

Minutes of the Authority meeting
9th December 2009
held in public at
The Vermont Hotel, Castle Garth, Newcastle Upon Tyne

Members

There were eighteen members in attendance, eleven lay members and seven professional members. Three members were unable to attend and sent their apologies.

Members present:

Lisa Jardine (Chair)	Lesley Regan
Alan Thornhill	Lillian Neville
Andy Greenfield	Mair Crouch
Anna Carragher	Neva Haites (up to item 9)
Clare Lewis-Jones	Rebekah Dundas
David Archard	Richard Harries
Emily Jackson	Ruth Fasht
Gemma Hobcraft	Susan Price
Hossam Abdalla	William Ledger

Apologies:

Debbie Barber
Sally Cheshire
Jane Dibblin

Observers

Ted Webb, Department of Health
Ros Gardner, Human Genetics Commission (co-opted member)

Staff in attendance

Alan Doran	Catherine Drennan	Paula Robinson
Peter Thompson	Danielle Hamm	Paula Woodward
Mark Bennett	Helen Richens	Zalife Ahmet
Trish Davies	Joanne McAlpine	
David Gomez	Juliet Tizzard	
Brenda Irons-Roberts	Charlotte Augst	

1. Apologies, Welcome and Declaration of Interests

- 1.1. The Chair opened the meeting by welcoming members of the public who had come to observe the meeting.
- 1.2. The Chair reported that prior to the open meeting members had a confidential session to consider personnel matter. The legal update was tabled and noted.
- 1.3. The Chair welcomed two new members of the Authority, Alan Thornhill and Andy Greenfield.
- 1.4. The Chair, members and staff also thanked Richard Harries, who steps down at the end of the year, for his work as a member of the Authority.

1.5. Apologies were received from:

- Debbie Barber
- Sally Cheshire
- Jane Dibblin

1.6. Declarations of interest were made by:

- Sam Abdalla
- Bill Ledger
- Alan Thornhill

2. Minutes of 21st October 2009

2.1. The minutes were agreed and signed by the Chair.

3. Chair's Report

3.1. The Chair reported a number of recent public appearances, namely:

- the Vanessa Feltz radio show;
- contributing to a BBC Radio 4 Analysis programme on transparency and secrecy;
- addressing the leadership forum Addenbrooke's hospital on the subject of "Patient Safety and Assisted Reproduction: The Regulator versus the tabloids";
- attending a dinner hosted by the Royal College of Obstetrics and Gynaecology.

3.2. The Chair reported that she would be participating in a debate on the BBC World Service on new ethical and political issues raised by advances in medicine and technology, to be broadcast in January. She also reported that she would be hosting a new series of A Point of View on Radio 4 from January.

3.3. The Chair reported that she had recently been contacted by a group concerned about recent media coverage of her comments on payments for egg donors. The Chair made it clear that their understanding of what she had said in relation to payments was not correct.

4. Chief Executive and Directors' Reports

4.1. The Chief Executive commented on recent media reports which had incorrectly stated that sperm from an unscreened donor had been used at a particular clinic. In fact the donor had been screened and the problem had occurred elsewhere in the clinic's procedures, details which had been reported in a statement published on the Authority's website. The incident had now been fully investigated and would be addressed by a licence committee shortly.

- 4.2. The Chief Executive reported that a letter had been issued to clinics outlining the actions that would be taken as a result of feedback gathered at the Annual Conference on 1st October.
- 4.3. Letters had also been sent to two sperm donation websites advising them that, subject to any decision taken by the courts, the Authority would take action if their activities were deemed to constitute procurement and require a licence.
- 4.4. In the light of a recent case, the Executive will be issuing an alert to clinics reminding them that specific consents must be obtained before gametes are retrieved in cases where a person is seriously ill or has died. The Executive will also be alerting NHS Trusts to the issue.
- 4.5. The Executive and the Medicines and Healthcare Products Regulatory Agency (MHRA) have agreed to work with manufacturers to bring culture media under the auspices of the CE mark within 12 months.
- 4.6. The Chief Executive reported a number of recent engagements, namely:
- attending dinner at the Royal College of Obstetrics and Gynaecology;
 - planting a tree for Infertility Network UK in the 'Fertility Forest' in Kent
 - making a presentation to the RCOG senior staff conference and to the BFS
- 4.7. The Executive had taken part in the Fertility Show in Olympia where a good number of patients had visited the HFEA's 'Choose a Clinic' stand.
- 4.8. He also reported that he would be at the ACE and BFS annual conference in January, taking part in a debate on IVF regulation.
- 4.9. The Chief Executive advised members that all employment agreements with the Human Tissue Authority, stemming from the proposed merger, had now been severed.
- 4.10. The Chief Executive gave a brief presentation on the recently published report of the Hampton review of the HFEA. The review team, whose visit took place in April, commended the Authority on a number of areas and had made a number of recommendations, some of which had already been implemented.
- 4.11. The Chief Executive informed members that the Executive will look closely at the report in order to see what further improvements could be made. A paper will be presented to the Authority in January.
- 4.12. The Director of Compliance informed members that there were minor changes to the compliance report. She reported that the number of planned inspections on page 5 had actually reduced to 96 from 148. The reduction in the number of inspections had resulted from the Authority's move to more targeted inspections.
- 4.13. The Director of Compliance also reported that, with two colleagues, she had attended the final conference on the European Commission's three year project to implement the EUTCD in Warsaw. A new three year project

will continue the work on vigilance and surveillance and that the World Health Organisation will now be participating.

- 4.14. The Director of Finance and Facilities reported that the office refurbishment was now complete, that a business continuity plan had been finalised and that the talent management programme had started. On the accounts, he reported that a balance was forecast for the end of the year.
- 4.15. The Director of Strategy and Information reported that much of the directorate's recent work had been following up the implementation of the new legislation. He also reported that the website, particularly the 'Choose a Fertility Clinic' pages, were receiving significantly higher numbers of visitors.
- 4.16. The Director of Strategy and Information also reported that the Executive had held a small event on PGD and that discussions had taken place with the Office for National Statistics and the Cabinet Office to look at whether the HFEA's data could become certified as official national statistics.

5. Responsibility for approving the inspection schedule

- 5.1. Alan Doran, Chief Executive, advised members that the law now required the Authority to approve the inspection schedule.
- 5.2. It was proposed that this responsibility should be assigned to the Compliance Committee as a delegated power.

Decision

- 5.3. Members agreed to delegate the power to approve the inspection schedule to the Compliance Committee.

6. Multiple Births: Moving Towards a Year 2 Target

- 6.1. Helen Richens, Policy Manager, introduced the paper, advising members that it was for information only and that she would be preparing a further paper for decision at the January meeting.
- 6.2. The paper presented the findings of a review of the first year of the Authority's multiple births policy, including feedback from clinics, patients and an initial analysis of the data collected so far for 2009.
- 6.3. Members were reminded that the HFEA's policy included working closely with patient and professional groups, through the Multiple Births Strategy Group, in order to develop a coherent approach.
- 6.4. Members were informed that the data used for the review was not complete and that a further analysis would be carried out when more complete data from clinics had been received.
- 6.5. Looking at the available data, it appears that the number of elective single embryo transfers (eSET) has increased although the predicted overall multiple birth rates had remained static. By looking more closely, the data revealed that the overall multiple birth rates for patients under age 35 had fallen while for those 35 and over it had increased.

- 6.6. Members were presented with some suggestions as to why the multiple birth rate had not yet changed and what work could be done to assist clinics further, including:
- the increased use of blastocyst transfer in women having two embryos transferred and embryo quality both appear to be playing a greater role than a patient's age.
 - the number of women actually having single embryo transfer is still relatively low, either because they do not fall within the criteria set by the clinics or they had decided not to agree with the clinic's recommendation.
 - many clinics reported that they had initially taken a cautious approach but, as the year progressed, clinics are gaining confidence and are able to provide patients with data demonstrating the effects of their policy. Some have amended their strategies as a result of these outcomes.
 - there was a need to improve patient information and staff training to ensure that consistent information was given at all stages of treatment.
 - the availability of NHS treatment and the ability to pay for private treatment plays a major role in patient uptake of single embryo transfer. There was a need to improve NHS provision, and to demonstrate to PCTs the advantages of funding frozen embryo transfers.
 - further analysis of clinics' strategies, alongside the full year's data, would need to be carried out before any conclusive results could be presented.
- 6.7. Helen set out a number of issues that would be included in the paper being presented to members in January:
- establishing how the Authority would identify those clinics that had not complied with the policy, those which had tried but struggled, and those which had done well.
 - deciding what approaches might be taken as regards compliance and enforcement around the multiple births policy.
 - deciding the next maximum rate to begin in April 2010.
- 6.8. Members suggested that data and information to support clinics' development of their strategies should be made available as soon as possible, and that the impact embryo quality and transfer timings may have on successful eSET should be investigated.
- 6.9. Members were particularly concerned that patients may not fully understand the risks of multiple births including miscarriage and other longer term complications. Helen reported that a patient leaflet was being developed through the Multiple Births Stakeholder Group and INUK and should be available early next year.

- 6.10. Members also raised concerns about whether patients were aware of the risks of multiple births following other forms of fertility treatment, in particular hormone treatments prescribed by GPs, such as clomid.
- 6.11. Members noted the impact funding plays in patient decisions about eSET. This is likely to become a greater concern as availability of both private funding and NHS treatment is likely to be reduced following the economic downturn.
- 6.12. Members thanked Helen for a clear presentation of a complex subject and noted the paper.

7. SEED Evaluation

- 7.1. Danielle Hamm advised members that an evaluation of the policies introduced following the Sperm Egg and Embryo Donation (SEED) review had been undertaken by the Executive. Proposals for future work on this and two additional issues – intrafamilial donation and donor codes – were set out in the paper.
- 7.2. The paper set out the findings of the evaluation which had been carried out through detailed conversations with various clinic staff, and with patient and professional organisations.
- 7.3. Members were asked to agree a set of recommendations for work that would be included in the business plan for 2010/11. To aid the discussion, members were asked to make decisions issue by issue. A further paper would be presented in March setting out the workplan in more detail.
- 7.4. Members thanked Danielle and other policy staff for their work on this paper.
- 7.5. On the selection of donors, members noted that there may be a risk of discrimination in some cases, but agreed that this was covered by anti-discriminatory guidance in the 8th Code of Practice.
- 7.6. Members noted the work that has been carried out to ensure that records of donors were not duplicated on the HFEA register.
- 7.7. On the ten-family limit, members noted the various factors that led to the introduction of the limit and discussed what new factors may be emerging, including variable geographic distribution in the use of donated gametes, and a new pilot donor recruitment system funded by the Department of Health.
- 7.8. On expenses and compensation, members noted the reasons for the introduction of the current policy including the law, the risks to egg donors, the quality of gametes provided, the views of donor conceived people and the principle of altruistic donation. The Director of Compliance informed members that the European Commission will shortly be investigating how the payment rules introduced by the EUTCD have been implemented across Europe.

Decision

- 7.9. Members agreed to the recommendation that no review was required on the selection of donors or on the import of gametes and embryos.

- 7.10. Members agreed to the recommendation that a review should be undertaken on the ban on the provision of donor codes, the ten-family limit, the reimbursement and compensation of donors and benefits in kind.
- 7.11. On the screening of donors, members agreed to the recommendation that the CMV standard licence condition should be removed and that professional guidelines on screening of donors should be summarised in the Code of Practice.
- 7.12. Members agreed to a review of the upper age limits for sperm donors and investigation as to whether a minimum age limit for egg donors may be appropriate.
- 7.13. Members agreed that the Ethics and Law Advisory Committee could review travel abroad for treatment using donated gametes and the restrictions some donors impose on the use of their donated gametes.
- 7.14. On intrafamily donation, members agreed that this should be dealt with separately from the SEED evaluation work. A workplan on this issue is to be included in the March Authority paper

8. Business Planning Update

- 8.1. Paula Robinson, Head of Business Planning, introduced a paper outlining the progress that had been made to date on the current 2009/10 business plan.
- 8.2. Paula reported that some slippage in targets was being managed but that progress overall was very good, despite the heavy workload resulting from the introduction of the new legislation on 1st October.
- 8.3. Some changes were proposed, including transferring some specific items to the 2010/11 workplan.
- 8.4. Paula also introduced the draft business plan 2010/11 and drew members' attention to the main proposed activities.
- 8.5. The Director of Facilities and Finance reported that the new plan would require the same budget as set for the 2009/10 business plan.

Decision

- 8.6. Members agreed that proposed changes should be made to the current business plan.
- 8.7. Members also approved the draft business plan for 2010/11.

9. Standing Orders

- 9.1. David Gomez, Senior Legal Advisor, introduced the proposed changes to the Authority's standing orders, part of the Authority's governing documents. He also introduced a new Code of Conduct for Authority members.
- 9.2. Members were advised that the changes to the Standing Orders were necessary following the overhaul of the Human Fertilisation and Embryology Act. The legal team had taken the opportunity to completely

revise the standing orders to simplify language, modernise procedures and make corporate governance framework clearer.

- 9.3. Members were advised that Cabinet Office guidelines on best practice for such documents had been used to aid the development of the Code of Conduct.
- 9.4. Both documents had been examined and approved by the Audit and Governance Committee. It was proposed that they should come into force on 1st January 2010.

Decision

- 9.5. Members agreed to the recommendation to approve the changes to the Standing Orders and the Code of Conduct, subject to minor amendments relating to the new staffing structure and job titles.

10. Update from Committee Chairs

- 10.1. The Chair of the Scientific and Clinical Advisory Committee (SCAAC) reported that Professor Bhattacharya had given a presentation to the committee on how HFEA data might be used by researchers.
- 10.2. SCAAC had also discussed an Academy of Medical Sciences consultation on the use of human tissue in animal studies, the EUTCD requirements on the screening of patients, and a number of new studies examining the efficacy of pre-implantation genetic screening (PGS). A paper setting out the committee's findings on PGS would be presented for consideration by the Authority in the near future.
- 10.3. The Chair of the Ethics and Law Committee (ELAC) reported that issues relating to donation had been discussed by the committee and their findings had been reported during item 7.
- 10.4. ELAC had appointed a new co-opted member, Erica Haimes.
- 10.5. The Director of Finance and Facilities, on behalf of the Chair of the Audit and Governance Committee (AGC), reported that the Authority's risk register would be presented to Authority for review in due course. Cabinet Office Information Asset training had now been completed by all staff and was now being undertaken by AGC members.
- 10.6. The Chair of the Compliance Committee (ComCom) reported that the publication of incident inspection reports had been discussed and welcomed.
- 10.7. ComCom had recommended that the Executive should consider how the financial stability of clinics might be examined to aid patient confidence at a time of economic uncertainty.
- 10.8. ComCom had also discussed the new self assessment questionnaire and the operational audit report examining the quality of data supplied by clinics to the HFEA. The Executive had been asked to look at the impact on clinics of the electronic data interchange (EDI) system.

