Renewal Inspection Report

Barts and The London Centre for Reproductive Medicine

Centre 0094

Date of Inspection: 6 May 2009
Date of Licence Committee: 30 July 2009

Centre Details

Person Responsible	Amanda Tozer
Nominal Licensee	Trevor Beedham
Centre name	Barts and The London Centre for Reproductive Medicine
Centre number	0094
Centre address	Kenton and Lucas Block St Bartholomew's Hospital Little Britain London, EC1A 7BE
Inspector(s)	Miss Paula Nolan Dr Andrew Lenoard Dr Neelam Sood Ms Risi Olusanya (HFEA Executive observing)
Fee paid	Renewal fee not paid at the time of inspection Paid on 28 May 2009
Licence expiry date	31-10-2009
NHS/ Private/ Both	Both

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About the Inspection:

This inspection visit was carried out on 6 May 2009.

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, the 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 centre provides NHS and self funded treatments: 1129 cycles of IVF/ICSI/FET and DI were provided in 2008. The centre also provides treatment with donated eggs and recruits sperm donors.

The centre is open from 8am to 5pm on Monday, Wednesday - Friday and for extended hours, 8am to 8.30pm on Tuesday. The centre is also open on Saturday from 8am to 1pm.

There is a planned closure of the laboratory for three weeks in June 2009 to allow for new equipment to be installed.

The satellite centre in Norfolk closed at the end of April 2009.

The Person Responsible (PR) has been in post since January 2006. She has completed the HFEA Person Responsible Entry Programme. She is registered with the General Medical Council (GMC) and is on the Obstetrics and Gynaecology (Reproductive Medicine) specialist register.

Activities of the Centre[1] for the time period from 1 January 2008 to 31 December 2008

In vitro fertilisation (IVF)	633
Intracytoplasmic sperm injection (ICSI)	457
Donor Insemination	39
Research	No
Storage gametes/embryos	Yes

Summary for Licence Committee

Barts and The London Centre for Reproductive Medicine is a large unit providing more than 1000 licensed treatment cycles per year.

The unit has appropriate premises, suitably qualified and experienced staff and in general adopts appropriate clinical and laboratory procedures. The centre has been proactive in the development and implementation of a quality management system.

Improvements should be considered relating to the following aspects of the centre's practice:

- The submission of information to the HFEA
- The documentation of training and assessment of competency

[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.

- Validation of key processes
- Payment of invoices
- Incident reporting

At the time of the last licence renewal in 2006, in response to operational audit findings in relation to the submission of HFEA treatment and outcome forms, a licence committee added an additional condition to the centre's licence and the centre has been the subject of ongoing audits to monitor submission of HFEA forms.

The inspection team supports the renewal of the centre's licence for a period of five years subject to compliance with the recommendations within the prescribed timeframes.

Evaluations from the inspection

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

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
For the year up to March 2009, the average time taken to pay HFEA invoices was 57 days. This is a breach of standard licence condition A.16.3.	The Person Responsible should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.	The PR should advise the HFEA of measures taken to reduce the average time to pay invoices by 6 July 2009.
9 cases of OHSS requiring hospital admission have not been reported to the HFEA via the incident reporting system.	The centre must report all adverse incidents (which includes serious adverse events and serious adverse reactions), and all near misses to the HFEA within 12 working hours to comply with Code of Practice S.9.4.2. The PR should review reporting procedures to ensure ongoing compliance with reporting requirements. The PR should report the incidents identified by the inspectorate during the inspection via the HFEA incident alert system.	Immediately. To be monitored at the next inspection. 7 July 2009 – all 9 cases of OHSS have been reported via the HFEA incident reporting system.
A document control system is in place however not all documents seen on the day of inspection were being reviewed or controlled according to the requirements of Code of	The PR should review all documents to ensure they contain appropriate document control information compliant with Code of Practice, S.5.2.5 (a), and are scheduled for annual review to	6 August 2009. To be monitored at the next inspection.

Practice S.5.2.5. and S.5.2.6.	ensure accuracy and future compliance with Code of Practice, S.5.2.6 (b).	
It was noted that the door from the patient waiting area leading to the clinical corridor and patient records store is not secure. This could be considered a security risk as the public have open access to the centre through these doors. While licensed material did not appear to be at risk on the day of inspection, patient records, clinical areas may be at risk.	The PR should assess the security of the clinical corridor and patient records store. Effective control measures should be implemented to ensure compliance with Code of Practice S.6.3.1 ('the centre shall have documented procedures for controlled access') and S.6.3.2 ('the centre shall provide a safe working environment for all staff.')	6 August 2009. To be monitored at the next inspection.
Review of 10 patient records indicated that two welfare of the child assessments were missing. In one set of notes the "terms of embryo storage" for one couple had been incorrectly completed.	The PR must ensure that a person's gametes or embryos are not stored unless there is an effective consent in place and they are used in compliance with that consent as required by schedule 3 section 8 of the HF&E Act. (1990) The PR must ensure that treatment services are not provided unless account has been taken of the welfare of any child who may be born as a result of the treatment as required by the HF&E Act (1990) with amendments Section 13(5).	Immediately. To be monitored at the next inspection.
The Centre has a considerable number of errors in data entered to the HFEA via the electronic data interface (EDI), and these errors prevent patient data entry onto the HFEA Register.	The accuracy of data entry on the EDI system must be improved, as should the frequency of clearing of errors, to ensure compliance with Code of Practice, 7th Edition, Standards, S.6.5.1 (b) and the HFEA policy on the collection, confirmation and publication of Registry data, which was attached to Direction 2008/6. It is essential that all EDI errors are corrected and that weekly clearance of errors occurs, compliant with Direction 2008/6.	It is recommended that the centre submit a plan for the resolution of reporting deficiencies to the HFEA by 6 July 2009.
Validation of key processes	The PR should draw up and	A validation plan

and procedures has not yet been fully established.	implement a plan for validation. The plan should take into account the particular needs of the unit and prioritise the validation of those processes and equipment considered to be most likely to impact on the quality of the service and compliance with Licence Conditions 11.11, 8.11 and 10.13.	should be prepared and submitted to the HFEA by 6 July 2009. Validation of processes and equipment should be completed by the time of the next inspection.
Nursing staff have not had their competency to perform designated tasks assessed.	The PR should ensure that the competence of each person to perform designated activities is evaluated at intervals specified in the Quality Management System. Re-training should be undertaken when required to comply with standard S.6.2.9. The PR should also ensure compliance with Code of Practice G.1.3.1 which requires all nurses to be able to provide evidence of competency in the duties performed, either by certification with a recognised qualification or by written testimonial from a suitably qualified and competent person in that discipline/function (e.g. ultrasound, embryo transfer, IUI, egg collection, etc.)	A programme of competency assessment should be developed and submitted to the HFEA by 6 July 2009. Full implementation of the assessment programme should be reported to the HFEA.

Non-Compliances

Non-compliance	Action required	Time scale
On checking the emergency resuscitation trolley it was noted by the inspection team that the daily check had not been completed for a three day period. The Resuscitation Council Guidelines[2] state that the responsibility for checking resuscitation equipment rests with	The PR should ensure that the emergency resuscitation trolley is checked in line with trust protocols.	To be monitored in the course of the next inspection.

[2] Cardiopulmonary Resuscitation Standards For Clinical Practice And Training, A Joint Statement from The Royal College of Anaesthetists., The Royal College of Physicians of London, The Intensive Care Society, The Resuscitation Council (UK), October 2004.

the department where the equipment is held and checking should be audited regularly. The frequency of checking will depend upon local circumstances but should ideally be daily.		
Procedures for witnessing are comprehensive but the requirement for cross checking sample identities against patient records is omitted at a small number of stages.	The PR should ensure witnessing protocols are reviewed in consideration of CoP guidance at G.13.1.1. If witnessing steps recommended in G.13.1.1 are omitted, the risks of these omissions should be evaluated, documented and controlled.	Review to be completed by 6 August 2009.

Changes/ improvements since last inspection

Recommendations	Action Taken
For the year up to February 2008, the average time taken to pay HFEA invoices was 32 days. This is potentially a breach of standard licence condition A.16.3.	Following the last inspection the PR advised the HFEA that the time taken to pay HFEA invoices had been highlighted to the Trust as a potential breach of a standard licence condition. It should be noted that since the last inspection however, the average time taken to pay HFEA invoices has increased to 57 days.
During the demonstration of the bring forward system it was observed that at the time of the inspection, the centre were storing cryopreserved material for 26 patients without written consent. At paragraph 1 of schedule 3 of the 1990 Human Fertilisation and Embryology Act it states that a consent under this Schedule must be given in writing.	Following the last inspection the PR advised the HFEA that a review of the procedures for disposing of cryopreserved material had been carried out. It was reported that all cryopreserved material where consent had not been obtained for continued storage, would be allowed to perish and this would be complete by the September 8th 2008. At the time of the inspection it was observed that all cryopreserved material has consent. It was also reported that a review of the protocols for contacting patients was made and no changes were considered

	necessary. It was reported that the laboratory manager would ensure that protocols are followed by the embryology team and that time is allowed for completion of this task.
Validation of key processes and procedures has not yet been fully established. This is potentially a breach of S 7.8.3 of the Code of Practice (COP) and standard licence condition A.11.11.	Following the last inspection the PR advised the HFEA that the validation of key processes and procedures was underway but validation remained incomplete at the time of the renewal inspection in 2009.
Diagnostic analysis of semen samples is carried out within the centre. COP S.7.8.2.states that if the centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patient partners or donors, or their gametes, embryos or any material removed from them, these laboratories shall obtain suitable accreditation.	Following the last inspection the PR advised the HFEA that the centre would work towards CPA of the semen diagnostic facilities with the guidance of the clinical pathology department. At the time of the renewal in 2009 the Quality Manager explained that the centre is in the process of obtaining ISO accreditation which will incorporate most of the CPA requirements of the semen diagnostic facilities.
In the course of the inspection it was noted that an alarm light was indicating malfunction of a flow hood in the laboratory. It was also noted that incubator temperatures and CO_2 levels are not monitored regularly. This is potentially non compliant with standard S. 6.4.2 (b) and standard licence condition A.10.13.	Following the last inspection the PR advised the HFEA that malfunction of the flow hood had been looked into and there has been no compromise to gametes and embryos.
Members of the nursing and embryology teams were not able to provide documented evidence of their competence to perform designated tasks having been assessed. This is potentially non compliant with standards S.6.2.7 (a).	In follow up provided to the HFEA following the last inspection the PR reported that the centre were in the process of staff competency assessments and would have full documentation of these by the next inspection. However, at the time of the renewal inspection in 2009, nursing staff had not had their competency to perform designated tasks assessed.
Evidence of screening for syphilis was absent from a sample of donor records reviewed in the course of the inspection. This is potentially non compliant with standard licence condition A.7.2.	All donor records now include a checklist to ensure all necessary screening tests have been completed
The service agreement with parties involved in	The satellite service with Norfolk is no

the provision of satellite IVF was provided in the course of the inspection. It was noted that the agreement is not fully compliant with the requirements outlined in the HFEA third party guidance.	longer active.
Egg donors have not been screened for *Neisseria gonorrhoea* as recommended in BFS guidelines	All donor records now include a checklist to ensure all necessary screening tests have been completed. This includes *N. Gonorrhoea* for egg donors.
Standard protocols for witnessing are comprehensive but the requirement for cross checking against patient records is omitted at a small number of stages.	The laboratory manager has reviewed the witnessing protocols but checking sample identities against patient records is omitted at a small number of stages.
Workload may be impacting on the abilities of staff to fulfil all of their responsibilities. It is recommended that the PR assesses how many cycles can safely be accommodated by the centre. The assessment should consider the centre's premises, equipment, staffing levels and the skills mix of staff members and activity should adjusted according to the findings of the assessment (A.10.9. and A.10.18).	The PR reviewed the workload within the unit in January of 2008 given the decrease in staffing levels particularly in the embryology team. The PR decreased the number of IVF/ICSI cycles performed from 25 per week to 17 per week. This was done in consultation with the nursing and embryology team and the PR felt that this provided staff with adequate time to perform their necessary duties. The PR reported that she was looking at the working practices of the teams to assess the effectiveness of use of time. Since the time of the inspection 1 more HPC registered scientist has started and a further one will start in August.

Additional licence conditions and actions taken by centre since last inspection

The Person Responsible must put measures in place to ensure an immediate and substantial reduction of errors in registration, treatment and outcome forms. Actions documented above.

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
The centre has an organisational structure with defined accountabilities and reporting relationships. The premises appeared suitably equipped and the PR reported that she is confident that the unit has sufficient staff with relevant expertise. The centre holds monthly audit meetings. Copies of the minutes of these meetings and evidence of the audit plan were reviewed during the inspection. The audit plan includes witnessing and consent in patient records, equipment, witnessing, referrals/patient pathway and traceability. A copy of an audit report including action taken and closure of the audit loop was made available during the inspection. Organisational and local policies to manage risk are in place e.g. infection control procedures as per trust policy, management of sharps as well as undertaking risk assessments where new or ongoing risks to patient, staff and gametes/embryos are identified. Information on the complaints process was seen to be available in the patient waiting room. A log of complaints is maintained and was reviewed by the inspection team. It was evident that corrective action is taken in response to complaints. For example, after receiving several complaints about difficulty in getting in touch with centre staff via telephone, the clinical operations manager has submitted a business plan to purchase a new telephone system as well as making extra phone lines available. The centre has also established an e-mail service for patients to submit their queries. The centre has established an agreement with a licensed centre to provide backup clinical

facilities. An emergency pager number is supplied to patients when they commence treatment. The centre is based within an acute hospital trust which provides emergency facilities for patients requiring admission. The centre laboratories have access to an emergency power supply to ensure essential equipment function is maintained in the event of failure of the main supply.

Third party agreements are in place and were made available to the inspection team to review. A sample of agreements were reviewed and were compliant with HFEA guidelines.

Regular monthly team meetings are held. Minutes of the meetings are taken and the minutes are stored on the central drive so that all staff have access to them. Minutes of the meetings were made available to the inspection team and provided evidence of discussion of a range of activities and issues at the centre.

The staff also participate in a daily meeting to discuss new cases, the daily workload and schedule, and clinical issues such as scan results and successful/unsuccessful cases.

Areas for improvement

While processes are in place to identify incidents and to investigate/resolve them several cases of severe OHSS (Ovarian Hyperstimulation Syndrome) have not been reported to the HFEA. For the year up to March 2009, the average time taken to pay HFEA invoices was 57 days. This has increased from 32 days at the time of the previous inspection.

Areas for consideration

None.

Executive recommendations for Licence Committee

The PR must report all adverse incidents (which includes serious adverse events and serious adverse reactions), and all near misses to the HFEA within 12 working hours to comply with Code of Practice S.9.4.2.

The PR should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payments of invoices as per Licence Condition A 16.3. The PR should advise the HFEA of measures taken to reduce the average time to pay invoices by 6 July 2009.

Evaluation

Some improvement required.

Areas not covered on this inspection

All areas covered.

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]
From the time period from 1 January 2004 to 31 December 2007 the centre's outcomes for IVF/ICSI, frozen embryo transfers and donor insemination in all patient age groups were in line with national averages.
Areas of firm compliance
The centre has an electronic quality management system in place and a full time quality manager has been in post since November 2008. The quality manager explained that the quality management system will be reviewed on an annual basis. The centre is currently working towards ISO 9000:2001 certification. Quality performance indicators have been established and evidence of monitoring clinical and laboratory practices was provided in the course of the inspection. There is a suggestion box in the waiting area so that patients' views on the quality of the service provided to them can be obtained. Any suggestions made are discussed by staff and where possible improvements are made. Evidence of discussion of patient feedback was recorded in the minutes of multidisciplinary team meetings. A patient satisfaction survey is currently in progress with the assistance of the clinical effectiveness department within the trust. 250 patients will be asked for their feedback and will be compared to the results from the previous survey. 10 patient questionnaires were returned to the HFEA: five respondents made positive comments about the treatment they received. The PR stated that staff suggestions are welcomed and that they are normally raised during the monthly multidisciplinary team meetings.
Areas for improvement
Some documents provided during the course of the inspection were not version controlled and one had a review date of 2007.

Areas for consideration
Feedback was obtained from a couple undergoing treatment. The couple had begun their treatment at the satellite centre in Norfolk (now closed). The couple explained that they had spent several hours travelling to London and upon arrival at the centre their notes could not be located. The couple were unhappy with the amount of time they had spent travelling and felt that the service was disorganised. This feedback was discussed with the PR who explained that she was aware of the distress the closure of the Norfolk centre has caused and that all patients at the Norfolk centre had been written to prior to the closure of the centre and a helpline for patients had been set up.
Executive recommendations for Licence Committee
To comply with S.5.2.5 (a) documents should be regularly reviewed, revised as required, dated and re-approved promptly by authorised personnel. The document control procedure should ensure that documents are uniquely identified: identification should include a unique identifier, the edition or current revision date, or revision number, the number of page/total number of pages (where applicable), authority for issue, and author identification S.5.2.6. (b).
Evaluation
Some improvement required.
Areas not covered on this inspection
All areas covered.

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
The inspectorate considered that the premises were appropriate for the centre's activities. The centre licence, complaint's procedure and mission statement were on display in the patient waiting area, as well as a range of patient information relating to fertility treatment, counselling and contact details for patient support groups. The premises are inspected for health and safety purposes and each room has been risk assessed in the last year. The centre premises are cleaned by a contractor who provides this service to Bart's and The London NHS Trust. Clinical facilities were inspected and considered to be appropriate for the activities provided by the centre. The two sperm producing rooms were seen to provide for the privacy and dignity of patients. All counselling sessions take place in a dedicated room and the notes are kept separately from the patients' treatment notes in a secure filing cabinet. All equipment at the centre is covered by contracts for annual servicing and maintenance and equipment sampled during the inspection was within servicing intervals. The centre has a maintenance activity log for each piece of equipment. The laboratory staff confirmed that since the last inspection, no significant changes have been made to the equipment. However there will be a planned closure of the laboratory for three weeks from 8 June 2009, to allow for new equipment to be installed. Evidence of air quality monitoring in all relevant areas was provided in the course of the inspection. The most recent air quality tests (February 2009) found that air quality in the laboratory background and critical working areas is in accordance with HFEA requirements. Gametes and embryos are stored in a laboratory to which access is effectively controlled. Cryopreservation dewars are fitted with low nitrogen level alarms and the laboratory housing the cryopreservation dewars is fitted with a low oxygen level alarm. The alarm system is

connected to an auto dial-out system to warn on-call staff if it is activated.

Facilities are provided for staff which include a rest area with basic catering facilities and a supply of drinking water, and a changing area with secure storage for personal effects.

Patient notes are stored in a designated controlled access area and tracking system for patient records is in the process of being implemented.

Areas for improvement

It was noted that the door leading from the patient waiting area to the clinical corridor and patients' record store is not secure. This could be considered a security risk as the public have open access to the clinical area and the records storage area through these doors.

Air quality is checked on a regular basis however this process has not been validated to support testing at these intervals. The laboratory manager explained that she has taken advice from an expert in pharmacology who performs the air quality monitoring. This information will contribute towards the validation process.

It was noted on inspection that the door to the andrology laboratory was propped open raising the possibility that air from the clinical corridor could contaminate the air within the laboratory, affecting background air quality such that it may not be compliant with HFEA air quality requirements, even if air quality assessment with the door closed indicates it is.

Areas for consideration

On checking the emergency resuscitation trolley it was noted by the inspection team that the daily check had not been completed for a three day period. Guidance provided by the Resuscitation Council (UK) states that the frequency of checking will depend upon local circumstances but should ideally be daily[3].

Executive recommendations for Licence Committee

To comply with S.6.3.1 the centre shall have documented procedures for controlled access and S.6.3.2 the centre shall provide a safe working environment for all staff. The inspectorate recommends that the PR risk assess security within the centre given the current practices and implement control measures if risk assessment indicates them to be necessary.

Procedures for monitoring air quality should be validated to demonstrate that air quality is maintained in the interval between testing (A.11.11).

The PR should ensure that gametes and embryos are processed under air quality compliant with Licence Condition A.10.19. If the andrology laboratory door is to be propped open during sperm processing, air quality assessment should be performed to ensure air quality is maintained at the required level when the door is open. Alternatively, the andrology laboratory door should be closed when sperm is being processed.

[3] Cardiopulmonary Resuscitation Standards For Clinical Practice And Training, A Joint Statement from The Royal College of Anaesthetists., The Royal College of Physicians of London, The Intensive Care Society, The Resuscitation Council (UK), October 2004 updated June 2008.

Evaluation
Some improvements required.
Areas not covered on this inspection
All areas covered.

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

Audit of notes
An audit was conducted on ten sets of patient notes. Two Welfare of the Child (WoC) assessments were also absent. In one set of notes the “terms of embryo storage” for one couple had been incorrectly completed (one partner had consented for 5 year storage while to other partner had consented for 10 years).
Areas of firm compliance
Information provided to patients in the form of treatment specific leaflets was made available to the inspectorate and was considered appropriate and comprehensive. The centre reports that they have a procedure for responding to patient requests for access to their health records through the local NHS trust policy.
Areas for improvement
An audit of ten sets of patient notes was conducted during the inspection. Three “consent to disclose” forms were missing. Two welfare of the child assessments were also absent. In one set of notes the “terms of embryo storage” for one couple had been incorrectly completed. The centre has a considerable number of errors in data entered to the HFEA via the electronic data interface (EDI), and these errors prevent patient data entry onto the HFEA Register. The PR explained that the centre have been experiencing considerable difficulties with I.T. issues regarding the EDI system. The centre is also in the process of setting up further terminals to allow more members of staff to input data in a timely fashion. It should also be noted that at the time of inspection, the HFEA register team estimated that approximately 185 individual data errors have been generated since January 2009. This is a significant decrease when compared to the same time period from the previous inspection when 3500 individual data errors were reported.
Areas for consideration
At the time of the licence renewal in 2006, in response to operational audit findings in relation to the submission of HFEA treatment and outcome forms, a Licence Committee added an additional condition to the centre’s licence and the centre has been the subject of ongoing audits to monitor submission of HFEA forms*.*

Executive recommendations for Licence Committee
The PR must ensure that the WoC procedure is always applied, so that WoC assessment is present in all cases. This will ensure compliance with the HFE Act (1990) with amendments, Section 13(5), and prevent the possibility of breaching Section 33 of the same Act. The accuracy of data entry on the EDI system must be improved, as should the frequency of clearing of errors, to ensure compliance with Code of Practice, 7th Edition, Standards, S.6.5.1 (b) and the HFEA policy on the collection, confirmation and publication of Registry data, which was attached to Direction 2008/6. It is essential that all EDI errors are corrected and that weekly clearance of errors occurs, compliant with Direction 2008/6. The licence committee may wish to consider whether regulatory sanctions should be imposed regarding submission of information to the HFEA which is non-compliant with the requirements of D2008/6.
Evaluation
Significant improvement required.
Areas not covered on this inspection
All areas covered.

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	11
NMC registered nurses	11
Non NMC registered clinical staff	0
HPC registered scientists	3
Scientists working towards registration	6
Support staff (receptionists, record managers, quality and risk managers etc)	11
Counsellors	3

Summary of laboratory audit
A summary of the findings of an audit of stored embryos and gametes was submitted prior to the inspection. 14 discrepancies were noted and rectified.
Summary of spot check of stored material
No spot-check was performed on this inspection as an audit of stored embryos and gametes had been performed by the centre and a summary had been provided to the inspectorate
Areas of firm compliance
The Centre has an established induction programme in which all new staff undertake a training programme covering the centre's activities, as well as the standard local trust induction programme (which covers basic life support, health and safety, fire safety and manual handling). Competency assessments for medical and embryology staff were seen on the day of inspection and were considered appropriate by the inspection team. All staff interviewed considered that on-going training and continual professional development (CPD) needs were well supported by the centre.

The centre recruits sperm donors and all donor screening is conducted in compliance with professional body guidelines. There are policies in place for assessment of patients seeking treatments and for screening of patients. This was evident from the documentation submitted for inspection and discussion held with staff. The centre's donor payment protocol and a sample of donor files were reviewed at inspection reimbursements made to donors were found to be compliant with HFEA Direction D.2006/1. The centre has a procedure in place to ensure that the 10 families limit is not breached.

There are documented procedures for procurement, packaging, distribution, recall and receipt of gametes and embryos that ensure: quality and safety of the gametes; risk of contamination is minimised; evaluation, assessment and safety of the provider and that procurement conforms with appropriate age limits for gamete providers

During the inspection, evidence was provided that materials and equipment which comes into contact with gametes and embryos are traceable from procurement to disposal.

All samples of gametes and embryos are labelled with the patient's initial, surname and the last three digits of the hospital number. This information is checked the night before treatments to ensure that the number is unique on the day. If the number is not unique a fourth digit of the hospital number is added to ensure its uniqueness. This check is documented in the laboratory set up procedure.

All the unit's counsellors are members of the British Infertility Counselling Association and one is an accredited member of the British Infertility Counselling Association. The counsellors have team and individual supervision. Three counsellors provide a full time service from Monday-Friday. There is no waiting list for counselling and appointments are made directly or by referral from another member of the team. Counselling is free and the number of sessions is unlimited. A counselling audit was submitted on the day of inspection. According to the audit report, counselling sessions were provided to 264 patients from 1 April 2008 to 31 March 2009. Support counselling accounted for 38.5% of referrals and implications counselling for 37.7%. Therapeutic counselling accounted for 2.4% of counselling referrals.

Areas for improvement

Validation of key processes and procedures has not yet been fully established. This breach was also noted at the time of the previous inspection.

Competencies have been developed for nursing staff although they have not had the opportunity to complete them. This breach was also noted at the time of the previous inspection.

Procedures for witnessing are comprehensive but the requirement for cross checking sample identity against patient records is omitted at a small number of stages recommended in Code of Practice, G.13.1.1. This was discussed with the laboratory manager who explained that witnessing procedures are being reviewed. It is also noted that gametes and embryos are labelled with the patient's initial and surname which is not compliant with the recommendations of G.13.1.2.

Areas for consideration

None.

Executive recommendations for Licence Committee

It is recommended that a plan for validation is drawn up. The plan should take into account the particular needs of the centre and prioritise the validation of those processes and equipment considered to be most likely to impact on the quality of the service, to ensure compliance with Licence Conditions 11.11, 8.11 and 10.13.

The PR should ensure that the competence of each person to perform designated activities is evaluated at intervals specified in the quality management system and re-training undertaken when required as required by standards S.6.2.9. The PR should also ensure compliance with Code of Practice Guidance 1.3.1 which requires all nurses to be able to provide evidence of competency in the duties performed either by certification of a recognised qualification or by written testimonial by another suitable qualified and competent person in that discipline/function (e.g. ultrasound, embryo transfer, IUI, egg collection, etc.)

The PR should ensure witnessing procedures are reviewed such that all witnessing steps recommended by CoP G.13.1.1 are documented within them. If witnessing steps recommended in G.13.1.1 are omitted, the risks of these omissions should be evaluated, documented and controlled. Following the last inspection it was reported that witnessing procedures were reviewed and at the 2009 renewal inspection it was reported that an audit of witnessing has been carried out in the last year. However, in consideration that non compliance with guidelines remains an issue of concern, the centre should review their audit procedures to ensure that audits are carried out in compliance with the requirements of S.9.2.5.

Evaluation

Some improvements required.

Areas not covered on this inspection

All areas covered.

Report compiled by:

Name Paula Nolan

Designation Inspector

Date 15 June 2009

Appendix A: Centre staff interviewed

PR, clinical operations manager, laboratory manager, counsellor, quality manager, trainee embryologist, clinician and a couple undergoing treatment.

Appendix B: Licence history for previous 3 years

Licence	Status	Type	Active From	Expiry Date
L0094/13	Active	Treatment with Storage	01/02/2008	31/10/2009
L0094/12	Replaced by New Version	Treatment with Storage	01/11/2006	31/10/2009
L0094/11	Replaced by New Version	Treatment with Storage	01/11/2003	31/10/2006

Current licence condition as applied to L0094/12 and L0094/13

The Person Responsible must put measures in place to ensure an immediate and substantial reduction of errors in registration, treatment and outcome forms.

Appendix C: Response of Person Responsible to the inspection report

Centre
Number……0094……

Name of PR……Amanda Tozer
……

Date of Inspection…6/05/09…
……..

Date of
Response……7/07/09……

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

Signed……

Name……

Date……

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.

Quality Manager started in Nov 2008 and not in March The centre is open from Monday to Friday (Thursday missed on report)

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

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

Arrangements for payment of invoices will be reviewed. All invoices are paid by the Trust and as PR I have met with the financial manager to ensure that all invoices are to be paid in a timely fashion. OHSS cases now reported

All documents reviewed with Quality Manager and now controlled with scheduled annual review dates.

A risk assessment has been made with respect to controlled access and we feel that the risk is low, as there is controlled access to the fertility centre via swipe card and a receptionist is present at all times at the reception desk. However, regarding the door from the waiting area to the clinical corridor: I am in discussions with the trust to fit a swipe card system/key lock.

The presence of welfare of the unborn child forms is part of the check list process. The importance of ensuring this is checked has been reiterated to all staff.

The centre is working hard to ensure that data is submitted correctly. It was identified that there was a need for more EDI terminals which have been installed to increase the number from 2 to 9. However they cannot be used as they have no licence. This has been brought to the attention of the HFEA but we still have no licences and therefore only 2 operational EDI systems which is clearly insufficient for a unit of our size. There have also been periods of time where the EDI system has been down and no support provided by the HFEA I.T. Department. Many of the errors are merge errors with the system not operating from the HFEA end and we do feel that significant improvements have been made but have been hampered by operational support from the HFEA.

Competency programmes developed for the nurses include:
IUI procedures
HyCoSy and Aqua scans
Yearly competencies
Assisting with embryo transfer
Information session
Venepuncture
Injection teaching
Attached is an example of one of the competencies.

The theatre co-ordinator has the responsibility for checking the resuscitation trolley and the responsibility to delegate this when absent. This will be periodically checked by the Quality Manager.

The witnessing steps are being reviewed by the Laboratory Manager and will be completed by 6th August as stipulated.

Validation of processes is attached

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

30 July 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 1

Barts and The London Centre for Reproductive Medicine (0094) – Renewal

Members of the Committee:	Committee Secretary:
	Alexandra Tydeman
Clare Lewis-Jones (lay) - Chair	
Ruth Fasht (lay)	Legal Adviser:
Sue Price (clinician)	Graham Miles, Morgan Cole
Apologies:	
Chris Barratt (andrologist)	
Roger Neuberg (clinician)	

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 (68 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 Centre provides NHS and self-funded treatment: 1129 cycles were provided in 2008. The centre also provides treatment with donated eggs and recruits sperm donors.

2. The Committee considered the papers, which included renewal inspection report, renewal application, validation of processes sheet, Executive summary, validation action plan, nurse competencies action plan and previous Committee minutes.

3. The Committee noted that the inspection took place on 6 May 2009 and the response of the Person Responsible (PR) in Appendix C was dated 7 July 2009.

4. It was noted by the Committee that the inspection report had identified five breaches:
    - The submission of information to the HFEA
    - The documentation of training and assessment of competency
    - Validation of key processes
    - Payment of invoices
    - Incident reporting

5. The Committee noted the PR's response to the report and the actions that had been taken to rectify these breaches. The Committee particularly noted the response with regard to the delays caused by the HFEA in obtaining the licences for the additional EDI terminals and the effects this delay had on the Centre. The Committee requested the Executive to investigate the cause of these delays and take steps to resolve them.

<u>The Committee's Decision</u>

6. The Committee noted that there were no issues regarding the character, qualifications or experience of the Person Responsible or her ability to perform her duties under section 17 of the HFE Act 1990 (as amended). It was noted that the PR was registered with the General Medical Council (GMC) and was on the Obstetrics and Gynaecology specialist register, she had also completed the PR Entry Programme to the satisfaction of the Executive. Therefore, the Committee was satisfied as to the suitability of the PR.

7. During the inspection, it had been demonstrated that the Centre's premises were fit for purpose and the Committee, on this basis, was satisfied regarding the suitability of the premises.

8. The Committee noted that there were five breaches, listed above, in relation to the practices of the Centre. However, the Committee was satisfied, on the basis of the response from the PR, that action was being taken in relation to the five breaches and therefore agreed that it was satisfied that the Centre had suitable practices.

9. It was agreed that the Committee had sufficient and satisfactory information to make a decision, and noted that it was in receipt of a signed application form and that the necessary fee had been paid.

10. The Committee endorsed the Executive's recommendation to grant a licence for 5 years on the understanding that the breaches would be implemented within the set timeframes.

11. The Committee agreed that the Centre should be inspected within the next 2 years.

Signed..... Date.....19/8/09
Clare Lewis-Jones (Chair)