

Minutes of the Authority meeting 7 July 2010 held at Glaziers Hall, London SE1

Members

There were 13 members at the meeting, 8 lay members and 5 professional members.

Members present

Lisa Jardine (Chair)	Debbie Barber	Ruth Fasht
Alan Thornhill	Emily Jackson	Susan Price
Andy Greenfield	Ermal Kirby	Jane Dibblin (attended for afternoon session)
Anna Carragher	Lesley Regan	
Clare Lewis-Jones	Lillian Neville	

Apologies

David Archard	Neva Haites	Ros Gardner (HGC)
Gemma Hobcraft	Rebekah Dundas	
Sam Abdalla	Sally Cheshire	
Mair Crouch	Bill Ledger	

Observers

Ted Webb, Department of Health
Kim Hayes, Department of Health
Steve Pugh, Department of Health

Staff in attendance

Alan Doran	Paula Woodward	Joanne McAlpine
Mark Bennett	Siobhan Kelly	Nick Spears
Nick Jones	Charlotte Augst	Lauren Crawford
Juliet Tizzard	Danielle Hamm	Sharon Neaves
Catherine Drennan	David Williams	Zal Ahmet
Helen Richens	Hannah Darby	Joanne Anton
	Emer O'Toole	

Welcome, Apologies and Declaration of Interests

- 1.1. The Chair, Lisa Jardine, opened the meeting by welcoming Authority members, staff and members of the public.
- 1.2. Apologies were received from:
 - David Archard
 - Gemma Hobcraft
 - Sam Abdalla
 - Mair Crouch
 - Neva Haites
 - Rebekah Dundas
 - Sally Cheshire
 - Bill Ledger

1.3. Declarations of interest were made by:

- Alan Thornhill
- Debbie Barber

2. Minutes of 12 May 2010

2.1. On matters arising, members were informed that a further paper on PGD and OMIM numbers (item 6 of the May minutes) will be presented at the Authority meeting in September.

2.2. 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 the Authority was now operating under the tight financial restrictions imposed on all public bodies by the new government. Members were asked to take these restrictions into account when carrying out their duties for the Authority. Executive staff would be able to assist members with, for example, low cost travel and accommodation if required.

3.2. Chairs of committees were also asked to bear in mind the organisation's reduced capacity when asking the Executive to carry out any additional work for their committees.

3.3. The Chair announced that the planned 'roadshow' events had been cancelled as a result of the financial restrictions. The Authority would make alternative arrangements, such as greater use of the website, in order to maintain its dialogue with stakeholders and the public.

3.4. On the media, the Chair reported that a number of statements and comments had been issued by the Authority in response to studies emanating from the European Society of Human Reproduction and Embryology (ESHRE) conference in Rome. Topics covered included treatment abroad and tests for those concerned about their fertility.

3.5. The Chair reported that the Authority held its annual scientific Horizon Scanning meeting at the ESHRE conference. Members noted that a presentation at the meeting by Prof Bill Ledger (an Authority member) on blastocyst transfer and elective single embryo transfer (eSET) was particularly well received.

4. Chief Executive and Directors' Reports

4.1. The Chief Executive, Alan Doran, gave a brief presentation on the restrictions issued by central government in recent weeks and their impact on the work of the organisation. Specific restrictions on spending were now in place, including:

- Recruitment, pay and consultancy
- Property, procurement and IT
- Advertising and marketing
- Business travel

- 4.2. The Chief Executive reported that the business plan had been updated to reflect the new restrictions. While funding for two major projects on centre information and records management had been approved by the Department of Health, the overall number of projects set out in the plan had been reduced. Those projects that had been removed from this year's plan had been set aside for consideration at a later date.
- 4.3. The business plan would be finalised following publication of the Arms Length Bodies (ALB) Review, due shortly. The organisation would continue to closely monitor spending and maintain a very tight control of its budget. Members were also informed that the organisation now had a two year pay freeze in place, in line with that announced for all public sector workers.
- 4.4. The Chief Executive informed members that the new patient information booklet, Getting Started, had recently been published. A leaflet advertising the new, smaller format publication had been distributed to GPs surgeries and the response so far was very positive.
- 4.5. The Chief Executive reported that work to ensure that the last three sets of inspection reports for each centre were published on the website was almost complete.
- 4.6. The Chief Executive reported that letters will shortly be issued to centres setting out:
- the legal position regarding treatment abroad, and
 - informed consent and patient understanding of risk.
- 4.7. The Chief Executive reported that the Authority had received its first request for right to appeal under the new appeals regulations. Members of the Appeals Committee are not members of the Authority and are appointed separately.

Directors' Reports

- 4.8. The Director of Finance and Facilities, Mark Bennett, informed members that the annual report 2009/10 had been laid before Parliament. Due to the financial restrictions only a small number of black and white printed copies would be available.
- 4.9. Juliet Tizzard, acting on behalf of the Director of Strategy and Information, informed members that the Register Research Panel, meeting for the first time, had approved two applications for register information for research purposes.
- 4.10. Catherine Drennan, Legal Advisor, informed members that the Authority was not involved in any litigation at present.
- 4.11. The Director of Compliance, Nick Jones, informed members that, having only recently come into post, he was collating some early thoughts on the work of the compliance directorate.

5. Feedback from Hampton Working Group

- 5.1. Juliet Tizzard, acting Director of Strategy and Information, reminded members that the Hampton review team visited the HFEA in May 2009 to assess the organisation's performance against the Hampton principles.

- 5.2. The Hampton review team recognised that the Authority was in the process of implementing significant changes across the organisation and many of the Hampton team's recommendations had in fact already been addressed by the time the report was published in December 2009.
- 5.3. Following publication of the report, the Authority established a working group of members who examined the recommendations closely. The paper sets out their findings in four main areas:
- advice and guidance;
 - transparent;
 - data collection and information use;
 - compliance and sanctions.
- 5.4. Members noted that the Authority must carefully balance its need to understand the sectors it regulates alongside the importance of maintaining its independence as a regulator.
- 5.5. Members also noted that a legal advisor is always in attendance at Licence Committee meetings.
- 5.6. Members thanked Juliet and members of the working group for their efforts to address the remaining recommendations.

Decision

- 5.7. Members agreed that the Executive should carry out the specific pieces of work set out in the paper, subject to some minor changes for clarity.

6. Multiple Births update: outcome data & progress with compliance

- 6.1. Helen Richens, Policy Manager, presented members with an update on the progress of the multiple births policy.
- 6.2. Members were reminded that the policy had been introduced to address the increased risks to mothers and babies that result from multiple pregnancy and birth following IVF. Members were also reminded of the work the multiple births stakeholder group had undertaken to support the policy.
- 6.3. Members were informed the focus of the policy was now moving on to increasingly emphasise monitoring and enforcement.
- 6.4. Members were presented with an initial analysis of the multiple births data collected so far for 2009. Over two thirds of centres were expected to achieve the 24% target for their overall multiple birth rates, with many achieving a significantly lower rate. However, multiple birth rates for women over 35 had not reduced as much as those for women under 35.
- 6.5. The data also indicated that by the end of 2009, when clinics had fully implemented their strategies:
- the proportion of elective Single Embryo Transfer (eSET) had increased, especially in women under 35.
 - the proportion of blastocyst transfers had increased to just over one third of all fresh embryo transfers.

- 6.6. An analysis of clinic feedback found that most clinics had already audited their strategies and were implementing changes to improve them. The analysis also found that clinics had initially taken a cautious approach with their criteria for eSET but their confidence was growing as additional data and evidence becomes available.
- 6.7. Feedback from patients provided some insight into the reasons why patients choose double or single embryo transfer. Those who choose eSET said they did so because:
- information from clinic staff is strong and consistent;
 - they trust the clinic's recommendation; and
 - they are concerned about the risks of multiple birth.
- 6.8. Patients who choose double embryo transfer did so because:
- they are concerned about maximising their overall chances of pregnancy;
 - the risks are acceptable to them;
 - they wish to avoid further treatment.
- 6.9. Overall, patients reported that they want more information to help them make an informed decision about eSET and that they particularly value the opportunity to discuss their concerns and questions with clinic staff. Most patients also reported that they look for further information elsewhere, particularly on websites.
- 6.10. Members noted that communication with patients and helping them understand the risks of multiple pregnancy is key to the success of the policy. In particular, members noted the importance of clinics discussing eSET with patients at an early stage in their treatment as this gives patients the opportunity to review and consider their options and fully understand the risks well in advance.
- 6.11. Members thanked Helen for her continued hard work on the multiple births policy.

7. Translation and Interpretation Policy

- 7.1. Sharon Neaves, Communications Manager, informed members that, while the Authority has a duty not to discriminate against any person requiring its services, there is no specific legal duty to provide interpretation services or translation.
- 7.2. Regarding the Welsh Language Act, the HFEA is not one of the public bodies listed under Section 7 of that Act and is therefore not required to have a Welsh language scheme in place.
- 7.3. Members were informed that the obligations of the HFEA and those of treating clinics are different. The Code of Practice provides guidance to clinics on their responsibility to provide information in a format that patients can understand.
- 7.4. Translating can prove to be very costly and additional costs are likely to be incurred where specialist medical translation is required, where it needs to

be carefully checked for accuracy (e.g. legal information) and where the information is updated frequently.

- 7.5. Members noted that only two requests for translation had been received in the last two years. Members also noted that the financial restrictions had imposed an even tighter limit on the capacity of the organisation as regards all communication activity.

Decision

- 7.6. Members agreed that requests for translation of documents should be considered on a case by case basis, with the decision tree set out in the paper used for guidance.

8. Communications Strategy

- 8.1. David Williams, acting Head of Communications, informed members that the paper set out an overarching communications strategy designed to support the themes in the HFEA's new three-year corporate strategy. More detailed strategies would be developed to support specific areas of communication, such as media.
- 8.2. The Authority has a duty to provide information and needs to communicate with a wide range of audiences with different needs. A number of surveys and feedback received from key stakeholders provided the organisation with an indication of how it is perceived by various groups. Some see the HFEA as an organisation that informs choice and guards patients rights and safety. Others believe that it is overly bureaucratic with too many rules, or misunderstand its role and remit.
- 8.3. Members were informed that in recent years the organisation had developed its digital communication methods. The new website is now complemented by e-newsletters and electronic mailings to centres. These have the advantage of being lower cost than traditional mailings and paper-based publications
- 8.4. All communications, particularly higher-cost items such as events and conferences, would need to be reviewed in the light of the new financial restrictions on communications and marketing activity.
- 8.5. Members discussed the key messages in some detail and suggested that faith groups and academics should be added to the list of audiences.

Decision

- 8.6. Members agreed that the key messages should be amended in the light of the suggestions made during the discussion and that a revised list should be circulated to members.

9. Donation Review – early findings

- 9.1. Danielle Hamm and Hannah Darby reminded members that the paper is one of a series being presented to Authority before the launch of the donation consultation.
- 9.2. Members were informed that staff had undertaken a variety of activities to gather evidence for the review process including a clinic survey, a workshop on intrafamily donation and a literature review. A meeting of the

advisory group had taken place and the Ethics and Law Committee (ELAC) had discussed many of the issues in detail, making a number of recommendations that were included in the paper.

- 9.3. On donor codes, members were reminded that in January 2009 the HFEA agreed that donor codes (an internal auditing tool used by clinics) should no longer be issued to patients, subject to a review in due course. Legal advice obtained as part of this review made it clear that the HFEA has no discretionary powers to permit the release of donor codes to patients.
- 9.4. Members noted that the legal advice related to HFEA only and suggested that the position for clinics as regards issuing donor codes should also be clarified.
- 9.5. On the upper age limit for sperm donors, members were informed that the issue had been discussed by SCAAC and by the Scientific Horizon Scanning Panel. The committee and the panel found that while the quality of sperm does deteriorate with the age of the man, there is no clearly defined age after which sperm quality is reduced below an acceptable quality level.
- 9.6. Members were also informed that legal advice, sought regarding age limits and the new Equality Act, stated that an age limit can only be imposed where there is a good medical reason for doing so.
- 9.7. On conditional donation, (where donors restrict the use of their gametes or embryos for use by, for example, only married heterosexual couples, or only people of a particular faith), members were informed that the majority of clinics felt that conditional donation should be allowed.
- 9.8. Legal advice had been sought regarding the impact of the Equalities Act on conditional donation but the position was not clear. The Executive had therefore begun discussing the issue with the Equalities and Human Rights Commission (EHRC).
- 9.9. Members suggested that the Executive also discuss the issue with the Equalities Commissions in Northern Ireland and Scotland.
- 9.10. Members noted that it was not yet clear how the new equalities legislation might affect faith groups, and that conditional donation of organs and tissue was not permitted.
- 9.11. On intrafamily donation, members were informed that the HFEA does not currently provide any guidance on this issue. However, this form of donation raises a number of issues that are different from those raised by 'standard' donation (where an unknown donor is used). These include concerns around genetic problems, social and family relationships, pressure or coercion to consent, and different counselling needs.
- 9.12. Intrafamily donation may fall into two broad types: replacing gametes (e.g. where one sister donates eggs to another) or where gametes of close relatives may be mixed. Members were informed that there were no known examples of the latter as it would be caught by the welfare of the child assessment. However, there is no explicit prohibition either by law or through HFEA guidance.
- 9.13. Members noted that donation between close friends may raise similar issues to those raised by 'replacement' donation (i.e. sister to sister), in particular the relationships with any resulting child.

- 9.14. On a lower age limit for egg donors, legal advice stated that age restrictions may only be imposed where there is a good medical reason to do so. Members noted that counselling in order to ensure properly informed consent would be particularly important where donation is carried out between close family members.
- 9.15. On the consultation process, members were asked to reflect on the broader social and political context, and that a number of matters under review may impact on or be affected by issues that are not within or go beyond the HFEA's remit. These include:
- new family forms e.g. single sex families
 - new storage limits for gametes that bringing about the possibility of inter-generational donation
 - recipient matching services online
 - private financial arrangements
- 9.16. Members noted that the draft plans for the consultation process had been changed as a result of the financial restrictions imposed on public bodies.
- 9.17. Members thanked Danielle and Hannah for their efforts to set out some very complex issues clearly and succinctly.

Decision

- 9.18. On donor codes, members agreed to accept the legal advice and prohibit the disclosure of donor codes on a permanent basis, with the legal position to be clearly communicated to clinics via a Chair's letter and to affected stakeholders.
- 9.19. On the upper age limit for sperm donors, members agreed the Authority should no longer specify an upper age limit for sperm donation and that guidance in the Code of Practice should instead:
- give clinics the flexibility to assess the possible impact of donor age on a case by case basis, referring to the professional body guidance and relevant literature;
 - require clinics to provide all patients with information on the increased risk of miscarriage associated with advanced age (both maternal and paternal), alongside any other relevant information on risks of treatment;
 - refer to the Royal College of Obstetricians and Gynaecologists (RCOG) recommendations on reproductive ageing.
- 9.20. On conditional donation, members agreed that the policy should be determined by legal advice and by consultation with the UK's equalities bodies (such as the Equalities and Human Rights Commission) and that a paper on the options should be brought to Authority in due course.
- 9.21. On intrafamily donation, members agreed to consult on the ethical issues, policy approach and consultation approach identified by the Ethics and Law Committee (ELAC).
- 9.22. Members also agreed that the following issues would not be included in the consultation:
- the disclosure of donor codes;

- upper age limits for sperm donors;
- conditional donation.

10. Update from Committee Chairs

- 10.1. Mark Bennett, Director of Finance and Facilities, reported on behalf of the Audit and Governance Committee (AGC). The committee meeting on 16th June was not quorate due to member illness. Those attending the meeting discussed the papers but decisions were limited.
- 10.2. The representatives from the National Audit office (NAO) who attended the AGC meeting reported that the Authority's accounts were very well prepared and in good order, and that the Statement on internal Control (SIC) was an excellent example of this type of document.
- 10.3. The AGC also discussed a paper on the revised whistleblowing policy and recommended that the policy be forwarded to all Authority members for information.
- 10.4. Ermal Kirby, the Chair of the Ethics and Law Committee (ELAC) reported that the committee had discussed various issues relating to the donation review and had looked at significant risk in relation to PGD licensing.
- 10.5. Susan Price, Deputy Chair of the Science and Clinical Advisory Committee (SCAAC) reported that the committee had discussed a number of issues in particular potential treatments for mitochondrial conditions and the effects of age on sperm.

11. A.O.B

- 11.1. There were no additional items.

12. Date of next meeting

- 12.1. The next meeting will be on **Wednesday 8 September 2010** at Glaziers Hall, London, time to be agreed.

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

Chair W.A. Fardme¹
Date 10. ix. 2010