

## Authority Paper



Committee:	Authority Meeting
Meeting Date:	14 June 2006
Agenda Item:	2.
Paper Number:	HFEA (14/06/06) 320
Paper Title:	Minutes of the Authority Meeting held on 14 June 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 14 June 2006

### **HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY MINUTES OF THE AUTHORITY COMMITTEE MEETING (Non-Confidential - PART 2)**

The Authority meeting was quorate with 16 members attending, 10 lay members and 6 professional members.

#### **PRESENT**

Suzi Leather (Chair)	Richard Harries
David Archard	Jennifer Hunt
David Barlow	Emily Jackson
Ivor Brecker	Maybeth Jamieson
Clare Brown	Walter Merricks
Iain Cameron	Sue Price
Ruth Fasht	Sam Abdalla
Helene Hayman	Christine Patch HGC

#### **APOLOGIES**

Simon Jenkins  
Sharmila Nebhrajani  
Chris Barratt

#### **IN ATTENDANCE**

Angela McNab	Frances Clift
Trish Davies	John Paul Maytum
Tim Whitaker	Stephanie Croker
Sally Townsend	
David Tellis	

Neva Haites arrived shortly before the end of the meeting.

- | <b>Item 1.</b> | <b>Apologies, Welcome &amp; Conflicts of Interest</b>   | <b>Action</b> |
|----------------|---|---------------|
| 1.0            | Apologies were received from:<br><br>Chris Barratt<br>Simon Jenkins<br>Sharmila Nebhrajani (Deputy Chair)   |               |
| <b>Item 2.</b> | <b>Minutes of the meeting held on 28 March 2006<br/>HFEA (10/05/06) 313]</b>  |               |
| 2.0            | The minutes of the 28 March meeting were approved with the following change:  |               |
| 2.1            | Page 10 para 15.6 - the last sentence should read '(same as donation but with embryos)'   |               |
| <b>Item 3.</b> | <b>Minutes of the meeting held on 10 May 2006<br/>[HFEA (10/05/06) 314]</b>   |               |
| 3.0            | Page 3 para 5.3 - should read 'The Authority heard that the Chief Executive had met with Dari Taylor, MP for Stockton South, and the Chair of NIAC to discuss patient feedback and how the HFEA are addressing patient problems'.   |               |
| 3.1            | Page 5 para 7.7 - a sentence should be added to the end 'It is also difficult to get the embryos to implant'  |               |
| 3.2            | Page 5 para 7.8 - should read 'The Authority discussed the differences between PND and PGD. PND happens at a much later stage of development and decisions about whether to offer PND are at doctors' discretion. The Authority thought it appropriate that PGD should be considered separately from PND' |               |
| 3.3            | Page 6 para 7.10- should read 'The severity of the condition is a significant factor in its own right even if penetrance is relatively low'   |               |
| 3.4            | Page 6 para 7.13 - the last sentence should read 'PGD for these conditions should not be fast-tracked'  |               |
| 3.5            | Page 7 para 8.5 - should read 'A research project seeking approval for gamete research would only need to seek local Research Ethics Committee approval'  |               |
| <b>Item 4.</b> | <b>Matters Arising and Previous Actions<br/>[HFEA (28/03/06) 315]</b>   |               |
| 4.0            | 11/01/06 3:6.4 - Complete<br><br>15/02/06 7:8.10 - Complete   |               |

28/03/06 7:8.4 - Complete

28/03/06 7:8.7 - Complete

10/05/06 3:6.4 - Complete

10/05/06 6:7.13 - Complete

- 4.1 Clare Brown requested a link from the HFEA website to the INUK survey. **DT**

**Item 5. Chair's Report (verbal)**

- 5.0 The Chair spoke at the INUK and Acebabes National Infertility Day at the New Connaught Rooms on the 10th June 2006.

- 5.1 The Chair attended an All Party Parliamentary Group on Infertility (APPGI) at the House of Commons last week.

- 5.2 The Chair spoke at the Telling and Talking launch of Donor Conception Network leaflets. The Chair requested that a set of these leaflets are sent to all Authority members. **TW**

**Item 6. Chief Executive's Report (verbal)**

- 6.0 The Chief Executive informed the Authority that the Annual Report and Accounts are being published as one complete document to be laid before Parliament before the Summer recess. The final draft will be circulated to all members by e-mail and they will have one week to comment before it is given to the National Audit Office for full approval. It will be laid before Parliament in July.

- 6.1 The new Guide to Infertility has proved successful. In the first week 1,200 patients requested the Guide compared with the normal number of requests of around 250. There have also been a significant number of requests from GPs.

- 6.2 The Authority heard that other groups have been targeted to receive information about the Guide to Infertility; health centres, sports & leisure facilities and women's groups. There have been 25,000 visits to the Interactive Guide which is twice the normal number.

- 6.3 The Chief Executive explained that there have been concerns raised about the completeness of data

published by the HFEA. The Chief Executive will come back to the Authority when more information is known about the concerns and actions can be considered.

- 6.4 A group of representatives from the HFEA are going to ESHRE, the European Society of Human Reproduction & Embryology next week in Prague. The Chief Executive will be meeting with the European Consortium to discuss EUTD planning across Europe.
- 6.5 The Chief Executive will be attending the next Horizon Scanning Group also to be held next week.

**Item 7. Regulatory, Finance & HR Report  
[HFEA (14/06/06) 316]  
Regulation**

Trish Davies introduced this report.

- 7.0 The Authority was informed that the regulation report has been revised to show the full complexity of the regulation workload. A total of 9 inspections were carried out in April (not 11 as stated in table 1.) and three of them were unannounced. Regulation Committee has requested that this is broken down further into the 2 different types of unannounced inspection, targeted and random, for the next report.
- 7.1 The Authority was informed that Appendix A is a summary of research applications received by the HFEA in the past 2 years. Research applications are a now a significant part of the regulation workload.
- 7.2 The Chair pointed out to the Authority that the timing may look inconsistent in Appendix A because when the application is sent out to peer review, the clock is stopped. The Chair requested the Research Licence Committee look at the process of peer review to see if there are any recommendations they can make to the Authority. **TD**
- 7.3 The Chair requested clarity on whether performance indicators in Appendix A have been achieved. The Chair also requested the Appendix include licence variations. These will be added to the next report. **TD**
- 7.4 Trish Davies informed the Authority that a company supplying non CE marked Petri dishes used in IVF has applied for licence for its dishes as a direct result of an HFEA Alert.

- 7.5 The Authority heard that report production from inspections has improved. She noted there has been a rise in incidents under the Grade B category because the new grading matrix has come into effect.
- 7.6 The Authority requested Page 9 – under figure 5 the sentence ‘one application to treat a patient with anonymous sperm’ should be deleted.

Finance Report

- 7.7 Sally Townsend informed the Authority that the finance report is in the new format as agreed at the last meeting.
- 7.8 The Authority heard that some overspends have been identified and these are due to the closure of the registry project and costs committed for the 05/06 budget being accounted for in 06/07 due to accounting rules. The surplus identified at the end of 05/06 is now being used for these committed costs.
- 7.9 The Authority was informed that there will be some amendments to the forecast and these will be undertaken when the 05/06 accounts have been signed off.
- 7.10 The Authority heard that the fee increase should increase income by approx. £30K and should be implemented by 1<sup>st</sup> October 2006.

HR Report

- 7.11 Sally Townsend informed the Authority that establishment figures are on target and in line with ALB requirements. The head count will be 80 by the end of the year.
- 7.12 Turnover of staff has been high due to a large number of fixed term contract staff leaving. This may also impact permanent staff. Staff may also feel unsettled due to the uncertainty of RATE. The number of leavers has settled down since this report was written. It has been reduced from 40% to 31% and will continue to be monitored.

**Item 8. Consent Forms**

**[HFEA (14/06/06) 317]**

- 8.0 Stephanie Croker introduced this paper.
- 8.1 The Authority was informed that HFEA inspections had highlighted a high error rate in the filling out of consent forms which invalidated consent. For this reason the HFEA have created 8 new forms to take into account new changes in legislation and to make them simpler to complete. Each form is accompanied by guidance for the clinic.
- 8.2 The Authority was informed that the new forms had undergone a detailed programme of development and testing in consultation with professional bodies, the Licence Centres Panel and others. The Regulation Committee has been involved at every stage. The forms were piloted at 5 centres and patients completed the new forms in parallel with the old forms. The feedback from patients and clinics was positive.
- 8.3 There has been one slight change to the WD (section 2) and MD (section 3) consent to donation forms since the papers were printed, instead of referring to 'the number of families created with the donors' gametes' the form now asks the donor to consent to the number of families that may have children with their donated gametes. The forms are also now consistent with the donor information forms. The guidance has also been updated to reflect these changes.
- 8.4 The forms will be brought into force by General Directions. The Authority is asked to approve the consent forms and guidance for clinics for publication at the end of June 2006 and implementation one month later.
- (Neva Haites arrived)
- 8.5 The Authority requested the following changes after a long discussion:
- 8.6
- The numbers need to be checked on each form for consistency
- 8.7
- Take out 'Guidance for Clinics' and replace with 'Guidance' and have an asterisk (\*) stating which boxes must be completed on each page (e.g. HFEA centre reference number, patient number, partner's patient number)

- 8.8
  - On each form change 'In the event of my death, or if I should lose the ability to decide for myself' to 'If I should lose the ability to decide for myself or in the event of my death'
- 8.9
  - Each form will have a box added to indicate whether the patient has completed other consent forms
- 8.10
  - Add a clear statement on each form saying 'Changing or revoking consent is most effectively done by completing a new consent form'
- 8.11
  - WT Form Page 1 of 3 title should read ' Consent to the use of eggs and use and storage of embryos in own treatment or research'
- 8.12
  - WD form Page 1 of 2 section 3iii) add '- these periods may vary. See guidance' to the end of the sentence
- 8.13
  - WD form - Guidance needs to be clear on the consent to storage of embryos where the person donating is sharing eggs with another woman and the medical circumstances are different for each woman
- 8.14
  - WD form Page 2 of 2 section 5. ii) and iii) substitute the word 'eggs' with 'embryos'
- 8.15
  - ES form Page 1 of 2 section 1 - this part will be filled out by clinics so should read ' Patient's surname etc'
- 8.16
  - MS form Page 1 of 1 section 2 - ii) substitute 'year' for 'years'
- 8.17
  - MS Guidance - Page 2 of 2 Section 2i) the guidance needs to be clear on statutory storage periods
- 8.18
  - The Authority approved the consent forms for publication with the request that the Licensed Centres Panel report to the Authority after four months' use of the new forms and they are reviewed in one year through inspection reports.

**Item 9. Communications Activities Update**

**HFEA (14/06/06) 318]**

9.0 The Chair congratulated David Williams for the work he has done in redesigning the HFEA website. The new design is based on the needs of different users and contains new patient information. The patient area of the website has been expanded significantly. The new website will be available from 17<sup>th</sup> June 2006.

9.1 Tim Whitaker introduced the report and highlighted the results of the fertility views panel questionnaire. The key issues arising from the panel were:

- Single Embryo Transfer
- Availability of donated gametes
- Complaints about clinics
- Cost of treatment

9.2 The Authority heard that the results of the Fertility Views panel will be sent to all clinics and shared with patient organisations. The Multiple Birth group has looked at the results as part of its deliberations. Some clinics have requested the report. The results will be put on the new HFEA website.

9.3 The Authority suggested that the results of the panel should be written in article format and distributed to professional organisations. TW

9.4 The Authority requested that DH and the All Parliamentary Group is informed about the key issues for patients as highlighted in the Fertility Views Panel TW

**Item 10. Achievements against objectives from the 2005/6 Business Plan  
[HFEA (14/06/06) 319]**

10.0 Angela McNab introduced this report.

10.1 The Authority was informed that the report is a detailed report highlighting HFEA achievements against objectives for the past year. In line with ALB requirements the Authority will now receive quarterly reports on progress against objectives.

10.2 The accountability review with the Minister is set for the 27<sup>th</sup> June 2006.

**Item 11. RATE update (verbal)**

11.0 There was nothing to report to the Authority.

**Item 12. Minutes from Other Committees (Regulation)**

**Committee - March/April and Audit Committee - April)**

12.0 The Authority noted the minutes of the Regulation and Audit Committees.

**Item 13. Any other business**

13.0 There was no other business to discuss.

**Item 14. Date of Next Meeting**

14.0 The next Authority meeting will be held on 26 July 2006.

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

.....  
**Chair**  
Date .....