



Human Fertilisation and Embryology Authority

Report of an interim inspection at

BMI Priory Hospital (0026)

Date of Inspection 23rd November 2005

Date of Licence Committee 10th April 2006

Contents

Key facts about the centre.....	3
Summary.....	4
Background to inspection.....	5
The centre's context.....	5
Type of work carried out.....	5
Staff.....	6
The premises, equipment and other facilities.....	7
Clinical, nursing and laboratory procedures.....	8
Procedures for assessing clients and for assessing and screening donors.....	8
Counselling process and facilities.....	9
Patient experience.....	10
Record keeping procedures.....	10
Data analysis.....	10
Audit.....	11
HFEA register.....	11
Clinical governance.....	11
Breaches of the Code of Practice or Act.....	13
Compliance with previous conditions and recommendations.....	13
Key points for the Licence Committee.....	14
Appendix A The inspection team and staff interviewed.....	15
Appendix B Sources of evidence.....	16

Key facts about the centre

Centre name The Fertility Centre

Centre address BMI Priory Hospital
Priory Road
Edgbaston
Birmingham
B5 7UG

Centre number 0026

Person responsible Robert Sawers

Nominal licensee Jane Cuthbert

Activities of centre

		2004/05
Licensed treatment cycles	IVF	204
	ICSI	131
	FET	59
	Egg Sharing	10
	Other	4
Donor Insemination		47
Unlicensed treatments	GIFT IUI	
Research	None	
Storage	Yes	

Focus of inspection General

Additional licence conditions None

Licence expires 30 April 2008
All payments to the HFEA are up to date.

Summary

1. The centre has been licensed since 1992 and is part of the BMI group of fertility centres. The centre offers licensed treatment to both private and NHS funded patients from Birmingham and the surrounding area.
2. The current licence is due to expire on 30 April 2008. The centre has a good history of compliance with no previous conditions on its licence. The three recommendations made by Licence Committee following the previous site visit have been implemented.
3. This interim inspection was undertaken on 23 November 2005. Currently the centre is carrying out around 450 treatments per year.
4. The centre is currently licensed to undertake Donor Insemination (DI), In Vitro Fertilisation (IVF), IVF with donor eggs, IVF with donor sperm, Intra Cytoplasmic Sperm Injection (ICSI), ICSI with donor sperm, Gamete Intra Fallopian Transfer (GIFT) with donor eggs, GIFT with donor sperm, storage of sperm, storage of embryos, assisted hatching (mechanical & chemical) and storage of sperm within testicular tissue.
5. The inspection team would like to draw the following points to the attention of the licence committee:
 - No breaches or issues were found during the inspection.
6. The inspection team supports the continuation of the centre's licence.

Background to inspection

7. This interim inspection report covers the period from November 2004 to November 2005. The report includes analysis of outcome data from 1 September to 31 August 2005.
8. The site visit took place on 23 November 2005.
9. The report was reviewed by the centre in January 2006.

The centre's context

10. The centre offers licensed treatment to both private and NHS funded patients from Birmingham and the surrounding areas.
11. Opening hours for the centre are from 9.00am to 5.00pm Monday to Friday and from 9.30am to 11am on Saturday and Sunday.
12. Since the previous inspection, some improvements have been made to the premises for example the completion of a new dewar storage room.

Type of work carried out

Licensed treatment

13. The centre carries out the following licensed treatments

- Donor Insemination (DI)
- In Vitro Fertilisation (IVF)
- IVF with donor eggs
- IVF with donor sperm
- IVF with egg sharing
- Intra Cytoplasmic Sperm Injection (ICSI)
- ICSI with donor sperm
- Gamete Intra Fallopian Transfer (GIFT) with donor eggs
- GIFT with donor sperm
- Storage of sperm
- Storage of embryos
- Assisted hatching (mechanical)
- Assisted hatching (chemical)
- Storage of sperm within testicular tissue
- Storage of eggs within ovarian tissue

Treatments that do not need a licence

14. The centre also offers GIFT, IUI and ovulation induction.

Staff

15. The inspection team was informed by the Person Responsible (PR) that there have been no staff changes since the previous inspection.

Staffing profile

Person responsible	Robert Sawers
Nominal licensee	Jane Cuthbert
Accredited consultant	Robert Sawers
Other medical staff	14
Embryologists	4 (one senior, two qualified and one locum)
ICSI practitioner	2
Nursing staff	3
Independent counsellor	1
Complaints manager	Jane Cuthbert (centre) and Kate Hayward (hospital)

Professional registration and continuing professional development (CPD)

16. Review of pre-inspection documentation sent to the HFEA and the information obtained during the site visit confirmed that the staff at the centre are registered with the appropriate professional bodies.
17. CPD for the staff at the centre is addressed in-house and where appropriate through external conferences and courses. The inspection team was informed by the centre's management team that recently one of the nurses has been on a fertility course and an embryologist was supported for ACE registration.
18. The nominal licensee informed the inspection team that all staff attend mandatory training on Health & Safety and resuscitation, this is provided by the hospital.
19. Regular multi-disciplinary team meetings are held by the centre to discuss clinical issues. The minutes of the meetings are available to all staff and an example of them was seen by the inspection team.

The premises, equipment and other facilities

Premises

20. The premises have not changed since last inspection.
21. The centre's current licence and complaints procedure were clearly displayed in the waiting area.

Equipment

22. The inspection team was informed that no significant changes have been made to the equipment since the last inspection. The centre has maintenance contracts for the equipment and these were seen by the inspection team.

Other facilities

23. There have been no other changes in the facilities since the last inspection.

Security

24. All clinical and laboratory areas are restricted to authorised staff only through a series of keypad locks.

Confidentiality

25. The centre has a dedicated storage room for the patient records which is secured by a keypad lock and only members of the staff have access to the records. This was seen by the inspection team and was found to be satisfactory.

Arrangements for collecting sperm samples

26. A dedicated sperm production room with a locked door and suitably equipped was seen during the inspection.

Cryostore facilities, oxygen and dewar alarms

27. It was noted by the inspection team that all of the dewars are equipped with low nitrogen level alarms and they are linked to an autodialler system.
28. The dewar room is equipped with a low oxygen level monitor, this was seen during the inspection.
29. The inspection team noted that samples for storage are being screened in line with the HFEA guidance on screening.

Emergency facilities

30. The PR informed the inspection team that the centre has access to the emergency facilities within the hospital and any patient who suffers from Ovarian Hyper Stimulation Syndrome (OHSS) can be admitted to the hospital under the consultants' care.

31. Staff have access to resuscitation equipment and a crash trolley both of which are kept updated by centre's staff.

Clinical, nursing and laboratory procedures

Clinical

32. The clinical protocols were fully reviewed and were found to be satisfactory, accurately reflecting clinical practice. The protocols are dated and version controlled.

Nursing

33. Development of nursing staff is encouraged. Their protocols are version controlled and reflect actual practices.

34. Nurses do IVF planning, information giving, non-diagnostic scanning and IUI. Nurses work one in three weekends on a rota basis.

Laboratory

35. The laboratory protocols are version controlled and reflect actual practices carried out at the centre.

36. Standard operating procedures for: cleaning vessels; filling vessels; securing vessels; freezing and thawing procedures; location and duration of storage and handling of contaminated samples were checked prior to the inspection and were found to be satisfactory.

37. Witnessing evidence in the patients records was seen by the inspection team.

38. The centre stores oncology samples and these have been split.

Procedures for assessing clients and for assessing and screening donors

Welfare of the child

39. During the inspection evidence was noted in the patient records of 'welfare of the child' assessment being carried out.

40. The inspection team was informed by centre's staff that the respond from the local GPs to the 'welfare of the child' assessment reports was satisfactory. The centre has a clear, concise protocol on how to handle cases where consent to disclosure is refused, the GP does not respond or the GP raises concerns.

41. Regular team meetings are conducted where potentially difficult cases are discussed.

Ethics committee

42. Over the last three years no case has been referred to the ethics committee. Any difficult cases are discussed at team meetings and no patient has been refused treatment since the last inspection.

Assessing and screening donors

43. A protocol for screening donors for HIV, Hepatitis B and C was seen by the inspection team.
44. All patients who are having treatment involving donor gametes have to see the counsellor prior to commencement of treatment.
45. The inspection team noted that procedures are in place to ensure that donors do not exceed the ten live birth events limit.

Counselling process and facilities

Counselling protocols

46. There are protocols to distinguish between counselling and assessment and they show a clear definition of staff roles in the process.

Counselling referral arrangements

47. All couples considering treatment with donor sperm or eggs are encouraged to attend a counselling session.
48. Patients are offered up to three free sessions of counselling as part of their treatment package. The counsellor informed the inspection team that additional sessions without charge are available, in particular for those patients who have had unsuccessful cycles. If required, the counsellor is able to refer patients to another counsellor.

Supervision and professional registration

49. Documentation submitted for the inspection showed that the counsellor is member of BICA. The counsellor receives regular supervision from a professional mentor and is up to date with her CPD.

Counselling audit

50. The inspection team was provided with a detailed statistical summary of counselling services offered to the patients. The data confirmed that there were 121 referrals from September 2004 to August 2005. Counselling sessions occurred for many of the treatments offered by the centre, with support counselling being the most frequent.

Location of counselling facilities

51. Patients are seen by the counsellor in a comfortable and dedicated room within the centre. Currently the counsellor keeps patients notes in her house in a safe with a combination lock. However, the counsellor is planning to transfer the notes to the centre.

Patient experience

Patient feedback

52. The BMI Priory Hospital conducts its own patient survey, which is broken down into individual departments and the information is shared with the senior staff from the centre. Any relevant information concerning the centre is discussed at the staff meetings.

53. A total of 29 completed questionnaires were returned to the HFEA. Comments received from all patients, except one, were positive. During the inspection, the findings of the patient questionnaires were discussed with the centre's staff.

54. During the inspection one couple was interviewed and their response was positive about the quality of service they had received.

Patient information

55. Patient information submitted to the HFEA was satisfactory.

56. Nurses and embryologists conduct most of the information giving and ensure that the correct consents are signed. The inspection team noted evidence of this in the patients records. This was also reflected in questionnaires returned to the HFEA.

Record keeping procedures

57. Ten sets of the patient records were examined from all types of treatment carried out in the centre. All the records were found to be satisfactory, except one of them had a missing consent form. The inspection team noted that the missing form was on the centre's computer database, yet to be printed.

Data analysis

58. The table below outlines the centre's outcome rates from licensed treatments between the 1 September 2004 and the 31 August 2005.

Type of Treatment	Number of cycles	Clinical Pregnancies as a % of cycles	Clinical pregnancies as a % embryo transfers
IVF	204	22.7%	27.9%
ICSI	131	22.1%	22.8%
FET	59	14.4%	20%
Total	394	22	27

59. The centre's DI success rate is above the national average of 11%.
60. In the 12 month data period supplied for the inspection, the centre had no ongoing triplet pregnancies and no triple live births.

Three embryo transfer arrangements

61. The 'three embryo log' checked by the inspection team showed that all the three embryo transfers undertaken by the centre were for patients over 40 years of age.

Audit

Centre's own audit of stored material

62. The senior embryologist at the centre reported that since the previous inspection, an audit of stored samples has been undertaken without any discrepancies.

Spot check of tracking process for stored material

63. A spot check of one embryo from records to the dewar and one embryo from the dewar to the records was carried out. The procedure was repeated for stored sperm samples. No discrepancies were found.

HFEA register

64. During the inspection, no issues regarding the HFEA register were raised

Clinical governance

65. The inspection team was informed by the PR that the Nominal Licensee (NL) is responsible for the clinical governance at the centre. The procedure for any internal incidents taking place has not changed since the last inspection.

Risk management

66. The NL informed the inspection team that copies of any HFEA Alert are distributed to staff and they sign a form when they have read it.
67. A hospital-wide incident policy which grades incidents as one or two is in place. Incidents are graded as two when there is some learning that can be shared with the rest of the hospital which may also lead to a change in practice.
68. The incidents are reviewed and analysed by the clinical governance manager of the trust to evaluate any trends and learning that can be shared. These are stored on the SAFECODE system. The inspection team was shown a log of the incidents relevant to the centre.

Incident Investigation

69. In August 2004, a dewar containing sperm for chemotherapy patients was found to be depleted of nitrogen and with a malfunctioning alarm attributed to power failure. The incident was investigated by the HFEA, Medicines and Healthcare products Regulatory Agency (MHRA) and the alarm manufacturer. A service bulletin was issued by the manufacturer to customers to check the twisting of power cables. Also an alert entitled Power Supply and Critical Equipment has been issued by the HFEA. During the inspection it was noted that various control measures have been implemented by the centre to avoid the re-occurrence of a similar incident.

Complaints

70. Thirteen complaints have been recorded since the last inspection. All, but one which is near completion, have been resolved. A log of complaints was seen during the inspection.

Breaches of the Code of Practice or Act

71.No breaches of the HFE Act were observed during the inspection.

Compliance with previous conditions and recommendations

Conditions

72.The centre does not have any additional conditions.

Recommendations

73.The licence committee made three previous recommendations they have been actioned as below.

<i>Recommendation</i>	<i>Adopted by centre (Y/N)</i>	<i>Comment</i>
1. Protocol for the treatment of ovarian hyperstimulation syndrome should be completed and submitted to the Executive within three months.	Y	
2. The centre should ensure that all clinical protocols are version controlled.	Y	
3. The counsellor does not keep a written record of the codes used on patient records.	Y	

Key points for the Licence Committee

74. The inspection team supports the continuation of the centre's licence for treatments set out in paragraph 13 above.

Issues

75. The inspection team would like to draw the following points to the attention of the licence committee:

Three recommendation made by the Licence Committee following the previous inspection have been implemented.

No issues were observed during the inspection.

Appendix A The inspection team and staff interviewed

The inspection team

Parvez Qureshi	Chair, HFEA inspector
Neelam Sood	HFEA inspector

Centre staff attending meetings with the inspection team

Meetings were held with person responsible and five other members of the staff

Conflicts of interest

None declared.

Appendix B Sources of evidence

1. Previous licence committee minutes
2. Previous inspection reports
3. Relevant correspondence between the centre and HFEA
4. Application form
5. Staff CVs
6. Outcome data from licensed treatments
7. Patient information
8. Consent forms
9. Treatment forms
10. Standard operating procedures and protocols
11. Audits of stored material; counselling and clinical practice
12. Interviews with centre staff
13. Feedback questionnaires from patients
14. Interview with a patient

Licence Committee Meeting

10 April 2006

21 Bloomsbury Street London WC1B 3HF

MINUTES Item 5

Centre: BMI Priory Hospital (0026) Interim Inspection

Members:

Walter Merricks, Lay Member – Chair
Jennifer Hunt, Senior Infertility
Counsellor, Wolfson Family Clinic
Hossam Abdalla, Clinical Director,
Lister Fertility Centre

In Attendance:

Trish Davies, Director of Regulation
Marion Witton, Head of Inspection
Claudia Lally, Secretary to the
Committee

Observing:

Sinead Glasgow, Legal Adviser, HTA
Sarah Hopper, HFEA Inspector

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 (44 pages)
- no papers were tabled:

1. The papers for this item were presented by Parvez Qureshi, HFEA Inspector. Mr Qureshi informed the Committee that this medium sized centre has a good history of compliance and currently has no additional conditions attached to its licence. Three recommendations made by a previous Licence Committee have all been implemented by the centre. The visit to the centre identified no issues to concern the inspection team.

2. The Committee agreed that the centre's licence should continue with no additional conditions.

Signed..... Date.....
Walter Merricks (Chair)