Interim Inspection Report

Barts and The London Centre for Reproductive Medicine 0094

Date of Inspection: 8 May 2008
Date of Licence Committee: 24 July 2008

CENTRE DETAILS

Centre Name	Barts and The London Centre for Reproductive Medicine
Centre Address	Kenton and Lucas Block St Bartholomew's Hospital London
Telephone Number	0207-601-7176
Type of Inspection	Interim
Person Responsible	Amanda Tozer
Nominal Licensee	Trevor Beedham
Licence Number	L0094-12-a
Inspector(s)	Debra Bloor Vicki Lamb Janet Kirkland (external advisor)
Fee Paid - date	Not applicable
Licence expiry date	31-10 -09

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About the Inspection:

This inspection visit was carried out on 8 May and lasted for 6 hours. The report covers the pre-inspection analysis, the visit and information received between 11 April 2007 and 8 May 2008.

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

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

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

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

NB: Where there are very minor issues to be addressed these are noted in the "minor issues to be addressed" section for each topic, and this will facilitate the evaluation of 'no improvements required'. 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 self funded and NHS funded treatments: 1146 cycles of IVF/ICSI/FET and DI were provided in 2007. The centre provides treatment with donated eggs and recruits sperm donors but does not sell sperm.

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

Activities of the Centre for 2007

Licensed treatment cycles (IVF, ICSI, FET)	1114
Donor insemination	32
Unlicensed treatments	timed intercourse, ovulation induction, infertility investigations
Research	No
Storage	Yes

Summary for Licence Committee

The Centre for Reproductive Medicine, St Bartholomew's Hospital is a large unit providing more than 1000 licensed treatment cycles per year.

The unit has appropriate premises, suitably qualified and experienced staff and adopts largely appropriate clinical and laboratory procedures. Patients report satisfaction with the treatment that they receive. 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 storage of cryopreserved material;
- Monitoring of equipment;
- Workload;
- Screening and recruitment of donors;
- Establishment of agreements with transport centres;
- Witnessing;
- The documentation of training and assessment of competency;
- Validation of key processes.;
- Payment of invoices.

The inspection team would recommend that progress in addressing the issue outlined should be made within the timescales specified.

The inspection team supports the continuation of the centre's licence.

Risk Assessment

In April 2008, the centre's risk score (HFEA risk tool v3) is calculated as 32%: this is considered a medium risk rating.

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 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.	The Person Responsible should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.	At the centre's discretion. Progress to be monitored at the time of the next inspection.
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.	The PR should consider whether there are any barriers to the team's ability to comply with the Act in relation to the storage of cryopreserved material. The PR should review the procedures for disposing of cryopreserved material for which there is no valid consent to storage as a matter of urgency. Any changes in procedure implemented as a result of the review should be communicated to the relevant staff and protocols should be amended as required.	The review of the procedures for disposing of cryopreserved material should be completed by 8 July 2008. The centre should have obtained written to consent to storage for all cryopreserved material or, where continued storage is not required, or if it is not possible to obtain written consent and all reasonable efforts have been made to contact gamete providers then embryos should have

		been allowed to perish by 8 September 2008. The PR should advise the HFEA when the issue is resolved and of the outcome of any review of practice.
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.	It is recommended that a plan for validation is drawn up. The plan should take into account the particular needs of the unit and prioritise the validation of those processes considered to be most likely to impact on the quality of the service.	Progress to be monitored in the course of the next inspection.
Diagnostic analysis of semen samples is carried out within the centre. COP standard 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.	The PR should seek local advice on the requirement for clinical pathology accreditation (CPA) of the semen diagnosis facilities.	The outcome of the review should be communicated to the HFEA by 8 September 2008. If accreditation is considered required then a timeline for completion of accreditation should also be submitted to the HFEA.
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.	The operation of the laboratory flow hood may affect critical processing parameters: the PR should ensure that all equipment which could affect critical parameters is identified and is the subject of appropriate monitoring, alerts, alarms and corrective action to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. In compliance with S.9.5.4 the PR should establish a documented procedure to eliminate the cause of	Corrective action should be taken immediately. If monitoring of the equipment indicates that the quality of gametes and/or embryos may have been compromised then this should be reported to the HFEA as an incident and a full investigation of any associated risks instigated. The centre should develop and implement procedures for eliminating non conformities by 8 September 2008.

	nonconformities.	
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).	Staff should have their competence assessed and documented.	A programme of assessment should be developed immediately. To be assessed at the time of the next inspection.
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.	Donor screening procedures should be reviewed as a matter of urgency to ensure compliance with the relevant standards. Patient information and standard operating procedures should be reviewed to ensure they reflect practice.	Procedures should be reviewed immediately and the HFEA should be informed of the outcome of the review and of any planned corrective actions.

Non-Compliance

Area for improvement	Action required	Time scale
The service agreement with parties involved in 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.	The PR should review the third party agreement with transport centres and ensure that the agreements are compliant with HFEA guidelines.	Agreement to be reviewed by 8 September 2008. Monitoring of the third parties compliance with the agreement to be monitored at the time of the next inspection.
Egg donors have not been screened for *Neisseria gonorrhoea* as recommended in BFS guidelines	The PR should review the standard operating procedures for screening of prospective donors after consideration of the BFS guidelines. The PR should also ensure that staff are aware of screening requirements and that all relevant screening tests are carried out on prospective egg donors. Alternatively, the rationale for non compliance with the guidelines should be documented. If screening procedures are changed, patient information should	Procedures to be reviewed immediately and any changes and/or corrective actions to be reported to the HFEA.

	be updated to include all of the screening tests carried out.	
Standard protocols for witnessing are comprehensive but the requirement for cross checking against patient records is omitted at a small number of stages	In compliance with guidelines at G.13 of the COP, the witnessing protocol should be reviewed to ensure that the protocol documents all stages where cross checking against records is required. If cross checking is omitted from the procedure then the risks of this omission should be evaluated and documented in compliance with G.13.3.1.	Review to be completed by 8 July 2008.

Recommendations

Recommendation	Time scale
It was reported that air quality will be monitored every six months. It is recommended that air quality monitoring procedures are validated to provide documented evidence that air quality is maintained in the time intervals between testing (A.10.19).	To be completed by the time of the next inspection.
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).	Review to be completed by 8 August and the HFEA to be advised of the findings of the review.
The protocol for transfer of cryopreserved material does not reference the requirement for shippers to be suitable for the purpose intended; they should be placed in suitable secondary protective container; procedures when labelling is not clear. The protocol for transfer of cryopreserved material should be revised in relation to the omissions described (Alert 21).	To be reviewed at the time of the next inspection.
Staff appeared uncertain about the restrictions on payment of gamete donors. Donor recruitment procedures should be reviewed to ensure compliance with HFEA directions D.2006/1. Standard operating procedures and patient information should be reviewed if any changes are made as a result of the review.	To be reviewed at the time of the next inspection.

Proposed licence variations by last L.C.

None

Changes/ improvements since last inspection

Recommendations	Action Taken
An operational audit performed on 27th and 28th February 2007 showed that of a random sample of treatments only 78% had been reported within the time requirements of Direction 1999/1. It was recommended that the centre work on the timeliness and accuracy of their reporting.	The centre was audited in July 2007: the conclusion of the audit was that the completion and timeliness of reporting had improved. Outstanding reporting was being addressed but was not complete at the time of the audit. The PR carried out and submitted the results of an audit of form submission in the first 6 months of 2007 in November 2007. The audit found that 81% of registrations, 93% of treatment forms and 43% of intention to treat forms had been submitted within prescribed timeframes. The centre was subject to a further operational audit in February 2008. The audit concluded that there was no significant improvement in the number of unreported treatments; there had been an improvement in timeliness and in data quality. At the time of the inspection, the HFEA register team estimated that approximately 3500 individual data errors have been generated since January 07. Of these errors, it is estimated that approximately 60 relate to missing registration forms, 40 to donor forms and over 100 for partner details.
Audit schedule to be formalised.	The findings of various clinical and laboratory audits were reviewed in the course of the inspection.
A health and safety assessment of the cryostore to be performed.	An assessment was completed as requested.
Documented competency assessments to be put in place for members of the clinical and embryology teams.	Extensive documentation for recording staff competence has been developed but staff competence has not yet been documented using the new procedures.

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 findings from inspection
Evidence is drawn from:

1. Leadership and management
2. Organisation of the centre
3. Resource management
4. Risk management
5. Incident management
6. Contingency arrangements
7. Payment of treatment fees

Areas of firm compliance
The Person Responsible (PR) has completed the HFEA PR entry programme. The responses submitted to the HFEA were considered consistent with suggested responses. The centre has an organisational structure with defined accountabilities and reporting relationships. The PR has implemented changes as recommended in the report of the previous inspection. The premises appeared suitably equipped and the PR reported that she is confident that the unit has sufficient staff with relevant expertise. The centre has made progress in establishing 3rd party agreements with suppliers: an agreement reviewed in the course of the inspection was compliant with HFEA recommendations. Processes are in place for the identification, notification and investigation of incidents: incidents have been reported within prescribed timeframes and have been investigated and resolved effectively. 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. Patients interviewed in the course of the inspection reported that they were aware of procedures for contacting the centre out of hours. It was reported that information from HFEA alerts is conveyed to all staff by email and that alerts are discussed at weekly management meetings. Evidence of this was seen in minutes reviewed in the course of the inspection.
Areas for improvement
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.

Areas for consideration
A number of potential breaches and/or non conformities were noted in the course of the inspection. On occasion, staff reported that workload pressures were impacting on the ability of staff to complete all of their duties (disposal of embryos for example). It is noted that the workload at the centre has been stable with 981 licensed treatment cycles provided in 2005, 1136 in 2006 and 1114 in 2007. However it is noted that in the time since the completion of the 2007 interim inspection report and the 2008 interim inspection, staffing levels in the clinical and emrbyology teams have declined: In 2006 the centre reported having 14 full time equivalent NMC registered nurses, 5 HPC registered scientists and 3 scientists working towards registration; staff numbers are now 11, 2 and 4 respectively. It was reported to the inspection team that one member of the embryology team is expected to become HPC registered in the near future and that there are plans for the recruitment of an additional two trainee embryologists in the summer of 2008. It was reported in the course of the inspection that cycle numbers were restricted following staff changes in the embryology team.
Executive recommendations for Licence Committee
The Person Responsible should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices. It is recommended that the PR assesses how many treatment 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: activity should adjusted according to the findings of the assessment.
Areas not covered on this inspection
Business planning Clinical governance Risk management Contingency arrangements

Evaluation
Some improvement required

2. Quality of service

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

Summary of findings from inspection:
1. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality objectives and plans
5. Quality Management review/evaluation
6. Monitoring and resolution of complaints
7. Staff suggestions
8. Live Birth Rates

Live Birth Rates
Outcomes for the time period from 31st March 2003 -1st April 2006 were in line with national averages. These data, which were extracted from the HFEA register, have not been verified by the centre and may be subject to change. In 2007 the centre reported an 18% multiple birth rate with one higher order pregnancy that followed a two embryo transfer. The centre provided 1114 cycles of IVF/ICSI and frozen embryo transfer in 2007: workload in 2007 was comparable to that of 2006 when 1136 cycles were provided.
Areas of firm compliance
The centre has a quality policy and manual. The centre has implemented quality management procedures. The PR is acting as the quality manager pending recruitment of an additional staff member. An organisational chart is in place that defines accountabilities and reporting relationships. The centre's documentation shows evidence of version control and review. The centre appears to have been proactive in developing quality management procedures. Some quality performance targets have been established and evidence of monitoring of clinical and laboratory practices was provided in the course of the inspection. The centre gathered patient feedback from 64 patients in the time since the last inspection: this represented a 34% response rate from the targeted patients. 91% of respondents rated their experience good or excellent. On the basis of patient feedback some improvements have been made to ensure patient privacy at reception and to procedures for contacting the unit. The HFEA has received feedback from 51 patients who have received treatment at the centre. The feedback is largely positive with 32 patients having compliments about the care they received while only 9 patients had any complaints. A couple undergoing treatment at the centre provided feedback on their experiences in the

course of the inspection. The couple reported that they their privacy and dignity had been given due consideration; they had experienced no difficulties in contacting the centre; they had been made aware of procedures for making a complaint and of the counselling service. They considered staff to be professional and supportive.

The centre has a complaints policy and a complaints log is maintained: the log was reviewed in the course of the inspection. It was reported that appropriate corrective actions had been implemented in response to a complaint reviewed in the course of the inspection.

Areas for improvement
A copy of the service agreement outlining the responsibilities of parties involved in the provision of satellite IVF was provided in the course of the inspection. It was noted that the agreement had expired on 31 March 2008. The agreement is not fully compliant with the requirements outlined in the HFEA third party guidance: the agreement does not summarise all of the responsibilities of the third party (for example in terms of obtaining consent, provision of counselling completion of welfare of the child assessment and/or provision of documentation to the primary centre).
Areas for consideration
None
Executive recommendations for Licence Committee
The PR should review the third party agreement with transport centres and ensure that the agreements are compliant with HFEA guidelines.
Areas not covered on this inspection
Staff Suggestions

Evaluation
Some improvement required

3. Premises and Equipment

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

Summary of findings from inspection:

1. General Suitable premises
2. Clinical facilities
3. Counselling facilities
4. Laboratory facilities
5. Air quality
6. Storage facilities for gametes and embryos
7. Staff facilities
8. Management of equipment and materials
9. Control of records
10. Risk assessments

Areas of firm compliance
On the day of the inspection the premises and facilities appeared well maintained, and suitably equipped. Patient notes are stored in a designated area with controlled access and new tracking systems have been implemented. Evidence of annual maintenance of a sample of laboratory equipment was provided in the course of the inspection. Evidence of air quality monitoring in all relevant areas was provided in the course of the inspection. Air quality was last monitored in May 2008: background air quality was assessed as grade D and air quality in processing areas was assessed as grade C. The centre participated in the National Quality Assessment Scheme (NEQAS) for the first time in May 2008: the outcome of the assessment had not been received at the time of the inspection. Gametes and embryos are stored in a laboratory to which access is 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 system. Procedures have been implemented to ensure the traceability of consumables that come into contact with gametes and embryos. Facilities are provided for staff and include a rest area with basic catering facilities and a supply of drinking water and a changing area and secure storage for personal effects. A service user providing feedback in the course of the inspection reported finding the sperm production facilities appropriate.

Areas for improvement
During a demonstration of the bring forward system it was observed that at the time of the inspection, the cryopreserved material of 26 patients was being stored without written consent. Paragraph 1 of schedule 3 of the 1990 Human Fertilisation and Embryology Act states that consent under this Schedule must be given in writing. Standard S.4.1.7 states that "the Person Responsible shall have responsibility for ensuring that proper arrangements are made for the keeping and disposal of gametes and embryos". Procedures for recording the batch numbers of medium and the equipment used during manipulation of gametes and/or embryos was not being recorded consistently at the time of the inspection. 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 licence condition A.10.13.
Areas for consideration
Diagnostic analysis of semen samples is carried out within the centre. COP standard 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.
Executive recommendations for Licence Committee
The PR should consider whether there are any barriers to the team's ability to comply with the Act in relation to the storage of cryopreserved material. The PR should review the procedures for disposing of cryopreserved material for which there is no valid consent to storage as a matter of urgency. Consent should be obtained for the material in storage as a matter of urgency. Any changes in procedure implemented as a result of the review should be communicated to the relevant staff and protocols should be amended as required. The operation of the laboratory flow hood may affect critical processing parameters: the PR should ensure that all equipment which could affect critical parameters is identified and is the subject of appropriate monitoring, alerts, alarms and corrective action to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. In compliance with S.9.5.4. The centre should develop and implement procedures for eliminating non conformities by 8 September 2008. The PR should see local advice on the requirement for clinical pathology accreditation (CPA for the semen diagnostic laboratory. The outcome of the review should be communicated to the HFEA by 8 September 2008. If accreditation is considered required then a timeline for completion of accreditation should also be submitted to the HFEA.
Areas not covered on this inspection
Clinical facilities Counselling facilities Risk assessments

Evaluation
Some improvement required

4. Information

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

Summary of findings from inspection:

1. General Information
2. Meetings and communication
3. Welfare of child
4. Confidentiality and access to health records
5. Traceability and coding
6. Coding/ identification of samples
7. Information for service users/consents
8. Donor information
9. Donor registration
10. Surrogacy
11. Procurement and distribution of receipt of gametes and embryos
12. Home procurement report documentation
13. Packaging &distribution
14. Labelling of packages containing procured gametes
15. Transportation, labelling of shipping container and recall
16. Receipt of gametes

Areas of firm compliance
The centre has developed standard operating procedures for the transfer of cryopreserved material in response to the recommendations of HFEA Alert 21.The protocol is comprehensive and largely compliant with the requirements as outlined in the Alert. A couple undergoing treatment at the centre provided feedback on their experiences of information provision in the course of the inspection. They reported finding both written and verbal information clear and easy to understand. They felt well informed about possible side effects of treatment.
Areas for improvement
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. At the time of the inspection, the HFEA register team estimated that approximately 3500 individual data errors have been generated since January 07. Of these errors, it is estimated that approximately 60 relate to missing registration forms, 40 to donor forms and over 100 for partner details. The outstanding errors were discussed in the course of the inspection with the PR and the

administrator with responsibility for HFEA form returns. It was reported that efforts to clear the backlog of errors had been hampered by long term absence of key staff and by lack of electronic data interface (EDI) hardware. Submission of registration forms has also been affected by the requirement recently introduced by the HFEA for male and female patient identifiers: previously, only the female partner was formally referred for treatment.

The senior administrator has recently returned to her post and the installation of further EDI terminals is planned. At the time of the inspection however, the installation of terminals on site was awaiting approval from local IT providers. Procedures have also been revised to ensure that both female and male partners attend for initial consultation with relevant identifiers.

The protocol for transfer of cryopreserved material does not reference the requirement for shippers to be suitable for the purpose intended; they should be placed in suitable secondary protective container; procedures when labelling is not clear. These are relatively minor omissions in an otherwise detailed protocol.

Areas for consideration
None

Executive recommendations for Licence Committee
Significant progress should have been made in the installation of EDI systems in the time since the inspection. If this has not been achieved then the licence committee may wish to consider whether regulatory sanctions should be imposed. The protocol for transfer of cryopreserved material should be revised in relation to the omissions described above.

Areas not covered on this inspection
General Information Meetings and communication Welfare of child Coding/ identification of samples Information for service users/consents Donor information Surrogacy Home procurement report documentation

Evaluation
Significant improvement required.

5. Laboratory and Clinical Practice

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

Summary of findings from inspection:

1. Laboratory processes
2. Selection and validation of laboratory procedures
3. Laboratory's documented procedures
4. Storage of gametes and embryos
5. Counselling
6. Witnessing

Full time equivalent staff

GMC registered doctors	9
NMC registered nurses	11
HPC registered scientists	2
Scientists working towards registration	4
Laboratory support staff	1
Support staff (receptionists, record managers, quality and risk managers etc)	6
Counsellors	4

Summary of laboratory audit / Audit of records
A summary of the findings of an audit of stored embryos was submitted prior to the inspection. No discrepancies were reported. It is anticipated that an audit of sperm samples stored at the centre will be completed within the two year prescribed timeframe.
Summary of spot check of stored material
No spot check audit was carried out.
Areas of firm compliance
Witnessing at the time of the embryo transfer was observed and was considered compliant with guidelines. Witnessing protocols were reviewed and were also considered largely compliant with guidelines. The documentation of witnessing was reviewed in three sets of patient records: all relevant witnessing stages were documented by two persons. A trainee member of the embryology team interviewed in the course of the inspection was able to provide evidence of training and competence assessment and continued professional development. It was reported that members of the nursing team are well supported in their continued professional development and attend annual mandatory health and safety training. All the unit's counsellors are members of British Infertility Counselling Association and one is an accredited member of British Association of Counselling and Psychotherapy. The

counsellors have team and individual supervision. A member of the counselling team interviewed in the course of the inspection had attended a six month course on oncology counselling a bereavement counselling conference and an infertility day.

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.

The counsellors attend the IVF information sessions and unit audit meetings. Counselling notes are stored securely and separately.

The centre has not carried out any three embryo transfers in patients aged less than 40 years in the time since the last inspection.

Areas for improvement

Standard protocols for witnessing are comprehensive but the requirement for cross checking against patient records is omitted at a small number of stages.

Validation of key processes and procedures has not yet been fully established. This is potentially a breach of S 7.8.3 of the COP and standard licence condition A.11.11.

Trained members of the embryology team have not had their competence to perform designated tasks assessed.

Members of the nursing team were not able to demonstrate that their competency to perform designated tasks had been 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. Egg donors are not screened for *Neisseria gonorrhoea* as recommended in BFS guidelines. Documentation of the outcome of the physical examination of donors was also absent from a sample of records reviewed.

There was a lack of clarity among staff participating in donor recruitment in relation to what payment of donors is permitted although it is noted that only two of the 22 sperm donors recruited have sought recompense for their time.

Areas for consideration

None

Executive recommendations for Licence Committee

In compliance with guidelines at G.13 of the COP, the witnessing protocol should be reviewed to ensure that the protocol documents all stages where cross checking against records is required. If cross checking is omitted from the procedure then the risks of this omission should be evaluated and documented in compliance with G.13.3.1.

It is recommended that a plan for validation is drawn up. The plan should take into account the particular needs of the unit and prioritise the validation of those processes considered to be most likely to impact on the quality of the service. Progress to be monitored in the course

of the next inspection.

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 that re-training is undertaken when required.

Donor screening procedures (including the screening of couples commissioning treatment with a surrogate) should be reviewed as a matter of urgency to ensure compliance with the relevant standards and/or guidelines. Patient information and standard operating procedures should be reviewed to ensure they reflect practice. The HFEA should be informed of the outcome of the review and of any planned corrective actions.

Donor recruitment procedures should be reviewed to ensure compliance with HFEA directions D.2006/1.

Areas not covered on this inspection
None

Evaluation
Some improvement required

Report compiled by:

Name…Debra Bloor…….

Designation…Head of Inspection…….

Date……10 June 2008……

Appendix A: Centre staff interviewed

The PR and eight other members of the centre's staff met with the inspection team.

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 L0004/12 and 13

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

Previous licence condition as applied to L0094/11:

That the Person Responsible ensure that copies of all documentation for satellite/transport patients be held at Centre 0094 (as the primary Centre). A copy of the agreement with Norwich should be submitted to the HFEA as required by HFEA Directions Ref D 2000/3.

Previous recommendations as applied to L0094/11:

- You as the Person Responsible must ensure that the client's consent is obtained and documented before approaching his or her general practitioner.
- You as the Person Responsible should ensure that you pursue an answer from the GP concerning Welfare of the Child, and the Committee suggested that the patient could take the relevant proforma to the GP.
- You as the Person Responsible should advise the HFEA of the outcome of the discussions with the Trust anaesthetic department concerning safe practice during egg collection.
- You as the Person Responsible should advise the HFEA when all storage dewars in

use are lockable and alarmed and should confirm that the new premises will be appropriately fitted with low level oxygen alarms.

- You as the Person Responsible consider redrafting the egg sharing agreements to provide separate agreements for the provider/donor and the recipient and ensure there is adequate counselling provision for all those going forward for egg sharing. The Licence Committee asked that the following points be brought to your attention: " An audit of counselling provision since January 2003 was to be provided to the HFEA (as agreed at the renewal inspection).
- That care should be taken to ensure that confidentiality of patient records is maintained at all times.

Appendix C: Response of person responsible to the inspection report

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number: 0094

Name of PR: Amanda Tozer

Date of Inspection: 8/05/08

Date of Response: 5/07/08

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

Signed:

Name: Amanda Tozer

Date: 5/07/08

1. Correction of factual inaccuracies

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

Page 14: The text discusses the service agreement involved with transport IVF. We do not do transport IVF[1]. We have a satellite clinic in Norfolk where scans are performed for licensed treatments but all patients attend Bart's for egg collections and embryo transfers. There is no need therefore for compliance with air quality etc as no treatment is performed at the satellite clinic in Norfolk.

The agreement was out of date and is currently being rectified.

[1] Body of text revised to correct this factual inaccuracy

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

1. The time taken to pay HFEA invoices has been highlighted to the Trust as a potential breach of standard licence condition

2. A review of the procedures for disposing of cryopreserved material has been made. Almost all cryopreserved material where consent has not been obtained for continued storage has now been allowed to perish and this will be complete by the given timescale of September 8th 2008. A review of the protocols for contacting patients has been made and no changes have been considered to be necessary. The laboratory manager will ensure that protocols are followed by the embryology team and that time is allowed for completion of this task.

3. As PR I am seeking advice regarding the requirement of clinical pathology accreditation of the semen diagnosis facilities and will communicate this to the HFEA by September 8th 2008

4. The alarm light indicating malfunction of a flow hood has been looked into and the problem is with the alarm light itself which will be replaced. I do not consider that there has been a comprimise to gametes and embryos.

5. All donor records now include a checklist to ensure all necessary screening tests have been completed. This includes N.Gonorrhoea for egg donors.

6. The laboratory manager has reviewed the witnessing protocols

7. As PR I reviewed the workload within the unit in January of 2008 given the decrease in staffing levels particularly in the embryology team. I 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 I do feel that this provides staff with adequate time to perform their necessary duties. Since the time of the inspection 2 1 more HPC registered scientist has started and a further one will start in August. I am looking at the working practices of the teams to assess the effectiveness of use of time.

8. Data errors and submission of data has been addressed and the Trust have employed assistance for this so that the backlog of errors can be completed as well as the ongoing submission of data in a timely fashion. This is being monitored so that progress is made and will continue to be monitored. The EDI systems have been installed allowing more than 1 staff member to input data.

9. The agreement with Norfolk was out of date and is currently being rectified.

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

Please return Appendix C of the report to:

Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

24 July 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 7

Barts and the London Centre for Reproductive Medicine (0094)
Interim Inspection

Members of the Committee:	In Attendance:
Anna Carragher, Lay Member – Chair	Debra Bloor, Head of Inspection
Ruth Fasht, Lay Member	Claudia Lally, Committee Secretary
Roger Neuberg, Emeritus Consultant in Obstetrics and Gynaecology, Leicester Royal Infirmary	Providing Legal Advice to the Committee: Mary Timms, Field Fisher Waterhouse

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 (32 pages)
- no papers were tabled.

1. The papers for this item were presented by Debra Bloor, HFEA Inspector. Dr Bloor informed the Committee that the inspection visit to this centre had taken place on 8 May 2008. The inspection found that the unit has appropriate premises, suitably qualified and experienced staff and adopts largely appropriate clinical and laboratory procedures. However a large number of areas for improvement were identified by the inspection team. These included:
    - the submission of information to the HFEA
    - the storage of cryopreserved material
    - monitoring of equipment
    - staff workload
    - screening and recruitment of donors
    - establishment of agreements with transport centres
    - witnessing
    - the documentation of training and assessment of competency
    - validation of key processes
    - payment of invoices.

2. Dr Bloor summarised the issues identified at the inspection, and described at pages 6 to 9 of the report, and the actions being taken to address these issues, as indicated by the Person Responsible in her response to the report, appended at pages 24 to 25.

3. Dr Bloor reported that she had spoken that morning with the Registry team who confirm that the error rate in the information submitted by the centre to the HFEA via the electronic data interchange system remains very high, the team also confirm that the centre has recently been working with the HFEA to correct errors in data submitted in 2007.

Legal Advice

4. In response to a question from the Committee, the Legal Adviser advised the Committee regarding its powers to revoke a licence and impose conditions on a licence under Section 18 of the Human Fertilisation and Embryology Act 1990.

The Committee's Decision

5. The Committee noted the areas for improvement identified in the report and the response by the Person Responsible. The Committee expressed its serious concern about the findings of the inspection, particularly as a similar range of findings were discussed in relation to the previous inspection of the centre, discussed at a Licence Committee meeting on 16 August last year.

6. In particular, the Committee noted with concern the continued very high error rate in the register data submitted to the HFEA.

7. The Committee decided that the centre should be required to attend a meeting with the HFEA Executive to discuss how they intend to address the breaches of the Act and Code of practice identified in the report and the high rate of errors in registry data submitted. The Committee agreed that it expected the centre to work with the Executive to ensure that significant reductions are seen in the error rate.

8. The Committee asked that the Executive reports back to the Committee in six months in order to assess the improvements that have been made. At that meeting the Committee may consider the option of further regulatory sanctions.

Signed……. … Date……..
Anna Carragher (Chair)