

Authority Paper



Committee:	Authority Meeting
Meeting Date:	18 October 2006
Agenda Item:	2.
Paper Number:	HFEA (13/09/06) 332
Paper Title:	Draft Minutes of the Authority Meeting held on 13 September 2006
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)

There were 14 members attending, 6 lay members and 8 professional members.

PRESENT

Lord Harries (Chair)
Sam Abdalla
David Barlow
Chris Barratt
Ivor Brecker
Clare Brown
Iain Cameron
Ruth Fasht

Neva Haites
Jennifer Hunt
Maybeth Jamieson
Walter Merricks
Susan Price
Jane Jeffs

APOLOGIES

David Archard
Emily Jackson
Simon Jenkins
Sharmila Nebhrajani
Sara Nathan

IN ATTENDANCE

Helena Hird
John-Paul Maytum
Nicholas Embling
Fiona Daffern
Jenny Dimond

Claudia Lally
Sarah Marsh
Frances Clift
Angela McNab
David Tellis

Tim Whitaker
Trish Davies
Sally Townsend

OBSERVERS

Christine Patch - Human Genetics Commission
Ted Webb - Department of Health
Gwen Skinner - Department of Health
Andy Earnshaw - Department of Health

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|----------------|---|---------------|
| Item 1. | Apologies, Welcome & Conflicts of Interest | Action |
| 1.0 | Apologies were received from:

Sara Nathan
Sharmila Nebhrajani
Emily Jackson
Simon Jenkins
David Archard | |
| 1.1 | The Chair welcomed two new interim members to the Authority, Jane Jeffs and Sara Nathan. | |
| Item 2. | Minutes of the meeting held on 26 July 2006
[HFEA (26/07/06) 325] | |
| 2.0 | The minutes of the 26 July 2006 meeting were approved with the following comments: | |
| 2.1 | 2:3.1 (14/06/06 4:7.2) should read 'Peer Review to be looked at by the Regulation Committee'. | |
| 2.2 | 2:3.2 Clare Brown stated that the Fertility Views panel article had been well received with no complaints | |
| Item 3 | Matters Arising & Previous Actions
[HFEA (26/07/06) 326] | |
| 3.0 | The Authority noted the matters arising and previous actions. | |
| Item 4. | Chair's Report
(verbal) | |
| 4.0 | The Authority has a new interim Chair, the Right Reverend Lord Harries of Pentregarth, until the end of November. | |
| Item 5. | Chief Executive's Report
(verbal) | |
| 5.0 | The Chief Executive informed the Authority that the Eggs for Research consultation had received good media coverage and was available on the HFEA website. | |
| Item 6. | Regulatory, Finance and HR Report
[HFEA (13/09/06) 327] | |
| 6.0 | <u>Regulation</u>

Trish Davies, Deputy Chief Executive and Director of Regulation, reported to the Authority that half of all renewal inspections had already been carried out for the year. Inspection report writing has improved; reports are promptly written and the new format has made them | |

easier to read and understand. All PGD applications are now included in the Regulation Report.

- 6.1 Trish Davies continued that an Alert had been sent out to all clinics about Dry Shippers, to ensure any clinic that transfers gametes from place to place is aware of potential problems.

Finance

- 6.2 Sally Townsend, Interim Director of Resources and Corporate Development, informed the Authority that the August management accounts include revised full year forecasts both for income and costs. Overall the forecast for the Authority has increased by £198K for both income and costs thus maintaining a break even position for the full year.
- 6.3 The increase in income has resulted from the inclusion of the 2005/06 surplus following formal agreement from DH for the retention of these funds. The increase in costs relates mainly to the finalisation of the HAP and Register Project workstreams. These closure costs were the basis for the DH agreement to the retention of the 05/06 surplus.
- 6.4 The Authority heard that fee income will continue to be monitored, as delays in reporting have resulted from slower than anticipated integration of computer patient record systems.

HR

- 6.5 Sally Townsend, Interim Director of Resources and Corporate Development, informed the Authority that staff turnover had reduced in July. The trend over the year remains high and as the HFEA move towards RATE uncertainty could impact on staff numbers. Sickness absence remains low.
- 6.6 Sally Townsend continued that work had begun on the Equality & Diversity project. Core training requirements have been identified and the HFEA are aiming to roll out the programme from October.

Item 7. EUTCD transposition regulations: response to DH consultation [HFEA (13/09/06) 328]

7.0 Jenny Dimond, Policy Manager, introduced this paper.

7.1 Jenny Dimond informed the Authority that when the EU Tissue and Cells Directive (EUTD) is introduced it will mean additional regulatory requirements to the sector. The following will be required:

- 7.2
- all existing licences must be varied by 7th April 2007
 - new licences to previously unlicensed centres that offer IUI, GIFT, sperm sorting, and internet donor gamete supply services
 - centres will be inspected against EUTD between 7 April 2007 and 7 April 2009

7.3 The Department of Health has published a draft regulation consultation which ends on 13 October 2006.

7.4 The following points were highlighted to the Authority:

7.5 Page 4, para 3.2 - IUI services do not need to be screened for HIV, Hep B or Hep C

7.5 Page 4, para 4.3 - PRs must now have a medical or scientific background. Clinics have been given a 6 month transitional period to enable some centres to appoint a new PR

7.6 Page 5, para 5.2 - imports from countries outside the EU would have to provide evidence that the establishment is accredited by a recognized accreditation body and work to a quality system

7.7 The Authority approved the issues to be included in the response to the Department with the following comments:

7.8 Page 6 - Regs Ref 123 - Grant of Licence - under Regulations that are expected to be published in 2007, the title 'counsellor' will become a restricted title and only people accredited as counsellors by the Health Professional Council will be able to use it.

TW

7.9 One member raised the issue of IUI and screening. A Chair's letter from 2002, states that *everyone* must be screened because IUI was not regulated by the HFEA at that time. The letter needs to be looked at to clarify to

- 7.10 clinics that IUI (using partner's gametes) does not need to be screened (page 4, para 3.2).
A request was made to stop using the term 'internet sperm company' (page 4, 3.2).
- 7.11 The Chair and Members thanked Jenny Dimond for all her hard work for both the HFEA and on this report and wished her good luck in her new job.

**Item 8. General Directions on Records
[HFEA (13/09/06) 329]**

- 8.0 Nicholas Embling, Head of Register, introduced this paper.
- 8.1 The Authority heard that the HFEA EDI system has been developed as part of the Register Project. This will be the standard method by which licensed centres submit information to the HFEA Register. This replaces the five paper forms currently in use as specified in General Directions 1999/1 and modified by General Directions 2004/3 (Donor Information) which will now become obsolete. Exceptions will be made for clinics with very low volumes and variations for centres who link their clinical records to EDI.
- 8.2 The Authority approved the use of General Directions with the following amendment:
- 8.3 The Directions should be signed - Lord Harries of Pentregarth, Interim Chair and not Rt Rev Richard Harries, Acting Chair.

**Item 9. Business Plan - contingency planning
[HFEA (13/09/06) 330]**

- 9.0 Sally Townsend, Interim Director of Resources and Corporate Development, introduced this paper.
- 9.1 The Authority was informed that to date the HFEA has been able to accommodate additional requests without having to significantly delay other work. Should a major piece of additional work be requested, the HFEA would need to activate some of the actions listed in this paper. Any impact on the achievement of objectives would be notified to the Authority as a matter of priority.
- 9.2 The Authority approved the plan incorporating the comments made by the OFC (Tabled Paper).

**Item 10. Draft Equality Scheme and Action Plan
[HFEA (13/09/06) 331]**

10.0 Fiona Daffern, Assistant Director of HR & Organisational Development, introduced this paper to the Authority.

10.1 The Authority was informed that the paper outlined the legal requirements of the HFEA and the progress made towards fulfilling those requirements. Since the paper was written, the Department of Health has recommended the HFEA be listed to comply with the specific duties of the Race Relations (Amendment) Act, i.e. produce a Race Equality Scheme.

10.2 The HFEA have started discussions with the HTA, sharing the process we have been undertaking, with the aim of ensuring commonality of approach across both organisations and a synergy of Schemes, moving towards RATE.

10.3 The Authority was informed that a training and development programme has been identified for all staff and members of the Authority and the HFEA has appointed a training provider.

10.4 Ruth Fasht commented on the helpfulness of the members' awareness session undertaken prior to OFC.

10.5 The Authority noted the legal requirements and support the development of the Scheme.

Item 11. Regulation Thematic Presentation

11.0 A copy of this presentation accompanies these minutes.

**Item 12. Patients Guide: time period
(verbal)**

12.0 Tim Whitaker, Director of Policy and Communications introduced this paper on behalf of David Tellis, Director of Information Management. It was explained to the Authority that the HFEA would like to move to a position whereby treatments are published on a calendar, rather than fiscal, year basis, in line with all other European countries. Secondly the HFEA would like to publish more recent data so that at the time of publication, outcome statistics relate to activities from 2 (not 3) years ago. Through the use of EDI it may be possible to move towards publishing treatment and clinical pregnancy numbers (either on a centre or more likely national basis) on an almost real-time basis although these figures would of course initially be unverified. Additionally, older age bands and the singleton live birth rate & implantation rates would be included.

- 12.1 Tin Whitaker explained that it is also proposed that the next interactive Guide relates to the calendar year 2004, the first 3 months of which have already been verified. This reduces the burden on the clinics for verification of their data for the next Guide. It is hoped that this would allow all clinics to complete the first stage of verification between September and December 2006, allowing a second stage early in 2007 and publication on our website during March 2007.
- 12.3 The process would be repeated immediately afterwards, allowing publication of 2006 figures in the early part of 2008 and would adopt this cycle for future years.
- 12.4 The Authority noted the changes to the Patients Guide and delegated to the Information Management Programme Board to consider the format of future Guides in more detail.

**Item 13. RATE
(verbal)**

An update on RATE was given by the Chief Executive in the Confidential meeting.

Date of Next Meeting

The next Authority meeting will be held on 18 October 2006.

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

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Chair

Date