Interim Inspection Report

Date of Inspection: 11 November 2010
Length of inspection: 6 hours
Inspectors Parvez Qureshi
Sara Parlett

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between 13 March 2009 and 18 February 2011.

Date of Executive Licensing Panel: 18 February 2011

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence interim 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 Authority's Executive Licensing Panel which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	BMI Priory Hospital
Centre Number	0026
Licence Number	L0026-14-b
Centre Address	BMI Priory Hospital Priory Road Edgbaston Birmingham B5 7UG
Telephone Number	0121 446 1501
Person Responsible	Robert Sawers
Licence Holder	Jane Cuthbert
Date Licence issued	01 May 2008
Licence expiry date	30 April 2013
Additional conditions applied to this licence	N/A

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Report to Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including four major area of non-compliance and two other areas of non-compliance or areas of poor practice.

Since the inspection visit on11 November 2010 the PR has provided information that, in the view of the inspection team, provides sufficient information to conclude that the centre has implemented the following recommendations:

Major areas of non compliance:

- The PR should ensure that all critical equipment is validated.
- The PR should ensure that quality indicators (QIs) are established and monitored for donor recruitment and selection processes.

Other areas of practice that require improvement:

- The PR should ensure that the assessment of staff competence to perform key activities is documented.
- The PR should ensure that the witnessing records include the name, status and signature of the person performing the activity and the name, status and signature of the person who witnesses the procedure.

The PR has also given a commitment to implement the following recommendations:

- The PR should ensure that all critical processes are validated.

In relation to the recommendation that the PR should ensure that donor recruitment and selection processes are audited at an appropriate frequency, the PR commented post inspection that there is a rolling audit of these activities on completion of a donor checklist. The Executive Licensing Panel is asked to endorse the further recommendation that the PR should ensure that the findings and corrective actions of this rolling audit are documented.

The inspection team considers that overall there is sufficient information on which to recommend the continuation of the centre's licence without additional conditions.

Details of Inspection findings

Brief description of the centre and its licensing history:

The BMI Priory Hospital has been licensed since 1992. The centre is privately owned and offers licensed treatment to both private and NHS funded patients.

Since the last unannounced inspection in March 2009 the premises have not undergone any major changes. Business hours are between 9.00am and 5.30pm Monday to Friday and weekends as required.

The PR is registered with the General Medical Council (GMC). He is also a Fellow of the Royal College of Obstetricians and Gynaecologists (FRCOG) and has extensive experience of working within the reproductive medicine field.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 September 2009 – 31 August 2010*
In vitro fertilisation (IVF)	300
Intracytoplasmic sperm injection (ICSI)	285
Egg Donation	1
Donor insemination	16
Intra uterine insemination (IUI)	77 (Note: cycles provided in the period 1 January to 31 December 2009).

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	N/A
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

*These data were extracted from the HFEA register for the period 1 September 2009 – 31 August 2010. 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.

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. The centre has a procedure in place to ensure that all patients are provided with a personalised costed treatment plan before treatment commences. The plan provides details of the main elements of proposed treatment, including investigations and tests. Patients are also informed of other additional costs, such as those for drugs, which they may incur depending on their treatment. Staff reported that patients are given the opportunity to discuss the costed treatment plan with the clinical staff prior to treatment (Guidance 4.3). Patients having treatment in situations where consent to parenthood is required are informed about parenthood laws verbally and in writing (Licence Condition T60 and T61). Members of staff interviewed during the inspection demonstrated an understanding of the requirements of legal parenthood legislation. The centre has written procedures for obtaining written records of consent to parenthood. Appropriately completed consents to parenthood were also seen during review of patient notes.
What they could do better. Patients are provided with a costed treatment plan. The centre could consider keeping a copy in the patient notes for reference purposes.

Consent - particularly consent to disclosure to researchers and consent to storage
What the centre does well. Six sets of patient notes examined during the inspection were found to contain appropriately completed consent forms, including those for the disclosure of information to researchers and for the use and storage of gametes and embryos in the provision of treatment (Licence Condition T57). A sample of consents to the disclosure of personal information held on the HFEA Register was reviewed on inspection. The consents recorded in the patient notes were found to be consistent with the consents reported to the HFEA, except for one discrepancy where a patient consented 'yes' on the HFEA CD form but the centre recorded 'no' via the electronic data interface (EDI) within the HFEA Registry. The centre staff agreed to rectify this discrepancy. Post inspection, a further sample of consents to disclosure to researchers was reviewed by the inspectorate without any discrepancies being found. The centre has established processes, documented in Standard Operating Procedures (SOP), which ensure that all stored gametes and embryos are within their statutory and consented storage periods. Interviews with staff and the centre's SOP for withdrawing storage consent, indicate the provision of a 12 months 'cooling off' period for cases where one gamete provider withdraws consent to embryo storage. Evidence was provided by the nursing staff showing that the centre has established quality indicators (QIs) relevant to obtaining consent and that these QIs are audited

(including storage consents) and, where required, corrective actions are documented and implemented (Licence Condition T35 and T36).

What they could do better.
Nothing noted at the time of inspection.

Multiple births

What the centre does well.
The PR reported an overall multiple pregnancy rate at the time of inspection of 20.4%.

The centre has a documented Multiple Births Minimisation Strategy, as required by General Direction 0003, paragraph 3(a), which includes:

- How the centre identifies suitable cases for single embryo transfer (SET), including criteria in relation to embryo assessment and patient selection (5(a)).
- How the centre aims to reduce the multiple birth rate and how to ensure that the rate does not exceed the maximum specified rate of 20% (5(b)).

The centre maintains a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for SET (3(c)). A review of the summary log by the inspection team indicated that from 1 January 2010 to 30 June 2010 the centre carried out only three double embryo transfers in patients who met the criteria for SET. Where more than one embryo has been transferred centre staff have recorded in the patient's notes the reasons for transferring more than one embryo in that case and a note confirming that the risks associated with multiple pregnancy have been fully discussed with the patient (7(a) (b)).

When three embryos are transferred to a patient, centre staff write a detailed record in the patient's notes explaining the reason for the transfer. The transfer is also recorded in a summary log in the format laid out in General Directions 1(a) and (b)).

The centre has carried out regular audits and evaluations of the progress and effectiveness of the Multiple Births Minimisation Strategy. Evidence of this was seen in the centres audit programme and in minutes of discussions at clinical meetings. (3(b)).

What they could do better.
Nothing noted at the time of inspection.

Validation of critical equipment and processes

What the centre does well.
Laboratory staff provided documented evidence that all critical equipment, with the exception of the dry shipper, have been validated. Validation documents were seen for various items of equipment including an incubator, flow hood and microscope (Licence Conditions T24). The centre provided a documented procedure stating the requirement for revalidation of equipment after repair. Evidence of revalidation after repair of an incubator was seen (Licence Conditions T25).

What they could do better.
The dry shipper has not been validated. The laboratory staff reported that this was in the process of being addressed (Licence Conditions T24).

The centre has begun validating its critical processes which influence the quality and safety of gametes and embryos but the validation is not yet complete. Validation records were observed for egg collection, sperm preparation, ICSI, insemination and IUI (Licence Conditions T72).

Witnessing

What the centre does well.
Review of the centre's witnessing SOP, discussions with staff and observations in the laboratory demonstrated that a procedure is in place to double check the identification of samples and the patients to whom they relate at all critical points of the clinical and laboratory processes. Four sets of patients' notes were audited for witnessing during the inspection. All were found to contain an appropriate record of the required witnessing checks, with one minor exception discussed below (CoP 18.8).

Staff involved in witnessing provided documented evidence of the assessment of their competence to perform witnessing (Licence Condition T15 (a)).

What they could do better.
It was noted in one set of patient notes reviewed that the witnessing step to confirm the identity of the sperm provider against the sample being received was not recorded (Licence Condition T71).

Review of patient notes showed that the signatures of the persons performing and witnessing procedures are captured, but not their names and statuses. The centre has a list with the names and signatures of staff performing witnessing but this list does not include their status (CoP 18.8).

The centre has established QIs relevant to witnessing but these are not documented (Licence Condition T35).

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.
The centre runs a sperm donor bank for its own patients and does not supply donor sperm to other centres. The centre also offers egg sharing and a sperm sharing programmes. There is a SOP in place for the process to be followed when selecting and recruiting donors (Licence Condition T33 (b)). A donor checklist is in use which must be completed prior to the PR releasing samples for use.

A review of three patient records confirmed that donors had been selected on the basis of their age and each file included a documented health and medical history in compliance with Licence Condition T52 (a). Patient records reviewed contained

screening test results indicating that donors are selected in accordance with the screening requirements of Licence Condition T52 and relevant professional bodies. Evidence was seen that the laboratory tests were carried out by a laboratory accredited by CPA (UK) Ltd (Licence Condition T53 (a)). With reference to HTLV-1 screening, the laboratory staff confirmed that they are aware of this and will test if necessary, but that this is unlikely to be required from their patient population.

Members of staff reported that the centre can provide donors with the following information if requested: the number of persons born as a result of the donation, the sex of each of those persons and the year of birth of each of those persons (HFE Act 1990 (as amended), Schedule 31ZD (3)).

Evidence was seen for reimbursement of travel expenses only. Logs of expenses given are maintained in the patient notes and include date of attendance, distance travelled and expenses given.

When sperm is imported the centre ensures that the donor has not received compensation for loss of earnings that exceeds the prescribed amount in General Direction 0001 version 2; this is verified via the supporting documentation that accompanies the sample.

What they could do better.

The centre has not established QIs relevant to selection and recruitment of donors (Licence Condition T35)

The centre has not undertaken audits of donor selection and recruitment processes against compliance with the approved protocols, the regulatory requirements and QIs (Licence Condition T36).

Staff were not able to provide documented evidence of the assessment of their competence to select and recruit donors (Licence Conditions T12 and T15).

Welfare of the Child (in relation to basic partner treatment services only)

What the centre does well.

As the centre offers a full range of treatment services, this theme was not relevant at this inspection. However, during an audit of patients' notes the inspectorate noted they contained welfare of the child forms completed and signed by both partners.

What they could do better.

Nothing noted at the time of inspection.

Embryo testing (if applicable)

What the centre does well.

Not applicable for this centre.

What they could do better

2. Changes / improvements since the last inspection on 13 March 2009

Area for improvement	Action required	Action taken as evidence during this inspection
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) and A.3.1(b) (CoP 7th).	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.	Post inspection information submitted to the HFEA confirmed that this issue was addressed by the centre. No further action required
The centre monitors air quality in the laboratory area but there is no documented procedure describing this process. A.10.19; S.6.3.6(b) and S.7.8.5(a) (CoP 7th).	Development of a documented procedure for measuring air quality in the laboratory area.	The centre has an SOP in place for monitoring air quality by particle and microbial counts. The SOP details the required air quality grades for both background and critical working environments, and corrective action to take if deviations occur. No further action required.
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 (CoP 7th).	Review/amendment of written witnessing procedures to be undertaken to ensure compliance with guidance G.13.1	The laboratory protocol was reviewed. All issues from the previous report have been revised. No further action required.
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 confirmed that this issue was addressed by the centre. No further action required.
Review of the embryology daily checklist revealed that personnel were recording	The centre should ensure that records are a reliable	The CO_2 level displayed on the incubators is recorded daily on the embryology

Area for improvement	Action required	Action taken as evidence during this inspection
%CO_2 levels which were at variance with the given 'acceptable limits' printed on the checklist recording sheet. S.5.2.7 (CoP 7th).	and true representation of the results.	daily checklist. Laboratory staff confirmed that the level is monitored for fluctuations in the level displayed. The pH of culture media is measured bi-monthly to confirm that the CO_2 concentration in the incubator remains within acceptable limits. No further action required.

3. Areas of concern

The analysis of the centre's self assessment questionnaire (SAQ) and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked at during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
Can all staff provide documented evidence of the assessment of their competence to provide the following: • Counselling. • Information to those consenting to treatment. • Information to those consenting to donation of gametes for treatment. • Conducting Welfare of the Child (WoC) assessments. • Storing cryopreserved material. [T12 and T15(a)]. (In the SAQ the centre answered 2 - almost compliant)	Documentation seen during the inspection and the subsequent information provided by the centre, indicated that the centre's counsellor is qualified to provide fertility counselling. However, no documented evidence of the assessment of her competence to provide counselling has been made available. Documented evidence was made available for the nursing staff indicating assessment of their competence to provide information to patients consenting to treatment and donation of gametes. WoC assessment is carried out by medical consultants who have had their competence to perform this task assessed and documented. A list of competence assessments required for the laboratory staff is in a SOP. A	A formal plan for the regular assessment of staff competence to perform key activities should be documented and implemented.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
	framework and assessments are in place and observed for some (e.g. egg collection), but not all processes.	
Is there an SOP for the process to be followed when providing information to patients before they consent to treatment, donation, research and training [T33(b)]. (In the SAQ the centre answered no)	The centre has a SOP in place detailing the process to be followed when providing information to patients prior to consent.	No further action required.
Has the centre established quality indicators or objectives relevant to: Provision of information, Consent, WoC, Storage, ICSI and the QMS [T35]. (In the SAQ the centre answered no)	The centre has established QIs for these aspects of the service, however some of the QIs and their monitoring mechanisms are not documented.	The PR should ensure that QIs relevant to all areas of practice are documented.
Have traceability procedures been audited against compliance with the approved protocols, the regulatory requirements and quality indicators in the last two years [Schedule 3A (10) 2006/86/EC, Appendix 1 F and T36]	Traceability audits are conducted six monthly. Evidence of this was seen during the inspection. The findings of the audits are documented and, where required, corrective action is taken.	No further action required.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
(In the SAQ the centre answered no)		
Is the identity of the person providing consent verified when consent is provided [5.10] Is the identity of the person who gave consent cross referenced to records when procedures are carried out [5.11] (In the SAQ the centre answered no)	The centre has a SOP in place for the process to be followed when obtaining consent. Copies of patient photo identification were observed in the patient notes and staff confirmed that the identity of the person providing consent is cross referenced to records when procedures are carried out.	No further action required
Does the centre have a quality manual [T33]. (In the SAQ the centre answered no)	A quality manual is in place and this was reviewed at inspection and it appeared to be compliant.	No further action required.
Does the centre have documented procedures for reporting serious adverse events and serious adverse reactions that occur [T118] (In the SAQ the centre answered no)	The centre has a documented procedure in place for reporting of incidents to the HFEA. This was reviewed at inspection and it appeared to be compliant.	No further action required.

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non compliance requires immediate action to be taken by the Person Responsible

Area of practice	Action required and timescale	PR Response	Executive Review
None identified at the time of this inspection.			

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

Area of practice	Action required timescale	PR Response	Executive Review
The centre has not established quality indicators relevant to the selection and recruitment of donors. Licence Condition T35	The PR should ensure that QIs relevant to all areas of practice, including selection and recruitment of donors, are established, documented and monitored. This action should be completed by the time the PR responds to this report.	Quality Indicators relating to both these issues were submitted on 16th November immediately following the Inspection, the extract of the Quality Management Manual reading as follows:- Strict parameters are in place to ensure only suitable donors are recruited. Before any donor is released for use the donor release form must be signed off by the Person Responsible to ensure that all screening is complete and the donor has met all requirements. 100% compliance is required. As The Fertility Centre has so few	The inspectorate considers this to be an acceptable response.

Area of practice	Action required timescale	PR Response	Executive Review
		donors this is assessed on a case by case basis. I believe that we have both strict criteria for the selection and recruitment of donors and audit this process for each and every donor for whom we complete the recruitment process. The audit form and selection criteria were made available at the time of the inspection and I believe meet the requirements of the standard. Indeed the use of this audit checklist for donor recruitment is discussed as part of the inspection report on page 7	
The centre has not undertaken audits relevant to the selection and recruitment of donors. Licence Condition T36	The PR should ensure that these processes are audited by 11 February 2011. These audits must be performed in an independent way, at least every two years. Findings and corrective actions must be documented.	Please see above response.	The PR states above that it is expected that there should be 100% compliance with donor recruitment requirement and has inferred that completion of a checklist before release of donor gamete acts to audit against this quality indicator.

Area of practice	Action required timescale	PR Response	Executive Review
			The PR should ensure that if the completion of the checklist is considered part of the audit process then the findings and any corrective actions of these rolling audits are documented in compliance with licence condition T36.
The centre has not validated all critical equipment. (Licence Conditions T24).	The PR should ensure that all critical equipment is validated. An updated action plan to be submitted by the time the PR responds to this report.	Plans for the validation of the dry shipper were submitted to you on 2nd December. Following further discussions with our data logging third party we have been able to initiate this validation and I have attached six days worth of stored data showing no deviation in temperature. The dry shipper was charged with liquid nitrogen on 6th January in exactly the same manner as we would normally do for the transportation of gametes or embryos and then left undisturbed for 6 days. The shipper showed no change in	The inspectorate considers this to be an acceptable response.

Area of practice	Action required timescale	PR Response	Executive Review
		temperature and remained at a level which we believe to be appropriate for the safe transport of embryos. We will continue this test over a 2 week period, however we believe that 6 days is more than sufficient to validate the shipper as our practice is to undertake only “same day” transfers with this equipment. I trust that you will find the data supplied satisfactory and will agree that we have now validated all critical equipment.	
Not all critical processes have been validated. Licence condition T72	The PR should ensure that all critical processes are validated. This validation may be based on studies performed by the establishment itself, data from published studies or from well-established processing procedures, or by retrospective evaluation of the clinical and laboratory results. An updated action plan to be submitted by the time the PR responds to this	A formal plan for the regular validation of all critical processes has been drawn up as follows :- • Egg collection : clinician completed • Egg collection : clinician – completed • Sperm Preparation – completed • ICSI – completed	The inspectorate considers this to be an acceptable response. Progress to be monitored.

Area of practice	Action required timescale	PR Response	Executive Review
	report.	• IVF – completed • IUI – completed • Transportation – now completed : January 2011 <u>Requiring Validation</u> • Embryo Freezing and Storage – February 2011 • Embryo Transfer – March 2011 • Donor Recruitment and Screening May 2011.	

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from good practice.

Area of practice	Action required timescale	PR Response	Executive Review
Not all staff were able to provide documented evidence of the assessment of their competence to perform their designated	A formal plan for the regular assessment of staff competence to perform key activities should be documented and implemented. This action should be implemented	A staff competency timetable will be drawn up in due course and submitted by 11th June 2011. Competencies will be reassessed every two years as	The inspector is unsure from the information provided by the PR as to how he is going to assure himself that all staff (including new staff) are

Area of practice	Action required timescale	PR Response	Executive Review
tasks. Licence Condition T15a	by 11 June 2011.	required in the 8th Code of Practice. This is discussed in the Competency SOP and will again take the form of a self assessment form which is required to be countersigned.	maintaining their competency to perform their designated tasks if he is allowing them to self assess. However, the centre was contacted for clarity on assessment of staff competence. An update received on17 January 2011 confirmed that the centre has an SOP documenting: the rolling programme of assessment per task rather than per member of staff; that all new staff have their competency assessed in all areas before they are allowed to perform that task unsupervised regardless of seniority; all trainees are assessed per task within a competency and have to pass all of these before they can perform these tasks unsupervised. The inspectorate considers this to be an acceptable

Area of practice	Action required timescale	PR Response	Executive Review
			response.
During witnessing, the signatures of the processor and witness are captured, but not their names and statuses. Licence condition T71	The PR should ensure that the witnessing records include the name, status and signature of the person performing the activity and the name, status and signature of the person who witnesses the procedure.	A list of personnel and their signatures who work at The Fertility Centre was submitted at the time of the inspection. Whilst I am in agreement that this list did not contain the designation of each member of staff I should like it noted that the witnessing forms themselves do indeed have the designation by the side of each person witnessing. The designation of each member of staff is now being added to the list of names and signatures.	The inspectorate considers this to be an acceptable response.

Additional Information from the Person Responsible

In a letter dated 11 January 2011, the PR gave the following additional information:

Many thanks for the Interim Inspection report from 11th November which you sent to us on 17th December. I am sure that you appreciate that a detailed response by 5th January was unrealistic given the season, with all of our key staff, including the Quality Manager, being on leave. I am grateful for the extension to 12th January, and I think that we have managed to deal with the outstanding issues.

I know that most of the issues raised at the end of the inspection were dealt with right away, and there appear to have been a few others of which we were not aware at the time of your visit.

Areas of Agreement

1. page 8. Staff were not able to provide documented evidence of the assessment of their competence to select and recruit donors (Licence Conditions T12 and T15). A staff competency relating to this matter will be drawn up in due course and submitted.

2. page 11. A formal plan for the regular assessment of staff competence to perform key activities should be documented and implemented. A staff competency timetable will be drawn up in due course and submitted.

It has been pointed out to me that the report contains some inaccuracies and should be grateful if you would note these, as well as taking into account our previous immediate responses, and amend as required.

1. page 3 and 8. “The PR should ensure that quality indicators (QIs) are established and monitored for donor recruitment and selection processes.” “The PR should ensure that donor recruitment and selection processes are audited at an appropriate frequency.” Quality Indicators relating to both these issues were submitted on 16th November immediately following the Inspection, the extract of the Quality Management Manual reading as follows:-

Strict parameters are in place to ensure only suitable donors are recruited. Before any donor is released for use the donor

release form must be signed off by the Person Responsible to ensure that all screening is complete and the donor has met all requirements. 100% compliance is required. As The Fertility Centre has so few donors this is assessed on a case by case basis.

I believe that we have both strict criteria for the selection and recruitment of donors and audit this process for each and every donor for whom we complete the recruitment process. The audit form and selection criteria were made available at the time of the inspection and I believe meet the requirements of the standard. Indeed the use of this audit checklist for donor recruitment is discussed as part of the inspection report on page 7.

2. page 5. The report states that our costed treatment plans document " the main elements of proposed treatment." The four costed treatment plans used by The Fertility Centre and in use since January 2010, were made available at the time of the inspection visit. As required by Code of Practice 8; the costed treatment plans "detail the main elements of the treatment proposed (including investigations and tests), the cost of that treatment and any possible changes to the plan, including their cost implications." I believe that using four costed treatment plans which detail all test, treatment options, variations and extras that may be required by patient's constitutes more that just the "main elements" and does in fact reflect ALL elements of the proposed treatment.

3. page 7. "The centre has established QIs to witnessing but these are not documented." Quality Indicators relating to witnessing were submitted on 16th November immediately following the Inspection, the extract of the Quality Management Manual reading as follows :-

An audit of 10 sets of notes is carried out every 6 months to ensure 100% compliance with the witnessing requirements. Should any deviation be discovered then an investigation is initiated and any trends analyzed. Where appropriate, staff are reminded of the requirement for witnessing. In the event of an individual continually failing to follow procedure, retraining will be initiated.

I believe that this Quality Indicator meets the requirement of Licence Condition T35.

4. page 11. “No documented evidence of the assessment of the Counsellor’s competence to provide counselling has been made available.” The Fertility Centre follows BICA guidelines for the assessment of counselling competency and uses an anonymous patient questionnaire. The matter is discussed at length in the “Competency SOP.” Evidence for this assessment going back to 2008 was presented at the inspection. As I am sure you are aware our counsellor’s supervisor has been somewhat reticent in providing a statement of competency, however this document has now been produced and I have attached it to this document. I trust that this meets your requirements.

5. page 11. “WoC is carried out by the consultants but their competence assessment was not available.” ALL consultants including the PR were assessed for WoC competency on the following dates[1] :-

    29/10/2010

    01/11/2010

    22/10/2010

    29/10/2010

    01/11/2010

These competencies were asked for and produced during the course of the inspection. Should you require scanned copies they can be provided.

6. page 11. “List of competence assessments required for laboratory staff is in a SOP.” The Competency SOP lists the required competencies required for ALL staff and consultants. The Fertility Centre has described these and a “prescribed list of tasks” and have requirements for staff in each of the following groups :-

[1] The text in the body of the report has been updated in response to this comment.

PR

Clinicians

Nurses

Embryologists

Andrologists

Counsellors

Administrative

9. page 12. “The center has established QI’s relevant to provision of information, consent, WoC, storage, ICSI and the QMS, however some of the QI’s and their mechanisms are not documented. .” Quality Indicators relating to these issues were submitted on 16th November immediately following the Inspection. The Centre is obviously keen to comply fully with the requirements, and if any remain outstanding please let us know.

Areas of Improvement

1. page 3. “The PR should ensure that the witnessing records include the name, status and signature of the person performing the activity and the name, status and signature of the person who witnesses the procedure.” A list of personnel and their signatures who work at The Fertility Centre was submitted at the time of the inspection. Whilst I am in agreement that this list did not contain the designation of each member of staff I should like it noted that the witnessing forms themselves do indeed have the designation by the side of each person witnessing. The designation of each member of staff is now being added to the list of names and signatures.

2. page 3 and 6. “The PR should ensure that all critical equipment is validated.” Plans for the validation of the dry shipper were submitted to you on 2nd December. Following further discussions with our data logging third party we have been able to initiate this validation and I have attached six days worth of stored data showing no deviation in temperature. The dry shipper was charged with liquid nitrogen on 6th January in exactly the same manner as we would normally do for the transportation of gametes or embryos and then left undisturbed for 6 days. The shipper showed no change in temperature

and remained at a level which we believe to be appropriate for the safe transport of embryos. We will continue this test over a 2 week period, however we believe that 6 days is more than sufficient to validate the shipper as our practice is to undertake only “same day” transfers with this equipment. I trust that you will find the data supplied satisfactory and will agree that we have now validated all critical equipment.

3. page 3 “Not all critical processes have been validated Licence condition T72 The PR should ensure that all critical processes are validated.” An updated action plan to be submitted by the time the PR responds to this report. A formal plan for the regular validation of all critical processes has been drawn up as follows :-

    - Egg collection : clinician completed
    - Egg collection : clinician – completed
    - Sperm Preparation – completed
    - ICSI – completed
    - IVF – completed
    - IUI – completed
    - Transportation – now completed : January 2011

    <u>Requiring Validation</u>

    - Embryo Freezing and Storage – February 2011
    - Embryo Transfer – March 2011
    - Donor Recruitment and Screening May 2011

PR Centre 0026

HFEA Executive Licence Panel Meeting

18 February 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 3

Centre 0026 (BMI Priory Hospital) – Interim Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Nick Jones, Director of Compliance	Joanne McAlpine

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that the centre has been licensed since 1992, and is privately owned offering licensed treatment to both private and self funded patients.

2. The Panel noted that since the unannounced inspection in March 2009, the centre has not undergone any major changes.

3. The Panel noted that the Person Responsible (PR) is registered with the General Medical Council (GMC) and is a fellow of the Royal College of Obstetricians and Gynaecologists (FRCOG) as well as having extensive experience of working in the reproductive medicine field.

4. The Panel noted that the centre offers a wide range of assisted reproductive treatments including IVF, ICSI, Egg Donation, IUI, Storage of Eggs/Sperm and Embryos and Donor Insemination.

5. The Panel noted that at the time of the inspection on 11 November 2010 there were a number of areas of practice that required improvement, including four major areas of non compliance and two other areas of non compliance or areas of poor practice.

6. The Panel noted that since the inspection the PR has provided information that satisfies the Inspectorate four of these recommendations have now been implemented.

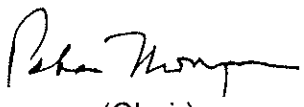
7. The Panel noted that the PR has also given a commitment to implement the recommendation that all critical processes are validated.

8. The Panel noted the Inspectorate's recommendation for the continuation of the centre's licence with no additional conditions, and noted and endorsed the recommendations on page 64 of the inspection report.

9. The Panel noted the progress already made within the centre, and would encourage the PR to continue in this positive approach.

Decision

10. The Panel endorsed the Inspectorate's recommendation to the continuation of the centre's licence, with no additional conditions.

Signed:  Date: 2/3/11.
Peter Thompson (Chair)