 4 Chair’s Report - [verbal report]

4. **DH review of ‘Arms length bodies’** The Chair and Chief Executive have had first meetings with the officials concerned regarding the review.
5. The annual conference was considered successful with a good range of subject matter and speakers and the workshops were popular. The most popular session was the welfare of the child and the meeting the Authority Panel was the least popular.
6. We have received some possible subjects for next year’s conference and these are being considered.
7. **HFE Act** The House of Commons Science and Technical Committee have launched their look at the Act. They have had a brief debate on sex selection and talks were given by Josephine Quintaville, John Harris and Marcus Pembury from Bristol. The consultation is ongoing.

8. **The Directory of Clinics** will be launched on 4 March at 6.30pm at Church House.
9. **Memorandum of Understanding (MOU)** The HFEA and HGC have agreed to develop an MOU. The Chair, Vice Chair and Chief Executive of the HFEA will shortly be meeting with their counterparts at the HGC. They will also be considering a joint meeting with the HGC.
10. **Donor Anonymity.** DH reported that work was proceeding but no details were available.

Item 5 Chief Executive's Report - [verbal report]

11. **ESHRE.** All data for 2001 has now been entered, six weeks ahead of schedule. The staff was thanked for their hard work.
12. **ESHRE Conference.** The HFEA has been asked to give a presentation at the conference on the Tissue Directive at the end of June. Suzi Leather will make the presentation.
13. **NHS Number Tracking System** HFEA hoped to be able to use the NHS unique patient identifying number in the future, but did not fulfil the NHS criteria to be allowed to use the system. However, following a meeting with the CE of the Information Authority, they have agreed to look at the HFEA's request to use this information. The HFEA will resubmit the request.
14. The CE has completed 3 routine clinic visits and found them very informative. In addition to this, the CE has received two written compliments thanking us for the way the HFEA have responded to adverse incidents.
15. The CE reported that Sandy Mather has recently joined the HFEA as the new Head of Inspections.

Item 6 Annual Business Plan & Budget & PGD/NLA – sign off
[Paper HFEA (18/02/04) 133]

16. The OFC welcomed the Business Plan and reviewed it in some detail. It was commended it to the Authority for approval. It was noted that the HFEA has achieved a lot in the past year and the aims and objectives for the coming year are very challenging.

17. The Authority voiced concern about the size of the Business agenda proposed; and the pressure on staff and members, particularly from Licence Committees. There was some discussion of the possibility of some issues being resolved by staff in Regulation, with the crucial licence decisions taken by the Committees. The Regulation Committee will be asked to consider if more work could be delegated to Regulation staff.
18. The CE acknowledged that the proposed Plan was demanding and reported that the SMT and Heads of Departments will be putting together detailed prioritised project plans, with timescales, and resources for submission to OFC. This will enable the Executive to make contingency plans to deal with unexpected issues which might arise. We will have to work more efficiently, and make more efficient use of technology and learn to work in different ways to ensure that we keep to the plan. OFC will monitor progress on this and report back to the Authority in three months.
19. Other points made:
 - **PGD and HLA** This is a substantial project which will require further finance and staffing. The aim is to recruit another member of staff for 6-9 months to oversee this project. The overview of public opinion will be fed into the review of the Act at the end of the year.
 - **Review of the welfare of child** This should concentrate on how the welfare of the child is assessed and the adequacy of the evidence base
 - **4.4 8th** bullet point add 'and implement findings of the working group'. A draft report has been seen and is expected out in the next month.
20.
 - **Page 11 3rd** bullet point change CHILD to Infertility Network
 - **13 6th** bullet point delete 'based on the advice of the new Clinical Advisor as to which circumstances will require them'
 - The authority would like a completed performance indicator sheet for the current year.
21. It was suggested that future Business Plans should show a fuller version of the fundamental values of the aims and objectives of the Authority.
22. The budget shows a projected increase of billing of 14%. This increase in fees was based on the assumption that we would not get a fall in volume of treatment.

23. As a result of the discussions, changes will be made to the Business Plan and it will be submitted to Ministers at the DH for approval before publication.

Item 7 Patient Feedback on Inspections
[Paper HFEA (18/02/04) 134]

24. After piloting different ways in gaining patient feedback, it was widely agreed that the questionnaire was the best way of obtaining this information.
25. The questionnaire in its present state seemed too long at 10 pages and should be reduced although it was felt that more searching questions could be asked.
26. It was felt that a letter should be sent out to patients advising them that this questionnaire would be sent to them.
27. A member suggested that the HFEA should look at developing the questionnaire in the future for use for egg and sperm donors, transport and satellite centres. HFEA needs to look at how this is distributed to patients and to avoid duplication or overwhelming patients. Consideration should be given on how it is incorporated into inspection reports.
28. A member suggested that some patients may prefer to meet the inspection teams rather than complete a form. Face-to-face meetings did not seem to be a successful way to gaining feedback as few patients attended the sessions. If patients didn't feel happy about completing the form, they could be asked to give their comments on the last page of the questionnaire.
29. It was suggested that patient comments are usually one of the most informative ways of gaining an insight into their experiences and this should be reflected on the form. In stead of yes/no answers some of the questions could be more searching and encourage answers.
30. It was important that a good procedure was in place to analyse the results of the questionnaire. This will be reviewed and the Regulation Committee will feedback responses to the Authority.
31. Any comments on the questionnaire should be directed to the Regulatory Manager. **PD**
32. The Chair agreed to seek advice from market research sources that have experience in questionnaires. **SL**

Item 8 Minimum Data Set
[Paper HFEA (18/02/04) 135]

33. **Historic Minimum Data set**
IMPB have agreed the details. These forms will go to the clinics to confirm the information we already have on individuals and will fulfil our statutory duty in identifying each child back to the cycle it came from. The Authority were advised that this is a two-part exercise; manual and electronic collection of data. The electronic part will check more fields than manual ones.
34. After discussion the Authority agreed that the following information should be added to the historical data set:
- number of embryos to be transferred
35. **Future Data Set**
Consultation has taken place with HFEA Staff, Members, the MRC and BFS. Consultation is currently taking place with ACE, the Fertility Nurses group, BICA and PROGAR.
36. The following information was confirmed:
- It was confirmed that an additional outcome form is available if the number of fetal hearts is more than three.
 - The forms refer to some treatments that are no longer done and these could be removed from the form.
 - Each individual has a unique HFEA identifier number and so any further treatments can be linked back to individuals so if a donor wants to include further important life changing events about themselves i.e. serious illness in family.
 - *Donor information form.* No decision can be made on this form until the DH has decided what information is required. HFEA will liaise with DH on donor identity information on the forms and will report back to Authority in May.

DT

- *Donor information form.* Needs to include whether individual was adopted
- It was felt that if HFEA could not gain access to the unique NHS numbers, then the postcode should be added to the forms.
- A member advised that forms in Australia had an additional 12 items on their forms. This information will be passed to DT.

37. The members were asked to contact DT directly with any further minor amendments to the forms.

All

38. **New Forms**

It was agreed that forms will be introduced at the same time as the EDI.

The Authority will be given an update in May.

DT

Item 9 Format for publication of inspection reports (consultation result) [Paper HFEA (18/02/04) 136]

39. The form has been drawn up with consultation from clinics but it was felt that further consultation with BICA and PROGAR is required. The form requires more amendment especially with regards to information on the form under section three which may identify patients.

The CE, Director of Regulation and Head of Audit will meet to review the report and report back to Regulation Committee. Further consultation will be sought on the form before it is piloted at selected clinics.

40. The form will need go to Communications for transparency and language check. The form should have a legal check to ensure that there will be no way of identifying patients.

41. It is planned that the forms will be ready by 1 April and available on the web by 1 October 2004.

Item 10 Communication Strategy [Paper HFEA (18/02/04) 137]

42. The Communication Strategy was discussed at the Authority meeting in October and concentrates on key priorities for the coming year and it dovetails into the Business Plan. It is proposed to provide a quarterly report to the Authority on progress.

43. The HFEA is continuing to maintain contact with GP's and Health Commissioners by sending them copies of the Code of Practice and the Directory of Clinics. This will open up a line of communication and spread more information about the HFEA. It was felt that the clinics should also be more pro-active and have a role to promote the HFEA. It was noted that communication was also being opened up with MPs and parliamentarians. .
44. To raise the profile of the HFEA, it was suggested that the HFEA website could be linked to appropriate websites and also we could make use of others mail-outs to GPs.
45. The Annual Conference is an important communication asset. HFEA needs to think about what it would like to achieve at the next conference and work towards this aim. It was felt that the Authority and the DH's roles could be clarified in future conferences to show more clearly HFEA's independence.

Item 11 Regulatory Activity Report
[Paper HFEA (18/02/04) 138]

46. The report was reviewed by the Authority.
- The targets for inspection activities are being met. We are continuing to review turnaround time in sending out reports and this has been incorporated into the Business Plan.
- Following an inspection of the Esperence Clinic in Eastbourne, the License Committee has temporarily suspended the clinic's licence for three months. This means that the clinic cannot do any licensed treatments until certain conditions have been met. This action was taken partly because previous conditions had not been met and because the inspection identified possible risks to patient safety.
- The patients have been notified of this and those patients currently undergoing treatment have been moved to other clinics.
47. The reports show an increase in incidents but this does not mean that incidents have actually increased, just that under the new strategy, the clinics are reporting them.
- It was felt that further clarification was needed on the status of 'active' and 'closed'. The information would need to be checked and will be reported back to the Authority with details of resolutions.

AM

Item 12 Any Other Business

48. No other business was reported

Item 13 Date of the Next Meeting

The next 'closed' meeting of the Authority will be Wednesday 24 March 2004.

The next 'open' meeting of the Authority will be 12 May and will be in Central London. It is planned to hold the October 'Open' meeting in Edinburgh.

The Open Authority meeting closed at 4:00p.m.