

## **ETHICS & LAW ADVISORY COMMITTEE**

**AT 21 BLOOMSBURY STREET**

**15 December 2009, 10.30am**

### **Members present:**

Richard Harries (Chair)  
David Archard  
Clare Lewis-Jones  
Sam Abdalla  
Mair Crouch  
Erica Haimes (External Member)

### **Executive present:**

Danielle Hamm (Secretary)  
Joanne Anton  
Juliet Tizzard  
Danny Edwards  
David Gomez  
Peter Thompson  
Catherine Drennan  
Alan Tipping  
Chris O'Toole (for item 8)

### **Observers:**

Craig Westwood (DH)  
Ellen Adams (Work Experience)

## **1. Apologies and declaration of interest**

- 1.1. Apologies were received from Neva Haites and Gemma Hobcraft.
- 1.2. Declarations of interests were declared both by Sam Abdalla (working in a licensed centre) and David Archard (Chair of the Licensing Committee). The Committee also noted that Peter Thompson is the Chair of the Executive Licensing Panel.

## **2. Minutes of the previous meeting**

- 2.1. The minutes for 20 October 2009 were taken to be a true record of that meeting following minor amendments, including that:
  - 7.10 be amended from 'in cases when there are no suitable embryos so clinicians carried out dummy treatment' to 'in cases when unnecessary treatment is carried out'; and
  - 7.12 be amended from 'stringent conditions' to 'stringent requirements.'

## **3. Matters arising**

- 3.1. The Committee noted and agreed the Matters arising from the previous meeting.

## **4. Chairman's business**

- 4.1. The Committee agreed the proposed alternative ELAC meeting date of 15<sup>th</sup> December 2010.

## **5. Secretary's business**

5.1. The Secretary gave a brief update on the PGD consultation event held on 1<sup>st</sup> December 2009 and of the Department of Health Hub and Spoke pilot. The pilot will support a donor recruitment centre to recruit, process and store sperm for use in the recruiting centre and several associated 'hub' centres, with the aim of increasing donor sperm availability.

## **6. Paper: HFEA Ethics and Law Horizon Scanning event – Update ELAC (12- 09) 1**

6.1. Joanne Anton presented an update paper on the HFEA Ethics and Law Horizon Scanning event. David Archard and Erica Haines, have liaised with the Secretariat and have agreed a proposed plan for the event.

6.2. Members were asked to consider an alternative date for the event. It was agreed however that, due to the limited availability of members to attend an alternative date, the event would be held on 24<sup>th</sup> February 2010 as originally scheduled.

6.3. It was agreed that David Archard would chair the event. It was also agreed that Sam Abdalla would participate as a panel member and that all other members of ELAC would participate as workshop facilitators.

6.4. The Chair invited members to contact Alan Tipping with further suggestions for invitees.

**ACTION: The Secretariat with the delegated members to continue to plan and organise the Ethics and Law Horizon Scanning event.  
JA/DH/AT**

## **7. Paper: Non-disclosure of genetic test results – proposed guidance ELAC (12-09) 2**

7.1. Joanne Anton presented a paper outlining the proposed guidance for the non-disclosure of genetic test results.

7.2. The proposed guidance was based on previous discussions by ELAC on the regulation of exclusion testing and PGD with non-disclosure and also reflected the feedback that was received from the consultation event on PGD licensing on 1 December 2009.

7.3. Members discussed the proposed guidance on the non-disclosure of genetic test results set out in section 5 of the paper. Discussion focused on sections (c) and d(ii) of the proposed guidance which would advise that dummy embryo transfers should not be performed

and for clinics to inform patients that where no embryos are suitable for transfer this is not evidence of their genetic status.

- 7.4. One member argued that patients may infer that they had the genetic condition, if informed that following treatment no embryos were suitable for transfer. The autonomy of the patient and their 'right' not to know would therefore be undermined if dummy embryo transfers were not permitted. This meant that patients would be unlikely to select PGD with non-disclosure if there was a risk of inadvertent disclosure. A minority of members therefore supported the view that dummy embryo transfers should be permitted as this would be the best option for the individual patient to prevent them from further suspecting that they had a genetic condition.
- 7.5. A small majority of members however felt that patients would already have strong suspicions that they had the condition, evidenced by the fact that they were choosing to undergo embryo testing in the first place. It was felt that the patients would have further suspicions and anxieties about their treatment if they were aware that pretend treatment may be performed. Members felt that such pretend treatment would amount to an unacceptable level of deception and could also lead to further distress and risk to the patient.
- 7.6. Members thought that the use of the term 'or other forms of pretend treatments' in section (c) of the draft guidance was unnecessary and should be deleted.

**DECISION: For recommendation to Authority:**

- **Following the amendment referred to at section 7.6, to agree the draft guidance on the non-disclosure of genetic test results.**

**ACTION: For JA to amend the draft guidance and to take a paper to the January Authority.**

**8. Paper: Case by case decision making in PGD  
ELAC (12-09) 3**

- 8.1. Danny Edwards presented a paper on case by case decision making in PGD for later onset, lower penetrance conditions and in cases of preimplantation tissue typing.

*Part one – the licensing of later onset, lower penetrance conditions*

- 8.2. Members discussed the proposed alternatives for licensing later onset, lower penetrance conditions.
- 8.3. Option one proposed that later onset, lower penetrance conditions continue to be licensed on a case by case basis. One member

highlighted that a benefit of this option was that it retained the importance of individual family and patient experience in licence applications. Another member identified that as treatment options improved this may sharpen public concern over the use of PGD for later onset, lower penetrance conditions. For this reason tight regulation of such applications was appropriate.

- 8.4. One member noted that in the updated PGD licensing scheme the Committee no longer received patient testimonies as most cases of PGD were now licensed on a condition by condition basis. This new regime brought advantages but it did mean that the Committee was in danger of losing the patient voice. The member emphasised the importance of robust mechanisms to ensure that the Licence Committee had sufficient evidence to consider any condition in general, whether it was a later onset, lower penetrance condition or fell into the standard PGD licensing scheme.
- 8.5. One member warned against changing the licensing practice solely on the grounds of reducing the time taken to licence applications. An alternative option would be to increase the frequency of the Licence Committee meetings.
- 8.6. No members supported option two which proposed continuing licensing applications on a case by case basis, but delegating all but novel decisions to the Executive Licensing Panel.
- 8.7. Option three and option four which proposed that applications be licensed on a condition by condition basis were considered jointly.
- 8.8. Members noted that option three proposed that clinicians would make decisions about the appropriateness of PGD in line with guidance in the Code of Practice on risk and seriousness. Members however noted that option four would make the consideration of risk and seriousness a mandatory requirement by introducing a Licence Condition.
- 8.9. The majority of members supported considering licence applications on a condition by condition basis as proposed in option three and four. Most members felt that there was little evidence of variability between applications and supported the speeding up of the application process that this method of licensing would entail, both for the patients and for the clinic staff.
- 8.10. The Committee heard that if the Authority were to introduce option three or four, the Licence Committee would maintain the discretion to licence conditions identified to be serious only in particular families on a case by case basis, if minded to do so.
- 8.11. Two members supported option three as opposed to option four as there was concern over how a clinic would be assessed and

regulated against a licence condition. The members emphasised that the preferable option would be for clinics to follow robust guidance in the Code of Practice on the appropriateness of PGD, rather than introducing a legal requirement.

- 8.12. The Committee noted that such a Licence Condition would apply to all PGD testing, and would not be limited to later onset, lower penetrance conditions. Members heard that this would require clinics to be satisfied in each case that the embryo was at risk of inheriting a particular mutation, that the condition was serious in that case and that the person with that mutation would be at risk of developing a serious genetic condition. Members noted that this could be evidenced through patient records showing discussions between the clinician, the patient, and the clinical geneticist on the risk and seriousness of the condition for the individual family case.
- 8.13. A small majority of members supported option four, for recommendation to Authority. Members noted that this option would not increase the regulatory burden on PGD clinics as they should already be using the guidance in the Code of Practice for assessing general PGD cases.
- 8.14. Following consideration of all the issues presented in the paper, the Committee agreed to recommend a move away from case by case regulation of later onset/lower penetrance conditions. Members decided, however, that in the absence of a clear consensus they would leave the question of how to regulate PGD more broadly i.e. through Code of Practice guidance (option 3), or through a Licence Condition (option 4) to the Authority to decide in January.

**DECISION: For recommendation to Authority (part 1):**

- **That later onset/lower penetrance conditions be licensed on a condition by condition basis in line with general PGD**
- **To decide on the method of regulation i.e. either through Code of Practice guidance or a Licence Condition**

**ACTION: For DE to incorporate the above discussion and recommendation into a paper to take to the January Authority.**

*Part Two – the licensing of preimplantation tissue typing*

- 8.15. Danny Edwards introduced the three proposed policy options for the licensing of preimplantation tissue typing as set out on page 18 of the paper.
- 8.16. The Department of Health updated the Committee regarding the then Minister for Public Health's comments in recent Parliamentary debate, as referred to in section 4.8 of the paper. The Committee was informed that it was the Department's view that the Authority does

have the latitude to review its policy on licensing on a case by case basis, provided it took into account the concerns raised during the Parliamentary debates (to which the Minister responded) in taking an evidence-based decision.

- 8.17. One member suggested that we recommend maintaining a case by case approach for now and that, in the meantime, we needed to consider how to acquire further evidence to inform our discussions. Possible sources of evidence might include a rigorously designed consultation exercise and also the views, values and experiences of donor siblings and their families. Members however noted the difficulty in obtaining the views of this very small group of children. It would also need to be clear how this evidence would be used to inform a change in licensing procedure.
- 8.18. Members agreed that there was evidence to support a move away from case by case licensing. However, the Chair of the Committee reminded members of the widespread concern in society on the issue of preimplantation tissue typing, and emphasised the arguments raised during the Parliamentary debates. The Chair identified that this matter was only recently debated in Parliament and that this should be noted by the Committee.
- 8.19. Members agreed with the concerns expressed in the paper regarding the time taken to licence preimplantation tissue typing. Members noted that steps had already been taken to reduce the time taken to licence such applications; however that the Authority should commit to further reducing the time taken for licensing decisions by the Executive Licensing Panel.
- 8.20. Members agreed to recommend to the Authority that for the time being the Authority maintain a case by case approach to tissue typing (policy option one).

**DECISION: For recommendation to Authority (part 2):**

- **That the Authority continues to licence applications for preimplantation tissue typing on a case by case basis; and that the Authority:**
  - **Commit to further reducing the time taken for licensing decisions by the Executive Licensing Panel**
  - **Produce more comprehensive patient information regarding tissue typing for the website.**

**ACTION: For DE to incorporate the above discussion and recommendations into a paper to take to the January Authority.**

**9. Any Other Business**

9.1. The Committee thanked and said farewell to Richard Harries as the Chair of ELAC and as a member of the Authority. The Committee noted that David Archard would become the Chair of ELAC for the interim period, until a permanent Chair is appointed.

**10. Time and date of next meeting**

10.1. The next meeting will be held on 23 March 2010, 10.30am.

**Control sheet**

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