Licence Committee Meeting

14 February 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

Newcastle Fertility Centre at Life (0017)
Licence Renewal

Members:
Emily Jackson, Lay Member – Chair
Ruth Fasht, Lay Member
Maybeth Jameson, Consultant Embryologist, Glasgow Royal Infirmary

In Attendance:
Frances Clift, Legal Adviser
Chris O'Toole, Head of Research Regulation
Claudia Lally, Committee Secretary

Observing:
Sally Cheshire, Lay Member
Anna Carragher, Lay Member
William Ledger, Professor of Obstetrics and Gynaecology, University of Sheffield

Conflicts 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:

- papers for Licence Committee (39 pages)
- no papers were tabled.

1. The papers for this item were presented by Debra Bloor. Dr Bloor informed the Committee that this centre treats a mixture of NHS and self-funded patients from North East England. Seven hundred treatment cycles were carried out at the centre in 2006, making this a large treatment provider, however, the number of frozen embryo transfers carried out is proportionally quite small. Some of the centre's facilities, including the laboratory, were undergoing refurbishment at the time of the inspection so these could not be covered by the inspection. One of the major issues arising at the inspection was the provision of counselling. This was because of the unusual practice at the centre of the clinical and nursing staff providing all of the implications counselling to patients. The Person Responsible explained that the staff providing the counselling are fully trained for this and the inspection team considered that the advantage of organising things in this way is

that all patients receive implications counselling and not only those who chose to arrange separate time with a counsellor.

2. Dr Bloor informed the Committee that another issue raised with the centre was an advert which the centre had used to recruit sperm donors which offered payment for the donation. However, the inspection team were reassured that the advert would no longer be used and that the senior andrologist was familiar with the requirements of sperm donor recruitment.

3. The report also noted that the centre does not tend to quarantine donor samples whilst awaiting test results, creating the risk (albeit small) that one affected sample would contaminate the others. The inspection team had suggested that the centre carries out a risk assessment of this practice.

4. Dr Bloor's presentation to the Committee also drew the Committee's attention to a number of other issues raised at the inspection. These were that the centre needed to improve the protocols setting out how the reasons for refusing treatment to a particular patient should be recorded, that the centre didn't have a way of formally recording training received by nursing staff, and that the centre asked patients for consent to storage of embryos at the time of embryo transfer, rather than earlier in the treatment cycle.

5. The Committee considered the points to which Dr Bloor had drawn their attention. They noted that implications counselling is provided by clinical staff at the centre and appreciated that this would ensure its wide accessibility to patients. However, the Committee agreed that what the centre refers to as implications counselling is in fact information giving. The Committee also agreed that it is essential that all patients are given the opportunity to discuss their treatment with someone who is not themselves involved in the treatment. For this reason the Committee agreed that it must be made clear to all patients that the option existed of talking about their treatment with a counsellor as required by section 13 of the Human Fertilisation and Embryology Act 1990. The Committee asked Dr Bloor to clarify this point with the centre and to report back to the Committee if this was not the case.

6. The Committee considered the issue of asking patients to complete consent documents relating to the storage of embryos at the point at which the patients have attended the centre to undergo embryo transfer. The Committee expressed a number of concerns about this practice, noting that it carries the risk that the patients will be so focused on the transfer itself that they will not be able to give the consent process the careful reflection that is required for informed consent. The most serious risk is that the male patient will not be able to attend the embryo transfer, or that the female patient is hospitalised and the transfer is therefore cancelled. This would result in a situation in which embryos required storage but could not be legally stored due to the absence of the necessary signed consent forms.

7. The Committee noted that the inspection team had asked the centre to perform a risk assessment of the practice of waiting for patients to attend the centre for embryo transfer before asking for consent to store any left-over embryos. The Committee agreed with this recommendation, but they asked that in performing this assessment the centre takes into account all the current and readily available advice (for example as produced by the Department of Health and the General Medical Council) about ensuring that consent given by patients for medical procedures is adequately informed. The Committee also agreed that the centre's risk assessment of its practice should take into account the risk of a damaging legal action brought by patients in a situation where embryos had to be discarded because consent to store them could not be obtained in time. The Committee noted that in any such action a court would take into account the fact that the centre's practice of obtaining consent to store only at the point of embryo transfer is contrary to established practice. The Committee agreed that the centre should subject its risk assessment within a month of receipt of these minutes.

8. On the issue of the centre's practice of not quarantining donor sperm the Committee noted that the risk of contamination between sperm samples is very small and that there have been no recorded instances where such contamination has occurred. They also noted that the centre is in the process of moving to vapour phase dewars which should reduce the risk even further. The Committee agreed, however, the centre should conduct a risk assessment of this practice and it further agreed that the centre might wish to consider delaying the re-start of its donor programme until vapour phase dewars have been installed.

9. The Committee endorsed Dr Bloor's recommendation she had made in the inspection report about the requirement to establish a more robust system for recording cases where patients had been refused treatment, and about the requirement to formally record the training received by nursing staff.

10. The Committee noted the centre's relatively low success rates and requested that the centre keeps these rates under review. The Committee noted that because the centre will soon be moving into its newly refurbished laboratory it would in any case be expected to be closely monitoring success rates in the coming months to acquire an understanding of how if at all the new facilities are affecting treatment outcomes.

11. The Committee noted the centre's low risk score and in light of this agreed that they were minded to grant a five year licence to the centre, subject to assurance on the counselling issue and on a satisfactory response from the centre to the issues raised in relation to obtaining consent to store embryos only at the point of embryo transfer. The Committee further decided that in order to synchronise the centre's treatment licence with its research licences, the licence

should be issued for four years and three months, to expire at the end of July 2011.

Signed……. … Date……..
Emily Jackson (Chair)