

Licence Committee Meeting

26 July 2007

21 Bloomsbury Street London WC1B 3HF

MINUTES Item 3

The Bridge Centre (0070) Licence Renewal

Members:

Clare Brown, Lay Member – Chair
Ruth Fasht, Lay Member
Roger Neuberger, Consultant
Obstetrician and Gynaecologist,
Leicester Royal Infirmary

In Attendance:

Marion Witton, Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice

Graham Miles, Morgan Cole Solicitors

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 (27 pages)
- one paper was tabled: "Report to the HFEA on the Findings of the Operational Audit Visit to 0070", dated 11 July 2007 (5 pages)

1. The papers for this item were presented by Wil Lenton, HFEA Inspector. Mr Lenton informed the Committee that the licence for this centre expires on 30 September and the renewal inspection visit took place in February. The centre has been licensed since 1992, it is one of the largest centres currently operating in the UK; it carried out a total of 1,800 cycles in 2005/6. Mr Lenton drew the Committee's attention to the fact that the centre has recently developed a new premises in Camden for the purpose of conducting PGS, being an area of their work that they are clearly looking to expand. The centre is working towards ISO accreditation and have recently made a number of key appointments to underpin the management structure. The premises appeared to be well appointed and fit for purpose. The centre's risk score at the time of the inspection was 21%, in the medium range, though this would be expected to reduce following the finding of the inspection visit that the centre has now fully complied with an additional condition previously attached to its licence requiring that low nitrogen level alarms are fitted to all dewars.

2. Mr Lenton informed the Committee that a focus of the inspection visit had been the fact that the centre runs an international egg donor and egg-sharing programme for women who cannot find suitable egg donors/sharers in the UK. Mr Lenton pointed out that since the implementation of the SEED guidelines (on 1 April 2006) the centre no longer imports or exports gametes or embryos with a view to patients receiving fertility treatment involving the use of gametes donated overseas, anonymously. However, the centre are providing drug treatment to patients by means of preparing them to receive treatment abroad with anonymously donated gametes.

3. The Committee expressed their concern about the international egg donor and egg-sharing programme. This concern focused on the fact that patients are receiving treatment, arranged by a UK clinic, with anonymously donated gametes. The Committee noted that it would not be legal to offer this treatment in the UK and that, in the case of children born following the use of anonymously donated eggs, the children concerned would have no means of learning about their biological parents. The Committee asked Graham Miles for his advice on this issue.

4. Mr Miles advised that paragraph G 3.1.1 of the Code of Practice (7th edition) states that a Licensed Centre should take into account the welfare of any child who may be born as a result of treatment. This requirement applies in relation to licensed centres because of the statutory licence condition contained in section 13 (5) of the 1990 Act. "Treatment services" are defined in the 1990 Act as meaning medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children. As paragraph G 3 1.1 of the Code confirms, treatment services include the administration of drugs. Accordingly, where the centre is proposing to administer drugs, or doing any other act amounting to treatment services, in relation to a patient who is to travel abroad to receive IVF treatment, the centre is under an obligation to take into account the welfare of the child. In taking into account the welfare of the child, the centre may be expected to have regard to the inability of any child born to obtain information about their genetic parents.

5. On the basis of Mr Miles' advice the Committee agreed to request that the centre provides information to them demonstrating that Welfare of the Child requirements are taken into account for those patients participating in its overseas programme and that these requirements consider the ability of any child born to know its genetic parents.

6. Taking into account the fact that the number of UK-run international programmes is not fully known by the Authority, the Committee agreed to refer this issue to the Regulation Committee, and asked the Executive to do some research on the extent of this practice and what options there might be for the HFEA to safeguard the right of children born from IVF treatment to access information about their biological parents.

7. The Committee then turned to consider the body of the inspection report and Mr Lenton briefly described the recommendations made by the inspection team on the day of the inspection visit (as detailed at page 8 of the inspection report). Mr Lenton informed the Committee that the centre has been working to address these recommendations and that in general he is satisfied with the progress that has been made to date.

8. The Committee asked Mr Lenton for more information about the recommendation relating to the timely reporting of treatment cycles. In reply Mr Lenton drew the attention of the Committee to the tabled report of a recent visit by the Audit Team. This report highlights the fact that to date there remain some difficulties with respect to the timely reporting to the HFEA of treatment outcomes. This was noted by the Committee, who requested that the centre works closely with the Audit Team to resolve the outstanding issues.

9. The Committee noted with concern the fact that errors relating to consents were found in three of 15 sets of patient notes reviewed by the inspection team, as described on page 19 of the inspection report.

10. The Committee discussed the comment at page 15 of the inspection report that the centre has given different answers to the question of who is going to take responsibility for improving communication between the centre and its satellite and transport units. The Committee agreed that it is not acceptable if, as seems the case, the centre has not yet appointed an individual to address this important issue. The Committee agreed to request that the centre forwards to the Executive, within one month of receipt of these minutes, an action plan to address this issue. The plan should be fully implemented no later than three months after the minutes have been received. The Committee asked the Executive to ensure that this is done and to make this issue a focus of the next inspection of the centre.

11. Page 15 of the inspection report also states that the number of complaints received by the centre have risen over the last three years. This was noted by the Committee who endorsed the suggestion made in the report that this trend is scrutinised as part of the Quality Management System.

12. The Committee decided to renew the centre's licence for a period of three years with no additional conditions.

Signed..... Date.....
Clare Brown (Chair)