

**Minutes of the Authority meeting  
24th March 2010  
held at Dexter House, Tower Hill, London EC3**

**Members**

There were 17 members at the meeting, 9 lay members and 8 professional members.

**Members present**

Lisa Jardine (Chair)	Ermal Kirby	Neva Haites
Alan Thornhill	Gemma Hobcraft	Rebekah Dundas
Andy Greenfield	Sam Abdalla	Ruth Fasht
Bill Ledger	Jane Dibblin	Sally Cheshire
Debbie Barber	Lesley Regan	Susan Price
Emily Jackson	Mair Crouch	

**Apologies**

David Archard	Clare Lewis-Jones
Lillian Neville	Peter Thompson (Executive)
Anna Carragher	

**Observers**

Craig Westwood, Department of Health  
Ros Gardner, Human Genetics Commission

**Staff in attendance**

Alan Doran	Helen Chowne	Richard Martin
Carmel Dodson-Brown	Joanne McAlpine	Sharon Neaves
Cathy Hodgson	Juliet Tizzard	Terence Dourado
Charlotte Augst	Mark Bennett	Trish Davies
Danielle Hamm	Nick Spears	Zal Ahmet
David Gomez	Paula Robinson	
David Williams	Paula Woodward	
Hannah Darby	Rachael Henry	

**1. Welcome, Apologies and Declaration of Interests**

- 1.1. The Chair opened the open meeting by welcoming Authority members, staff and members of the public.
- 1.2. Apologies were received from:
  - David Archard
  - Lillian Neville
  - Anna Carragher
  - Clare Lewis-Jones
  - Peter Thompson (Executive)
- 1.3. The Chair, Lisa Jardine, announced the appointment of Alan Doran as Chief Executive of the Authority.

1.4. Declarations of interest were made by:

- Sam Abdalla
- Bill Ledger
- Alan Thornhill
- Debbie Barber

## **2. Minutes of 20<sup>th</sup> January 2009**

2.1. The minutes were agreed subject to some minor amendments. Following the amendments being made, the minutes were signed by the Chair.

## **3. Chair's Report**

3.1. The Chair informed members that two forms had been set out for them to sign at the meeting: the updated members' interests register, and the members' Code of Conduct (Annex E of the Standing Orders).

3.2. The Chair informed members that, following agreement by the Remuneration Committee, members' fees would be replaced by an annual salary from 1<sup>st</sup> April 2010. The Appointments Commission will write to members in due course to inform them of the change to their appointment conditions.

3.3. The Chair reported that she had attended a meeting of the Human Genetics Commission in Cambridge, and that she had given a speech at the 'Late Effects of Cancer' conference in Sheffield.

3.4. On forthcoming events, the Chair reported that she would be attending an event in Manchester for PCT commissioners, organised by Infertility Network UK. The event is one of a series designed to help PCTs better understand the needs of patients when commissioning fertility services.

3.5. The Chair informed members that the Licence Committee's workload had been increasing, mainly due to a large number of PGD applications having been received. It was proposed that two additional members be appointed to the Licence Committee to enable the committee to better manage its workload.

### **Decision**

3.6. Members agreed that two additional members should be appointed to the Licence Committee, Debbie Barber and Mair Crouch.

## **4. Chief Executive and Directors' Reports**

4.1. The Chief Executive, Alan Doran, reported that the review of arm's length bodies (ALBs) was progressing. All ALBs had now met to discuss the issue with their sponsor departments and a number of workshops would be held to assist ALBs with the process.

4.2. The Chief Executive reported that information about the salaries of senior employees of public bodies, including the HFEA, was due to be published today, but this has now been postponed to a later date.

4.3. On staffing, the Chief Executive reported that a new Director of Compliance had been appointed. Further details would be sent to members when the appointment had been accepted in writing. He also

reported that the senior legal advisor was to take three months unpaid leave. In both cases, arrangements had been made to provide cover.

- 4.4. Members were informed that the Executive held a health and wellbeing week in February which had been welcomed and enjoyed by staff. Members also heard that a number of students from Oxford, who are studying for an MSc in embryology, had visited the Executive to find out more about the work of the organisation.
- 4.5. Members were informed that a number of workshops on multiple births, consent to research and incident management were being held around the country to help clinic staff better understand current policies and improve practice.
- 4.6. Alan Thornhill withdrew from the meeting. The Chief Executive informed members about the Executive's actions following media reports of a London clinic linked to an egg donation 'raffle' by a US clinic. The Executive had written to the clinic concerned and further investigations were being undertaken to establish the exact nature of the reported scheme. Alan Thornhill returned to the meeting.

#### **Directors' Reports**

- 4.7. The Director of Finance and Facilities, Mark Bennett, informed members that a project is being developed to examine the organisation's accommodation needs in the coming years.
- 4.8. On contracts, members were informed that the majority of the organisation's contracts related to the ALB talent management consortium and that there were currently no single tender contracts in place.
- 4.9. On projects, members were informed that the fees review project was being developed and that the Annual Report project was underway. Members were advised that an electronic copy of the Annual Report would be sent to them for final review. Members were also informed that that Management Statement was ready to be agreed with the Department of Health.
- 4.10. On finance, members were informed that the number of treatment cycles remained high, despite the economic downturn, leading to more income from fees than had been estimated at the start of the financial year.
- 4.11. Juliet Tizzard, acting on behalf of the Director of Strategy and Information, informed members that the Executive had recently published a report, "Fertility Treatment in 2006", setting out in detail the various treatments and outcomes in 2006.
- 4.12. Members were informed that the donor sibling contact register, "Donor Sibling Link", had recently been launched. Members will be updated on the progress of the new service in due course.
- 4.13. Members were informed that the final three sets of regulations, resulting from the revised HFE legislation, will come into force in April. An update to the Code of Practice was issued in February to allow time for centres to prepare for the changes.
- 4.14. The Senior Legal Advisor, David Gomez, informed members that the Authority was not involved in any litigation at present.
- 4.15. The Director of Compliance, Trish Davies, reported that the directorate was expected to exceed most performance indicators by the end of the

year. Inspectors had dealt with an increasing number of PGD applications, but staff illness meant that only 3 out of the 4 planned unannounced inspections would now be carried out by the end of the financial year.

- 4.16. Members were informed that the inspection team was running a series of risk management workshops for clinic staff.
- 4.17. Members were informed that, following the success of the pan-European EUSTITE project to implement the EU Tissues and Cells Directive, the European Commission had now agreed to fund a further project to develop work on vigilance, surveillance and inspector training. The HFEA would continue to participate in this project.
- 4.18. Members were informed that the Executive had recently hosted a delegation from Turkish Cyprus. Members commented that it was helpful to develop strong links with regulators in other countries in the light of concerns about cross border fertility treatment.

## **5. Translation of Patient Information**

- 5.1. David Williams, Communications Manager, introduced the paper by outlining the efforts that were being made to make HFEA information as accessible as possible, particularly when patients are required to provide consent.
- 5.2. The HFEA has an obligation under the Welsh Language Act and work on a Welsh translation of the Guide to Consent is to begin soon. It was proposed that the HFEA should also develop the capacity to translate information into other languages, focussing on the twelve most common languages identified by the NHS.
- 5.3. Members commented that some clinics have already translated information into various languages and that many NHS facilities use telephone interpreting services.
- 5.4. Members noted that the cost of translation can be high, particularly for long documents, and that any translation would require careful review in order to ensure that it is accurate. There did not seem to be a case to offer translation 'on demand' so there was a need to produce a policy.
- 5.5. Members also noted that the recently introduced Equalities Act would need to be considered during the development of a translation policy.

### **Decision**

- 5.6. Members agreed that the Executive should translate the Guide to Consent into the twelve most common NHS languages (in addition to the Welsh translation) and make the translated documents available on the website.
- 5.7. Members also agreed that a more detailed policy on the provision of translated materials should be developed before any other materials were translated.

## **6. Business Plan 2010/11**

- 6.1. Paula Robinson, Head of Business Planning, introduced the paper by drawing members' attention to the changes that had been made to the business plan since the previous draft. Although broadly in its final form, a

number of figures would need to be added to the document at the end of the financial year which may also affect the accompanying text.

- 6.2. Members thanked Paula for developing a clear and comprehensive business plan. Members noted that, at present, a number of major projects depended on resources that had not yet been approved by the Department of Health.
- 6.3. Members commented that, in light of economic conditions, there should be a cautious approach to projected income from fees.

#### **Decision**

- 6.4. Members approved the business plan 2010/11, subject to the addition of end of year information relating to delivery and performance during 2009/10.

### **7. Executive Licensing Panel (ELP) 3-month Review**

- 7.1. Mark Bennett, Director of Finance and Facilities, introduced the paper by setting out the work of the ELP since its inception in October 2009..
- 7.2. Members were informed that a total of 46 items have been considered over eight meetings and that most of the items were licence renewals, interim inspection reports and changes of PR or Licence Holder.
- 7.3. This first review concluded that, overall, the new process was working well. The presence of at least two directors at all but one meeting meant that the panel was able to make consistent decisions and it appeared that there may be scope for the panel to consider more items.
- 7.4. Members were reminded that further reviews were planned: a six-month interim review and a more comprehensive twelve-month review.
- 7.5. Members welcomed the review but noted that this was still at a very early stage.
- 7.6. Members suggested that the Executive should examine whether it would be appropriate for Licence Committees to have the power to delegate decisions to the ELP.
- 7.7. With regard to membership of the twelve-month review panel, members suggested that both internal and external individuals with the necessary knowledge and expertise should be considered.

### **8. Getting Started: Your Guide to Fertility Treatment**

- 8.1. Sharon Neaves, Communications Officer, introduced the paper by setting out the work that has been done to ensure the new patient guide meets the needs of people considering fertility treatment.
- 8.2. Members were informed that the new guide would provide a broad overview of fertility treatment and what to expect at a clinic. Readers looking for more detailed information would be directed to the website which now contained much more comprehensive patient information following its relaunch last year.
- 8.3. At a number of focus groups, patients reported that the guide would be most helpful at the very start of the treatment journey. Efforts were therefore being made to ensure that leaflets advertising the guide were made available at GP surgeries. Patients had also provided comments on

the type of images and tone of voice which had been used to inform the new design.

- 8.4. "Getting Started" would be launched at the end of April. An evaluation of feedback from patients and professionals, and of demand, would take place in due course.
- 8.5. Members thanked Sharon for her hard work developing this important document for patients. Members suggested that the leaflet and the booklet could be made available to patients via the electronic printing system used by many GPs.
- 8.6. Members also suggested that, in the next edition, it would be helpful to provide some statistical information, particularly with regard to the impact of age on success rates.

## **9. Risk Tool Presentation**

- 9.1. Carmel Dodson-Brown, Head of Clinical Governance & Patient Safety, began by providing members with an overview of the new four-year compliance (inspection and licensing) cycle and the role of risk assessment within that process.
- 9.2. Members were reminded that the new approach to risk was developed as part of the HFEA's 2010 change programme and that it incorporates both the sector's response to the consultation (conducted in 2009) and the Hampton Principles.
- 9.3. The risk assessment brings together various pieces of data, such as the self-assessment questionnaire (SAQ), register information, finance data, policy information and inspection themes, to provide an overview of each clinic's performance. The vast majority of clinics have now submitted their SAQs, which completes the first phase of implementation.
- 9.4. The risk assessment will help inspectors identify which areas should be the focus of an inspection at each clinic. Any improvements or discrepancies in performance or practice that are found during the inspection will be fed back to aid the production of the inspection report.
- 9.5. Members noted that inspectors will also carry out spot checks on areas where a clinic has reported itself as compliant to ensure that the clinic is providing accurate information to the HFEA.
- 9.6. Members were informed that clinics will be able to view the data through the online clinic portal, allowing them to see the information held by the HFEA and to help them monitor their own performance.
- 9.7. Feedback from clinics about the process so far has been broadly positive and the Compliance Committee will continue to monitor the ongoing implementation of the new process.
- 9.8. Members thanked Carmel for her presentation and noted that further updates will be presented to members in due course.

## **10. Work Plan for Donation Policies Review**

- 10.1. Danielle Hamm, Policy Manager, introduced the paper by outlining the reasons for the review and reminded members of the decisions made at the December 2009 meeting.

- 10.2. Hannah Darby, Policy Manager, presented members with the three proposed stages to the work plan and proposed that the review's findings would be presented to members for decision next spring. It was proposed that an advisory group should be established, comprising both stakeholder representatives and Authority members.
- 10.3. Hannah outlined the various components of the proposed evidence gathering stage including:
- a communications plan to publicise the review as widely as possible;
  - the inclusion of a number of questions on donation in a wider public survey;
  - a literature review, to be discussed by SCAAC and ELAC, and an analysis of data held on the HFEA register;
  - a stakeholder workshop and a clinic survey;
  - the recruitment of two public policy research fellows from the Economic and Social Research Council to carry out some qualitative research.
- 10.4. The proposals for the consultation stage of the review were less detailed as this would be informed by the findings of the evidence gathering stage. Because of the sensitive nature of some of the issues involved, participants would be given the opportunity to give their views in private through, for example, one to one interviews.
- 10.5. The final analysis stage would bring together both the consultation findings and research evidence, and would examine the impact of various possible policy changes on individuals and clinics.
- 10.6. Members were informed that legal advice had already been sought regarding the Authority's suggestion of raising the minimum age for egg donation from the current age of eighteen. It was recommended that this should not be included in the review. However, issues of concern around younger egg donors would still be covered by the consultation.
- 10.7. Members thanked Danielle and Hannah for a clear presentation and a comprehensive set of proposals for the review.
- 10.8. Members commented that the location and accessibility of clinics may be a factor for potential donors, and that it would be interesting to hear the results of the 'hub and spoke' donation pilot scheme (funded by the Department of Health) in due course.

### **Decision**

- 10.9. Members approved that the approach set out in the workplan, subject to consideration of the following issues:
- donation in other countries, particularly differences in compensation schemes, incentives and discouragements, and levels of donation;
  - whether the motivation of donors has changed over time;
  - the different types of donors and how they could be included in the consultation (e.g. egg share and altruistic donors, or known and unknown donors).
- 10.10. Members agreed that three Authority members should sit on the working group, namely Jane Diblin, Bill Ledger and Erial Kirby.

## 11. Disclosure of Information for Research Purposes

- 11.1. Juliet Tizzard introduced the paper in the absence of Richard Martin, author of the paper. The paper sets out proposals for managing the disclosure of information for research purposes, a scheme brought into effect by the new HFE legislation.
- 11.2. Members were informed that regulations allowing the scheme to include HFEA data collected before 1<sup>st</sup> October 2009 were expected to be in place by 6<sup>th</sup> April 2010.
- 11.3. Members were informed that there had been an issue around patients providing consent for their children's data early in their treatment when those children had not yet been conceived. The consent form will be modified to ensure that patients fully understand how their children's data will be used.
- 11.4. Members noted that consent to disclosure for research is just one of a series of consents patients are asked to provide before treatment. The way these consents are explained may have a significant impact on patients' understanding of consent to research. It was noted that, at a recent Licensed Centres Panel, clinic staff reported that patients were happy to consent once they fully understood the type of information that was to be used and what it was to be used for.
- 11.5. Members were informed that, at the current series of clinic workshops, efforts were being made to better understand how consent is explained to patients and what concerns patients have.

### Decision

- 11.6. Members:
- approved the memorandum of understanding with the National Information Governance Board for Health and Social Care (NIGB);
  - agreed that the fees regime should apply to disclosure of all register data for research purposes, whether made available through the regulations or under the consent provisions of the HFE Act;
  - agreed that lay summaries of the data research projects should be published on the website in line with those published for embryo research projects;
  - agreed that NIGB should hear appeals against its own decisions and that all other appeals should be managed within the HFEA's structure.
- 11.7. On the structure needed to consider applications and oversight, members agreed that:
- the Authority should be the Oversight Committee, fulfilling a requirement set out in the regulations;
  - an Executive Register Research Panel should be established to consider applications to access register data, and that an Executive Register Research Review Panel should hear appeals.
- 11.8. On consent to the use of children's data, members agreed the proposed amendments to the wording of consent form (CD), subject to some further changes for clarity.
- 11.9. On linkage studies, members agreed that dataset linkage work usually should only take place on HFEA premises. However, members agreed in

principle to the Register Research Panel permitting linkage work to be carried out on the premises of research establishments in exceptional circumstances. This will be assessed on a case by case basis.

- 11.10. Members also agreed that patient information on consent to disclosure for research should be improved to help patients better understand what sort of information is involved and why the data may be made available.
- 11.11. Members agreed that the process and the policy framework used by the executive panel should be initially reviewed three months after the panel starts operation.

## **12. Knowledge and Information Management Strategy**

- 12.1. Juliet Tizzard introduced the paper in the absence of its author, Richard Martin and reminded members that they considered an Information Strategic Framework in 2008.
- 12.2. Members were informed that the proposed strategy takes into account the legislative, policy and procedural changes that have taken place since then. Its aim is to make the HFEA a better collector, keeper and provider of information by encouraging and developing a culture of knowledge sharing within the organisation.
- 12.3. Members noted that the plan was comprehensive and that it linked to a number of other projects across the organisation, many of which are already underway. Members commented that with such an ambitious strategy it is important to make sure that the organisation has the capacity to deliver.

### **Decision**

- 12.4. Members agreed
- that a rolling knowledge and information (KIM) strategy should be linked to the HFEA's corporate plan,
  - the approach set out in sections 5 and 6 of the paper,
  - the strategic objectives.

## **13. Update from Committee Chairs**

- 13.1. The Chair, Lisa Jardine, reported on the Remuneration Committee, informing members that the committee had agreed the recruitment plans for the director of compliance and unpaid leave for the senior legal advisor. The committee agreed that fees for members should be replaced by a salary, bringing the organisation into line with other Arms Length Bodies (ALBs). The committee also took initial views on the Executive's pay remit for 2010/11.
- 13.2. The Chair of the Audit and Governance Committee (AGC), Sally Cheshire, reported that the Committee had reviewed the skeleton annual report and the latest version of the risk register. Members noted that the risk register is updated and reviewed on a regular basis by teams across the organisation.
- 13.3. The AGC had identified a number of projects resulting from the HFEA's change programme (Project 2010) that were still to be concluded. These

projects would need to be closely examined to see whether additional resources were needed in order to complete them.

- 13.4. Members were also informed that the chairs of the various committees would shortly be asked to provide feedback for the internal governance review.
- 13.5. The Deputy Chair of the Ethics and Law Committee (ELAC), Ermal Kirby, reported that the committee's horizon scanning event had been very successful and that a report of the event would be published shortly. A number of issues raised during the event have now been incorporated into the committee's workplan for the coming year.
- 13.6. The Chair of the Compliance Committee (ComCom) reported that the committee had approved updates to the Code of Practice, consent forms and General Directions, and had monitored the development of a new inspection template. The committee, working with the licensing chairs, had also agreed a number of modifications to the new licensing process.
- 13.7. Members were informed that ComCom had discussed the issue of licence application fees for research projects that take place at more than one centre. The committee recommended that the issue should be incorporated into the forthcoming fees review.
- 13.8. ComCom also approved additional inspection themes to address areas of practice that apply to centres which only carry out basic partner services. This decision required approval by the Authority.

#### **Decision**

- 13.9. Members of the Authority agreed the additional themes.

#### **14. A.O.B**

- 14.1. The Chair, Chief Executive and members thanked Trish Davies for her contribution to the work of the Authority during her tenure as Director of Compliance.

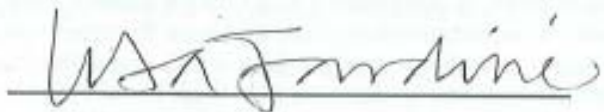
#### **15. Date of next meeting**

- 15.1. The next meeting will be on **Wednesday 12 May 2010** in London, time and venue to be agreed.

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

Chair

Date

  
19 May 2010