

HFEA Licence Committee Meeting

03 December 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0049 (IVF Wales) – Breach of Licence Conditions

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair	Terence Dourado
Sue Price (lay)	Note Taker:
Rebekah Dundas (lay)	Stacey Kennedy
Apologies:	Legal Advisers:
No apologies	Mary Timms

The meeting convened at 10.35 with three members and a Legal Adviser. Members were requested to review two additional documents listed below at Minute 1.

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- Correspondence to the Person Responsible regarding the storage of gametes of patient SJF – Referral to the HFEA Licence Committee dated 11th November 2009.
- Investigation Report dated 10th November 2009
- Person Responsible's response to the report
- Redacted consent forms and patient records
- Correspondence between the Inspector Dr Andrew Leonard and the Head of Embryology Mr Lyndon Miles dated 26th October 2009
- Note of judgement in "L" case
- Judgement approved by the court for handling down "L" case
- R v HFEA, ex parte Blood
- Summary of advice from Dinah Rose QC of Blackstone Chambers
- Previous Licence Committee Interim Inspection Report
- Previous Licence Committee Minutes (for the past three years – note that some of the enclosed minutes are not to be published)

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance on periods for which new or renewed licences should be granted
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Decision on tabled documents

1. Two additional papers were presented to the Committee:-
 - i. An email from Ms A's Solicitor dated 2nd December 2009 enclosing a statement from Ms A dated 2nd December 2009 and a copy of an MT consent form completed by Mr B dated 2nd September 2009. The Committee noted that the consent form differed from the version in the committee bundle in that it contained a signature by a representative signed by a registered general nurse;
 - ii. A letter from the Executive to the Chair dated 3rd December 2009.
2. The Chair reminded the Committee of paragraph 6.2 of the Licence Committee Protocol which states that 'The Licence Committee shall not normally receive the recommendation of the Authority's Inspector dealing with the matter or any relevant supporting documentation from that Inspector, unless the applicant or person concerned (as appropriate) has been provided with a reasonable opportunity to comment on this material beforehand'.
3. The Legal Adviser reminded the Committee of paragraph 14.1 of the Licence Committee Protocol which states that 'The Committee may receive any written or real evidence whether or not such evidence would be admissible in a civil court of law in England and Wales, provided that it is satisfied that such evidence is relevant to the issues

on which it has to make a decision, and that it is fair to admit such evidence’.

4. The Committee agreed that the information from Ms. A was relevant. The Committee noted that it had been seen by the Executive. Although it was not clear that it had been seen by the Centre the Committee decided that it was fair to allow it into evidence because the contents were materially the same as the case previously put by the Person Responsible.
5. The Committee decided not to allow into evidence the letter from the Executive dated 3rd December 2009 because paragraph 6.2 of the Licence Committee Protocol states ‘The Licence Committee shall not normally receive the recommendation of the Authority’s Inspector dealing with the matter or any relevant supporting documentation from that Inspector, unless the applicant or person concerned (as appropriate) has been provided with a reasonable opportunity to comment on this material beforehand’. The Legal Adviser reminded the Committee that it could adjourn to allow the Person Responsible the opportunity to comment on the letter. The Committee decided not to adjourn because given the nature of the case it considered it was in the public interest for the matter to be decided expeditiously.
6. The Legal Adviser directed the Committee to put out of its mind the content of the letter from the Authority given that it was not allowing the letter into evidence.

Background

7. The Committee noted that the facts of this case did not appear to be in dispute. The issue was whether those facts amounted to unlawful activity and/or a breach of licence conditions.
8. The Committee noted that Ms A and Mr B were in the process of undergoing IVF treatment. An egg donor had been identified and was undergoing down regulation in preparation for egg collection. Mr B was admitted to the Royal Glamorgan Hospital on 22nd October 2009 unconscious following a brain haemorrhage. On 24th October 2009 sperm retrieval was undertaken at the Hospital and the sperm is now stored at the Centre.
9. Mr B had previously completed MT forms which provided consent for his sperm to be used to create embryos after his death or mental incapacity, but had not provided written consent for storage of his sperm. The Committee noted that the lack of written consent was acknowledged by the Centre. The Centre’s argument is that because Mr B had previously consented to use of his sperm after his death or mental incapacity consent to storage must be implied. The Centre also question whether a consent form for storage could be signed ‘at the direction’ of Mr B even though he could not sign the form himself.

10. The Committee noted that Ms A in her statement states that her and her partner's understanding was that the forms they signed by implication effectively gave consent for the storage of sperm before treatment. She states that she and her partner clearly understood the form Mr B signed to mean that he was formally authorising the storage of his sperm for use in treatment.
11. The Person Responsible made every effort to contact the Authority with a view to securing advice on how to proceed prior to procurement. She also took legal advice before proceeding. She also notified the HFEA as soon as she could that the procedure had been conducted. These events transpired at a weekend when it was difficult to secure the advice of the HFEA. The Committee also noted that Mr B's condition was such that the procedure could not be delayed beyond the weekend.

Decision on breach of licence conditions:

Procurement

12. The Committee was satisfied that sperm retrieval falls within the definition of procurement under Section 2(1) of the Human Fertilisation and Embryology Act 1990, as amended ("the Act"). In accordance with Section 4(1A) no person shall procure any gametes intended for human application except in pursuance of a licence or third party agreement. Dr Evans, the Person Responsible, accepts that the Royal Glamorgan Hospital is not licensed premises, and that there was no third party agreement in place. The sperm retrieval was therefore unlawful. This also constitutes a criminal offence under Section 41(2)(bb) of the Act.
13. In accordance with Section 12(1)(aa) of the Act it is a condition of every licence granted that the procurement of gametes shall be carried on only on the premises to which the licence relates, or on relevant third party premises. Since the Centre's licence does not relate to the Royal Glamorgan Hospital, that Hospital is unlicensed and there is no third party agreement in place with it, the Committee is satisfied that there has been a breach of the Centre's licence conditions.

Storage/ Consent

14. The Committee has decided that storage of Mr B's gametes is unlawful and a breach of the Centre's licence conditions for the following reasons:-
15. In accordance with Section 4(1)(a) of the Act, no person shall store any gametes except in pursuance of a licence.

16. In accordance with Section 12(1)(c) it is a condition of every licence that the provisions of Schedule 3 to the Act shall be complied with.
17. Paragraph 1(1) of Schedule 3 provides that consent must be in writing and subject to paragraph 1(2) signed by the person giving consent.
18. The Committee is satisfied that paragraph 1(2) of Schedule 3 is not relevant in this case. It applies to circumstances where a person has capacity to consent to storage and does consent, but is physically unable to sign the consent form. This is because that paragraph refers to a person who is “unable to sign” rather than unable to consent or lacking capacity to consent. There is also a requirement under that paragraph for the consent to be signed “at the direction” of the person unable to sign and in their presence, and in the presence of at least one witness. This indicates that the person consenting is instructing a third party to sign the consent on their behalf.
19. In accordance with paragraph 8(1) of Schedule 3 to the Act, a person’s gametes must not be kept in storage unless there is an effective consent by that person to their storage, and they are stored in accordance with the consent.
20. Paragraph 10 of Schedule 3 provides a limited exception to this principle allowing storage of gametes without consent where a person is 16 years or over if a number of conditions are met. However, the Committee has concluded that this exception is not relevant because paragraph 12 of Schedule 3 makes it clear that even if paragraph 10 applies a person’s gametes must not be kept in storage by virtue of paragraph 10 after the person’s death. Also, it is a condition of paragraph 10(2) that the gametes are “lawfully taken or provided” and the Committee has already determined that procurement was unlawful.
21. Given that Mr B did not give written consent for storage and given that the Committee has decided that paragraph 1(2) and paragraph 10 of Schedule 3 to the Act do not apply in this case, the Committee is satisfied that storage of Mr B’s sperm is unlawful and a breach of the Centre’s licence conditions.
22. The Committee took in to account Ms A’s submission that she and Mr B thought they were consenting to storage by signing the forms. The Committee also took into account the Centre’s submission that it considers consent is implicit in this case. Unfortunately the Act is specific regarding the requirements for consent and there is no provision in the legislation for consent to be implied.

Conclusion:

23. For the reasons stated above the Committee concluded that a breach of licence conditions has occurred and that Mr B’s gametes are not

lawfully stored in the UK. The Committee then went on to consider what action it should take in these circumstances.

24. The Committee asked the Legal Adviser whether they had power to issue special directions under Section 24 of the Act directing the continued storage of Mr B's gametes. The Legal Adviser advised that it is not clear whether such a power existed. Mr Justice Charles in *L v HFEA* [2008] EWHC 2149 (Fam) gave a preliminary review that he thought such power might exist. However, there has been no final decision by a court on this and when Mr Justice Charles referred to the power to issue special directions he was predominantly referring to such directions being made prior to retrieval of sperm, not after it (for example paragraphs 63, 99, 116 of his judgment). In this case it was not possible for directions to be made prior to retrieval.
25. Given the uncertainty of the legal position the Committee decided not to issue special directions requiring the storage to continue. The Committee noted that the Authority has confirmed in its letter to the Person Responsible dated 11th November 2009 that it would not be referring the matter to the Police.
26. The Committee then considered whether to impose conditions or revocation of the licence given that under Section 18(2)(b) the Committee would have grounds for being satisfied that the Person Responsible has failed to discharge her duty under Section 17. Such failure would be that she has failed to secure that the conditions of the licence are complied with in accordance with Section 17(1)(e).
27. However, the Committee decided not to impose a regulatory sanction at this stage given that there are a number of mitigating circumstances:
 - The Centre was faced with a difficult situation over a weekend period;
 - The Centre obtained legal advice before retrieving the gametes and made an attempt to contact the HFEA before retrieval of the gametes;
 - The Centre fully cooperated with the Inspector and has made no attempt to conceal the breaches of their licence conditions;
 - The Centre notified the HFEA promptly of their actions.
28. Given the breach of conditions and the unlawful procurement and storage identified the Licence Committee has determined that the gametes should no longer be stored in the UK. The Committee considered whether to require the Centre to dispose of the gametes immediately. It is clear from the Centre's submission in the Committee bundle that this possibility has been foreseen and discussed with Ms A. However, the Committee considered immediate disposal of the

gametes would be disproportionate given the mitigating factors and the tragic and unforeseeable circumstances of the case.

29. The Committee wishes to give the Centre an opportunity to make an application by 8th January 2010 for a special direction under Section 24(4) for the export of the gametes outside the UK. Ms A has indicated within her statement dated on 2nd December 2009 that she wishes gametes to be exported "for treatment abroad". The Committee was minded to make the time period 21 days given the seriousness of the breaches of the licensing requirements. However, given the Christmas and New Year period the Committee has determined that 8th January 2010 is a reasonable and appropriate deadline.

30. However, if the Centre does not avail itself of this opportunity by 8th January 2010, because the gametes are unlawfully stored within the UK they will have to be disposed of. If the Centre does not make the application within the specified timeframe or within that timeframe confirm to the Authority that the gametes have been disposed of the Licence Committee requires this case to be brought back to it immediately. At that stage the Committee would consider the possibility of further regulatory action.

31. The Committee recognises that this is a tragic case and has every sympathy with Ms A and Mr B's family but the Committee has a duty to ensure that the legislation is properly observed.

32. The Committee considered that the Centre obtained the appropriate consent for the treatment that was planned for this couple. With hindsight the Committee considers that the consent form MT could be more specific regarding storage and while the circumstances of this case were unforeseeable at the time consent was obtained the Committee wishes the Authority to give urgent thought to the redrafting of the consent forms to prevent any future ambiguity. The Committee would also support the Authority's decision to issue an alert to all centres reminding them of the "L" case and the requirements for effective consent.

33. After the Committee had concluded its deliberations and made its decision an email dated 3rd December 2009 and timed 14.10 was received by the Authority and brought to the Committee's attention at 14.21. The Committee considered this email but its contents did not alter the Committee's decision or reasoning.

Signed:

Date: 03/12/2009



David Archard (Chair)