Unannounced Inspection Report

BMI Priory Hospital
0026

Date of Inspection: 13 March 2009
Date of Licence Committee: 22 June 2009

Centre Details

Person Responsible	Robert Sawers
Nominal Licensee	Jane Cuthbert
Centre name	BMI Priory Hospital
Centre number	0026
Centre address	BMI Priory Hospital Priory Road Edgbaston Birmingham B5 7UG
Type of inspection	Unannounced
Inspector(s)	Parvez Qureshi (Lead)
	Wil Lenton
Fee paid	Not applicable
Licence expiry date	30 April 2013
NHS/ Private/ Both	Private

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About the Inspection:

This inspection visit was carried out on 13 March 2009 and lasted for 6.5 hours.

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 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.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

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 has been licensed since 1992. The centre offers licensed treatment to both private and NHS funded patients.

Since the previous inspection in October 2007, refurbishment and some expansion of the premises have taken place. However, plans have been drawn up for a possible relocation of the centre to a new site in the near future. There is an organisational chart in place defining key functions and lines of accountability within the unit. The centre is open for business seven days a week.

The centre underwent a renewal inspection in October 2007 and the Licence Committee granted the centre a 5 year licence with no additional conditions.

The Person responsible (PR) Mr Robert Sawers is registered with the General Medical Council (GMC) and is appropriately qualified to discharge his duties, as outlined in Section 17 of the HF&E Act (1990).

Activities of the Centre[1] for the time period from 01/01/2008 – 31/12/2008

In vitro fertilisation (IVF)	377
Intracytoplasmic sperm injection (ICSI)	246
Egg Donation	4
Intra uterine insemination (IUI)	110
Research	No
Storage gametes/embryos	Yes

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

Summary for Licence Committee

This was a randomly selected unannounced inspection of the centre. The inspection team considered the centre to be well organised and managed by an experienced team.

Some improvements are required in the centre's premises and equipment and laboratory and clinical processes: improvements relate to the following aspects of the centre's practice:-

- Development of documented procedures for the management of equipment and materials that include: traceability of any materials that come in contact with gametes or embryos in compliance with S.6.4.3(d), S.7.3.1(d) and A.3.1(b).

- Development of a documented procedure for measuring air quality in the laboratory area, licence condition A10.19; S.6.3.6(b) and S.7.8.5(a) In addition the centre should validate the procedures for air quality monitoring to provide evidence that the air quality is maintained in the interval between testing as required by S.7.8.3.

- When reviewing the document entitled, 'Laboratory Protocols' several areas (as mentioned in section 5) were found to be non-compliant with guidance G.13.1

- The protocol for transportation and receipt of gametes and embryos is not fully compliant with HFEA Alert 21.

- Review of the embryology daily checklist revealed that personnel were recording '%CO_2 levels' which were at variance with the given 'acceptable limits' printed on the checklist recording sheet.

Organisation, quality of service and information were found to be compliant.

A positive post inspection response has been received from the centre indicating that issues highlighted during inspection have already been addressed or are in the process of being actioned.

The inspection team supports the continuation of the centre's treatment and storage licence without any additional conditions.

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 matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
The centre has a traceability system in place for materials that come into contact with gametes and embryos, however, no documented procedure is in place for this process.	The centre shall establish documented procedures for the management of equipment and materials that include: traceability of any materials that come in contact with gametes or embryos in compliance with S.6.4.3(d), S.7.3.1(d) and A.3.1(b).	Post inspection information submitted to the HFEA confirms that this breach has subsequently been addressed by the centre.
The centre monitors air quality in the laboratory area but there is no documented procedure describing this process.	Development of a documented procedure for measuring air quality in the laboratory area in compliance with licence condition; A.10.19; S.6.3.6(b) and S.7.8.5(a).	To be monitored at the time of the next inspection.

Non-Compliance

Area for improvement	Action required	Time scale
When reviewing the document entitled, 'Laboratory Protocols' several areas as mentioned in section 5 were found to be non-compliant with guidance G.13.1	Review/amendment of written witnessing procedures to be undertaken to ensure compliance with guidance G.13.1	To be monitored at the time of the next inspection.

Recommendations

Area for improvement	Action required	Time scale
The protocol for transportation and receipt of gametes and embryos was not fully compliant with HFEA Alert 21.	The centre should review its documented procedures for procurement, packaging, distribution and recall, and receipt of gametes and embryos to ensure that it is fully compliant with the recommendations of Alert 21.	Post inspection information submitted to the HFEA confirms that this issue has been addressed by the centre.
Review of the embryology daily checklist revealed that personnel were recording $\%CO_2$ levels which were at variance with the given 'acceptable limits' printed on the checklist recording sheet.	The centre should ensure that records are a reliable and true representation of the results in compliance with S.5.2.7.	To be monitored at the time of the next inspection.

Changes/ improvements since last inspection

Recommendations.	Action Taken
Contingency arrangements to be formalised	Evidence of implementation provided.
Establishment and review of contracts with third parties and transport.	All third party agreements are in place.
Monitoring of air quality in the laboratory.	Evidence of implementation provided.
Capturing patient feedback by counsellor.	Evidence of implementation provided.
The centre's complaints procedure requires updating to include HFEA details.	Complaints procedure has been amended.

Additional licence conditions and actions taken by centre since last inspection

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 the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
There is an organisational chart in place showing key responsibilities and lines of accountability. The inspectorate considered the centre to be well organised and managed by an experienced team who have been working in the fertility field for a considerable time. This was further reflected in the timely manner in which information requested was provided during the course of this unannounced inspection. Issues highlighted during the previous inspection in October 2007 have been addressed and documented evidence of this was made available for the inspectorate. There are procedures in place for the identification, notification and investigation of incidents. Review of incidents log showed that the HFEA had been informed of all appropriate incidents within the required time frame. Documented evidence was seen for the management and dissemination of HFEA alerts and this was further confirmed by the staff who met the inspection team. The centre's complaints log was reviewed during the visit and evidence of actions taken to resolve complaints effectively were noted. There are contingency arrangements in place with Birmingham Women's Hospital centre 0119. All third party agreements are in place a sample of which were reviewed and considered to be compliant with HFEA guidelines. Evidence of multi-disciplinary team meetings held at the centre to discuss practice related issues was seen by the inspectorate. All staff have access to the minutes of these meetings.

A review of minutes of recently held meetings showed that in addition to the centre's business, HFEA related issues were also discussed.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
No improvement required.
Areas not covered on this inspection
Clinical governance Payment of licence/treatment fees Risk management

2. Quality of service

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

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
For the time period from 1 January 2004 to 31 March 2007 the centre's live birth rates were in line with national averages for all treatment types and in all age bands. In the time period from 1 January 2008 to 31 December 2008 the centre provided 110 cycles of IUI and report that 11 clinical pregnancies resulted from the treatments.
Areas of firm compliance
A quality policy and a comprehensive quality manual are in place. Evidence of implementation of the quality management system (QMS) was made available to the inspectorate and was considered to be compliant with the Code of Practice 7th Edition. There are arrangements in place for conducting audits of practice including reviews of outcome of treatments, patient satisfaction and cost of treatment. The inspection team was informed by staff that findings of audits are discussed at Quality Team meetings and any areas of concern are subject to corrective action. Evidence of this was seen in the minutes of a recently held Quality Team meeting. The centre has an effective document control procedure in place. This was evident from the documents reviewed during the course of inspection and discussions held with staff who met with inspectorate.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
No improvement required.

Areas not covered on this inspection
Feedback.

3. Premises and Equipment

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

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
Since the last inspection in October 2007, some refurbishment and expansion of the premises has taken place. During this visit not all the facilities were inspected. However, those areas which were seen appeared clean and well presented with controlled access to them. Air quality in the laboratory is measured by an external contractor at 6 month intervals to ensure that processes take place in an environment of at least Grade C air quality with the background air quality being of at least Grade D. Maintenance contracts are in place for key pieces of equipment and documented evidence of a sample of contracts was reviewed by the inspectorate.
Areas for improvement
Although air quality is measured in the laboratory area, there is no documented standard operating procedure in place for this process**.** Review of the embryology daily checklist revealed that personnel were recording '%CO_2 levels' which were at variance with the given 'acceptable limits' printed on the checklist recording sheet.
Areas for consideration
None.
Executive recommendations for Licence Committee
Centres must include in their Standard Operating Procedures all processes that affect quality and safety of gametes and embryos (specifically processes for monitoring air quality) in compliance with S.7.8.5(a); S.6.3.6(b) and licence condition A.10.19. The centre should ensure that records are a reliable and true representation of the results in compliance with S.5.2.7.

Evaluation
Some improvement required.
Areas not covered on this inspection
Clinical facilities. Counselling facilities. Laboratory facilities. Storage facilities for gametes and embryos. Staff facilities. Storage of records.

4. Information

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

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance
Five sets of patient records were reviewed by the inspection team. The notes were found to be well organised and all contained consents which were compatible with the treatment provided. Evidence of welfare of the child assessments being conducted at the centre was also noted in the patient records. Since the previous inspection, the centre's complaints procedure has been updated to include HFEA details Patient confidentiality is well maintained and access to patient records is controlled. The centre has a procedure in place through which patients can obtain a copy of their medical notes. No issues were raised by the HFEA registry regarding quality of data being submitted by the centre.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
No improvement required.
Areas not covered on this inspection
Information for service users.

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	
NMC registered nurses	
Non NMC registered clinical staff	
HPC registered scientists	
Scientists working towards registration	
Support staff (receptionists, record managers, quality and risk managers etc)	
Counsellors	

Summary of laboratory audit
An audit of cryopreserved samples was conducted in June 2008. No discrepancies were identified.
Summary of spot check of stored material
Not carried out during this inspection.
Areas of firm compliance
Evidence of continuous professional development (CPD) for staff was made available for the inspectorate. In addition, where appropriate, staff competencies have been documented. Mandatory training such as basic life support and manual handling is provided on a regular basis. The centre has policies in place for the assessment of patients seeking treatments and for screening of patients. This was evident from the review of the documentation during the course of the inspection and discussions held with staff who met with the inspection team. A system of unique coding of patients to assist the traceability of samples is in place.

Areas for improvement

The centre's protocol for transportation and receipt of gametes was reviewed against the requirements of HFEA Alert 21 and was found to be not fully compliant. The protocol does not cover the procedure if labelling on the samples has degraded in anyway.

The centre has a traceability system in place for materials that come into contact with gametes and embryos. However, no documented procedure is in place for this process. S.6.4.3(d), S.7.3.1(d)

During the review of the document, 'Laboratory Protocols' it was noted that;

1. On page 27; section entitled, '8 Cryopreservation Protocols'; '8.1 Preparation'; point 2 it states, '.label each dish and lid with patient's name' – which refers to only one identifier and which is contrary to guidance at G.13.1.

2. On page 30; section entitled, '9 Embryo Thawing';

i. point 1) is incomplete. 'Enter the treatment onto EDI. Complete ********** and witnessing form'

ii. point 2) states, 'prepare a labelled and witnessed Nunc 4-well dish'
There is no specification as to exactly what, 'labelled' or 'witnessed' is pertaining to and needs more specific instructions for standardisation of procedure.

iii. There are two point 5)'s within the protocol.

iv. At the first 'point 5)' it states, 'This must be witnessed and recorded' – there needs to be more specific instruction as to what is witnessed and recorded.

3. On page 61/62; section 17.2, 'Discarding sperm or embryos' at paragraph 2 it states, 'These details are then transferred onto the frozen sperm/embryo audit sheet' – need to specify what details are to be transferred/recorded.

At paragraph 4 it states, '.embryo straws should then be identified' but again does not mention specifically what these identifiers are and how they are checked.

At paragraph 5 it states, 'Prior to allowing the straws to thaw, straws must be cross-checked.' It should be specified which patient identifiers on the straws are to be checked (as being correct as cross-referenced against patient notes.)

4. On examination of a patient's notes it was noted that there had been a deviation from the centre's written witnessing policy as only 2 signatures had been recorded when the patient was identified prior to egg collection. The centre should either keep to the written policy or change the written policy to reflect practice.

The areas highlighted during inspection require to be reviewed and amended in order to be compliant with current guidance G.13.1

Areas for consideration
The centre should review/amend its documented procedures for procurement, packaging, distribution and recall, and receipt of gametes and embryos to ensure compliance the recommendations of Alert 21
Executive recommendations for Licence Committee
The centre shall establish documented procedures for the management of equipment and materials that include: traceability of any materials that come in contact with gametes or embryos in compliance with S.6.4.3(d), S.7.3.1(d) and A.3.1(b). Review/amendment of written witnessing procedures to be undertaken to ensure compliance with guidance G.13.1
Evaluation
Some improvements required.
Areas not covered on this inspection
Selection and validation of laboratory procedures. Coding/ identification of samples. Screening of donors. Counselling practice. Counselling audit. Storage of gametes and embryos.

Report compiled by:

Name……Parvez Qureshi…….

Designation……..Inspector…….

Date……...14 April 2009…….

Appendix A: Centre staff interviewed

No formal interviews were conducted. However, a number of staff were asked for assistance with the inspection.

Appendix B: Licence history for previous 3 years

2008

Licence Committee 28h January 2008
The Committee unanimously decided to grant a 5 year licence with no additional conditions. The Committee requested that the licence only be issued on receipt of the licence fee.

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

Appendix C: Response of Person Responsible to the inspection report

Centre Number……0026……

Name of PR……..Mr Robert Sawers…….

Date of Inspection…..13.03.2009……..

Date of Response……02.06.2009……

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

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

Name……Mr Robert Sawers …….

Date……02.06.2009……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

The recording of CO_2 levels by the duty embryologist are the actual readings taken on a daily basis. These are "a reliable and true representation of the results". The recorded results are the required levels of CO_2. The centre accepts that the form on which this information was recorded required alteration at the time of the inspection. The "set points" – the acceptable limits, required alteration from previously set levels to the new levels of CO_2 which were required by the recently introduced new media. We continue to maintain that the levels recorded were "reliable and true."

The centre continues to maintain the assertion that the inspection team were in attendance at The Priory Hospital from 9.15am until after 5.15pm. The inspection therefore lasting more than 8 hours. The validity of this can be proven as the inspectors signed into the hospital and we can show that they stayed for this length of time if needed.

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

The centre would like it noted that all areas where the inspection team had concerns with the documents provided at the inspection were addressed immediately and revised documentation sent to the Lead Inspector. Unfortunately some of the areas which required amendment on page 17 were not brought to our attention at the time of the inspection feedback or at the previously issued inspection report. The centre was therefore unable to promptly provide amended paperwork in a timescale which it would have wished. The areas of concern have now been address and revised paperwork has now been sent to the lead

inspector.

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

Protocols have been re-written to fully `comply with the requirements of the Code of Practice. As noted in the inspection report the documents which we were aware of needing revision were revised immediately post inspection and the documents sent to the lead inspector. As stated above the most recent documents requiring revision have now been sent to the lead inspector.

The laboratory sheet for recording the daily temperature and CO_2 levels has been amended so that the set values have been removed from the form so that the “confusion” over the actual recorded levels has been resolved.

In order to facilitate the inspection process the centre should like it noted that a senior embryologist was required to be called in on their day off to provide laboratory cover to enable The Centre Manager and Quality Manager (the two duty embryologists on this day) to assist the inspectors. The longevity of the inspections process also required staff to extend their normal childcare arrangements beyond the normal clinic opening hours for this day.

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

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

HFEA Licence Committee Meeting
22 June 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 8

BMI Priory Hospital (0026) – Unannounced Inspection

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Jennifer Hunt (counsellor) Hossam Abdalla (clinician)	Kristen Veblen Legal Adviser: Mary Timms, Field Fisher Waterhouse Observers: Mark Bennett, HFEA Peter Thompson, HFEA

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:

- papers for licence committee (24 pages)
- no tabled papers.

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009.

1. The Committee noted that the previous inspection of this licence was a renewal inspection conducted in October 2007 and that the Centre had been granted a 5 year licence following this inspection.

2. The Committee considered the papers, which included the report of the unannounced inspection, a response from the Person Responsible (PR) and the minutes of the Committee meeting on 28 January 2008.

3. The Committee noted that the unannounced inspection had been conducted on 13 March 2009 and the following areas for improvement relating to the Centre's practices were identified:
   - development of documented procedures for the management of equipment and materials that include traceability of any materials that come in contact with gametes or embryos in compliance with 7th Code of Practice S.6.4.3(d), S.7.3.1(d) and Standard Licence Condition A.3.1(b)
   - development of a documented procedure for measuring air quality in the laboratory area, in compliance with licence conditions A.10.19 and standards, S.6.3.6(b) and S.7.8.5(a). Additionally, validation of the procedures for air quality monitoring to provide evidence that the air quality is maintained in the interval between testing as required by standard S.7.8.3
   - ensuring compliance with guidance G.13.1 in relation to laboratory protocols
   - the protocol for transportation and receipt of gametes and embryos was not fully compliant with HFEA Alert 21
   - discrepancies regarding the recording of CO2 levels and the stated 'acceptable limits' on the printed checklist.

4. The Committee noted the positive actions in the response made by the PR and the submission of information confirming that some of the breaches had been addressed and confirmation that the other issues were being addressed. It also noted the recommendation by the Executive that the Licence should continue without any additional conditions.

The Committee's Decision

5. The Committee decided to continue the licence with no additional conditions.

6. The Committee noted that the outstanding issues would be monitored at the time of the next inspection, and endorsed the recommendations of the inspectorate in relation to the outstanding breaches.

Signed..... ... Date 7/July/09
David Archard (Chair)