Licence Renewal Inspection Report for Treatment and Storage Centres

BMI Priory Hospital
0026

Date of Inspection: 30 October 2007
Date of Licence Committee: 28 January 2008

CENTRE DETAILS

Centre Address	BMI Priory Hospital Priory Road Edgbaston Birmingham B5 7UG
Telephone Number	0121 446 1501
Type of Inspection	Renewal Treatment and Storage
Person Responsible	Robert Sawers
Nominal Licensee	Jane Cuthbert
Licence Number	L0026-13-a
Inspector(s)	Parvez Qureshi (Lead)
	Neelam Sood
	David Gibbon (External)
Fee Paid - date	To be invoiced
Licence expiry date	30 April 2008

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About the Inspection:
This inspection visit was carried out on 30 October 2007 and lasted for 6 hours. The report covers the pre-inspection analysis, the visit and information received between November 2005 and October 2007.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements, recommendations or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The BMI Priory Hospital is privately owned and has been licensed since 1992. It has a good history of compliance with no previous conditions on its licence. The centre is privately owned and offers licensed treatment to both private and NHS funded patients. Currently the centre is carrying out around 500 treatments per year.

Since the previous inspection no major changes have been made to the premises. However refurbishment and some expansion of the premises will commence towards the end of year. An organisational chart is in place indicating key functions and lines of accountability.

The centre is open seven days a week between 7.15am and 5.00pm Monday – Friday and 7.15am and 2.30pm over the weekend.

The Person Responsible (PR) has completed the PR Entry Programme and is appropriately qualified to discharge his duties.

Activities of the Centre

01/01/2006 – 31/12/2006	
Licensed treatment cycles IVF ICSI Egg Donation	 273 185 23
Donor Insemination	11
Research	No
Storage	Yes

Summary for Licence Committee

Since the previous inspection a number of improvements have been made at the centre. However, some additional improvements are required to the service provided. Overall the centre appears to be well organised.

A number of Breaches of the Act or Code of Practice were identified. The weight to be attached to these reported breaches is a matter for the Licence Committee to determine.

The inspection team recommends the renewal of the centre's licence for treatment with storage for 5 years without any additional conditions.

Risk Assessment

The current risk matrix score for the centre is 5%.

EUTCD

The centre scored a low risk rating of 7% with regard to compliance with the requirements of the EUTCD

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	x	

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		x	
2. Quality of the service	x		
3. Premises and Equipment		x	
4. Information	x		
5. Laboratory and clinical processes	x		

Breaches of the Act, Standard Licence Conditions or Code of Practice
The table below sets out matter which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and or Code of Practice. The weight to be given to any breaches of the Act, Standard Licence Conditions or Code of Practice is matter for the Licence Committee.

Breach	Action required	Time scale
Contingency arrangements **(S.6.3.1, S.6.3.4)**	Written agreements need to be formalised.	Within a month from report being presented to a Licence Committee (LC).
Establishment and review of contracts with third parties and transport**. (S.4.2.10)**	All third party agreements need to be formalised.	Within three months from report being presented to a (LC).
Air Quality. **(S 7.8.5)** **(G9.4.1)**	Monitoring of air quality in the laboratory.	Within three months from report being presented to a LC.

Non-Compliance

Area for improvement	Action required	Time scale
None.	None.	---

Recommendations	Time scale
Currently the counsellor does not have a system in place for capturing patient feedback.	On-going.
The centre's complaints procedure requires updating to include HFEA details.	As soon as possible

Proposed licence variations

None.

Changes/ improvements since last inspection

Change of centre's ownership.
Resolution of issues raised in last inspection.
Updating of patient information.
Appointment of a Quality Manager.
ISO 9001 accreditation.

Additional licence conditions and actions taken by centre since last inspection

C	None.
A	None.

Report of Inspection findings

1. **Organisation**

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence is drawn from:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
Documentation including an organisational chart showing main functions and lines of accountability within the unit were submitted for the inspection. Key members of staff have extensive experience of working in the fertility field and have been at the centre for a considerable for time. A Quality Manager has been appointed to ensure that the centre complies with the new HFEA Standards and the requirements of the EU Tissue and Cells Directive. Issues highlighted in the recent application to vary the centre's licence to include intra-uterine insemination (IUI) treatment have been actioned or are in the process of being addressed. Regular multi-disciplinary team meetings are held to discuss practice related issues. Minutes of these meetings are made available to all staff including those who are unable to attend the meetings. Documented evidence for a number of recently held meetings was reviewed by the inspection team and considered to be satisfactory. Arrangements are in place for risk management and these are carried out as and when required, evidence of risk associated with security of information at the centre was made available for the inspection. The centre has an incidents log in place and this was reviewed during the visit and considered to be satisfactory. Entries in log showed that the HFEA had been informed of all appropriate incidents. The PR informed the inspection team that staff are made aware of the HFEA alerts and any action required is taken by the appropriate staff. This was further confirmed by the discussions held with members of staff. Review of the complaints log showed that all complaints received by the centre since the last inspection had been resolved.

The centre does not have access to an ethics committee. However, the PR stated that any difficult cases are discussed by the staff.

There are procedures in place for conducting regular audits of practice including patient feedback and centre's success rates, any areas of concern are addressed accordingly.

No issues have been raised by the HFEA finance department regarding payment of treatment fees.

Areas for improvement
The PR stated that in the event of an emergency the centre has informal contingency arrangements in place with other local centres. Written agreements need to be formalised. Currently not all third party agreements are in place.

Executive recommendations for Licence Committee
Contingency arrangements to be formalised. All third party agreements need to be formalised.

Areas not covered on this inspection
All areas covered.

Evaluation
Some improvement required.

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates
The information from the HFEA Success Rate Assessment (31st March 2002 – 1st April 2005) can be summarised as follows: The IVF/ICSI for all age groups except for 40-42 higher than national average. The FET for the age groups lower than national average. The DI for all age groups is above national average.
Areas of firm compliance
Discussions held with staff and a review of the documentation submitted for the inspection showed that 'Welfare of Child' assessment procedures are in place, further evidence of this was seen in the patients' notes. Patients' confidentiality is well maintained and evidence of this was seen by the inspectors. Treatment notes are stored in a secure area with only members of staff having access to them. Consultations with the patients are held in private rooms and any resulting treatment is documented in their notes. A patient was interviewed during the inspection and made complimentary comments about the quality service she received at centre. A total of 46 patient questionnaires were returned to the HFEA and majority of the responses made by the patients were positive regarding their experience at the unit. Counselling service at the centre is provided by two counsellors, both of them are member of the British Infertility Counselling Association (BICA). Patients are made aware of the counselling service through the patient information and at their initial consultation. The counsellor interviewed during the inspection confirmed that she receives regular supervision from a mentor, her continuous professional development (CPD) was up to date and she was well supported by staff.

No additional charge is made for counselling and currently there is no waiting list. Patients can contact the counsellors directly or through the staff. Counselling sessions take place in a dedicated room at the centre. A reference is made in the patients' notes. The counselling notes are kept separately from the clinical ones in a secure place.

The counselling audit submitted for the inspection confirmed that 250 referrals were made between July 2006 and August 2007, indicating a good uptake rate for the number of patients seeking treatment**.** Referral data show that implications counselling was the most frequently attended followed by supportive counselling.

A donor recruitment programme is in operation at the centre. Those accepted are required to undergo a thorough assessment procedure.

Areas for improvement
Currently the counsellor does not have a system in place for capturing patient feedback.

Executive recommendations for Licence Committee
None.

Areas not covered on this inspection
Protection of children arrangements (for patients under 18yrs).

Evaluation
No improvement required.

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
Since the last inspection no major changes have been made to the premises. However, the PR stated that refurbishment and some expansion of the centre will be taking place towards the end of 2007. This will address the current and anticipated increase in workload. Access to all rooms within the centre is via coded locked doors. All areas seen during the visit were clean and well presented. The scientific inspector considered the centre's current cryostore facilities to be adequate for the volume of work carried out. Access to the storage area is restricted to authorised personnel only. All dewars are alarmed and linked to an auto dialler. A spare dewar is available for emergency use. Gametes from patients with impaired fertility have been split into separate dewars. The cryostore facilities are fitted with a low oxygen monitoring system and there are adequate procedures in place for responding to alarms. There are procedures in place to ensure that all gametes and embryos are traceable from procurement of gametes to patient treatment. Since the last inspection, no major changes have been made to the equipment. Maintenance contracts are in place for key pieces of equipment and evidence of this was seen during the visit. Logs of activities carried out in the laboratory are kept. These were seen by the inspection team and considered to be well organised. In the event of a power failure the centre has access to a back up power supply.
Areas for improvement
Currently the air quality in the laboratory is not measured. However, the PR stated that this will be addressed when improvements are made to the facilities.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
All areas covered.
Evaluation
Some improvement required.

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of findings from inspection:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
Fifteen patient records were reviewed by the inspection team. The notes were found to be well organised with the relevant documents being in place. However, some discrepancies were found and these were discussed with staff for rectifying.
Areas of firm compliance
The information management system seen during the inspection was considered to be well organised. All treatment related information is stored in a secure area which is only accessed by staff. The patient information submitted for the inspection, including Ovarian Hyperstimulation Syndrome (OHSS), was reviewed and found to be of a good standard, The following information was also seen during the course of the visit: The Centre's treatment licence. Complaints procedure. Details of various treatments offered at the centre. HFEA leaflets. Counselling services. Forms to the HFEA Registry are sent within the required timescale.
Areas for improvement
The centre's complaints procedure requires updating to include HFEA details.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
All areas covered.
Evaluation
No improvement required.

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	5 (equivalent to 1.5 FETs)
NMC registered nurses	4 (equivalent to 3.24 FETs)
HPC registered scientists	4 (equivalent to 2.78 FETs)
Scientists working towards registration	1
Support staff (receptionists, record managers, quality and risk managers etc)	6 (3 contracted equivalent to 2.36 FETs) (3 bank equivalent to 0.92 FETs)

Summary of laboratory audit
The inspection team was provided with information of a recent laboratory audit of stored samples showing that all embryos have been audited but only one third of the sperm have been completed. No discrepancies were identified.
Summary of spot check of stored material
An audit of 2 embryos and 2 sperm samples was carried out. No discrepancies were found.
Areas of firm compliance
There are policies in place for assessment of patients seeking treatments and for screening of patients. These were evident from the documentation submitted for inspection and confirmed by the staff interviewed. Key protocols, including the management of OHSS reviewed by the inspection team, do reflect the quality of service being offered. There are robust witnessing procedures in place for the laboratory processes, documented evidence of this was seen during the visit. All staff from receptionist to the consultants have an opportunity to participate in an annual joint review of the service, improvements are made where needed. CPD for staff is well maintained and training requirements are discussed at annual

performance review.

Review of the 3 embryo transfer (3ET) log showed that a total of 25 were carried out between August 2006 and July 2007. The PR stated that 3ET is only carried out for patients who are above 40 years and reasons are documented in their notes.

Backgrounds including CRB are checked for all new staff joining the centre. A thorough induction programme is in place for new staff. Competencies are assessed in line with professional guidelines. Evidence of this was seen during the inspection and was further confirmed by staff interviewed.

Areas for improvement
None.

Executive recommendations for Licence Committee
None.

Areas not covered on this inspection
PGD/ PGS.

Evaluation
No improvements required.

Report compiled by:

Name……..Parvez Qureshi……

Designation…Inspector……

Date……6 December 2007……

Appendix A: Centre Staff interviewed

The PR and six other members of staff.

Appendix B: Licence history for previous 3 years

2007

Licence Committee 26th April 2007
The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

2006

Licence Committee 10th April 2006
The Committee agreed that the centre's licence should continue with no additional conditions.

2005

Licence Committee 20th January 2005
The Committee agreed to renew the centre's licence for three years with no additional conditions and made three recommendations.
The Committee agreed to licence the centre for the storage of eggs within ovarian tissue.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……...0026…….

Name of PR…….Robert Sawers……..…

Date of Inspection.…30 October 2007…….

Date of Response.…19 December 2007…….

Please state any actions you have taken or are planning to take following the inspection with time scales

(Comments taken from PR response received).

Contingency arrangements being formalised with Birmingham Women's ACU. Written agreements will be submitted within timescale specified.

Air quality now being measured.

Complaints procedure amended to include HFEA details.

Counselling questionnaire designed and agreed. To be implemented in early 2008.

I have read the inspection report and agree to meet the requirements of the report.

Signed……..Hard signed copy received from PR …….

Name…….Robert Sawers……

Date……..19 December 2007……

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

Third party agreements are in place and have been since 1 August 2007. These were viewed at inspection.

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

28 January 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

BMI Priory (0026)
Licence Renewal

Members of the Committee:

Jennifer Hunt, Lay Member – Chair
David Archard, Lay Member
Sally Cheshire, Lay Member
Hossam Abdalla, Director of Lister Fertility Centre

In Attendance:

Stephanie Sullivan, Interim Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice to the Committee:
Stephen Hocking, Beachcroft LLP Solicitors

Observing:
Ellie Suthers and Carol Horner, HFEA Inspectors
Simon Achonu, Beachcroft LLP (trainee)

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 (32 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 centre has been licensed since 1992 and has a good history of regulatory compliance. The centre is privately owned and offers around 500 treatment cycles per year to a mixture of private and NHS patients. Mr Qureshi summarised the issues highlighted in the inspection report and informed the Committee that the centre management has responded very positively to the findings of the inspection visit.

2. The Committee noted the response from the Person Responsible and suggested that it would be useful for the Executive to clarify the situation in relation to third party agreements.

3. The Committee noted the breaches identified in the inspection report and noted the prompt response to the inspection by the Person Responsible.

4. The Committee agreed that they were satisfied as to the suitability of the Person Responsible, the centre premises and the use of suitable practices at the centre. The Committee further agreed that it was satisfied that it had sufficient and satisfactory information on which to make a decision on the licence renewal.

5. The Committee unanimously decided to grant a 5 year licence with no additional conditions.

6. The Committee requested that the licence only be issued on receipt of the licence fee.

Signed..... Date.....6/2/08
Jennifer Hunt (Chair)