Licence Renewal Inspection Report for Treatment and Storage Centres

Queen's Medical Centre Fertility Unit, Nottingham
0162

Date of Inspection: 8 February 2007
Date of Licence Committee: 23 May 2007

CENTRE DETAILS

Centre Address	B Floor, East Block Derby Road Nottingham NG7 2UH
Telephone Number	0115 924 9924
Type of Inspection	Renewal Treatment and Storage
Person Responsible	James Hopkisson
Nominal Licensee	Marion Macpherson
Licence Number	L0162/12/a
Inspector(s)	Parvez Qureshi (Lead Inspector)
	Neelam Sood
Fee Paid - date	To be invoiced
Licence expiry date	30 June 2007

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About the Inspection:
This inspection visit was carried out on 8 February 2007 and lasted for 6 hours. The report covers the pre-inspection analysis, the visit and information received between February 2006 and January 2007.

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

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

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

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

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

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

Brief Description of the Centre and Person Responsible

Queens Medical Centre Fertility Unit has been licensed since 1992 and has a good history of compliance with no previous conditions on its licence. This is a small centre to which NHS and self-funded patients from Nottingham and the surrounding areas are referred by their GPs.

Over the last year 30 donor insemination (DI) cycles were carried out at the unit. Since the last inspection no major changes have been made to the premises. The merger between centre 0162 and NURTURE centre 0076, which is also located within the same building, is still being considered.

Opening hours at the centre are Monday - Thursday 8am - 4pm. Friday 8.30am - 1.30pm and Saturday morning. An organisational chart is in place indicating key functions and lines of accountability within the unit

The Person Responsible (PR) is appropriately qualified to discharge his duties as outlined in section 17 of the HF&E Act.

Activities of the Centre

Donor Insemination	30	
Unlicensed treatments	Intra-uterine insemination (IUI)	
Storage	Yes	

Summary for Licence Committee

Since the last inspection, some improvements have been made at the centre. However, additional improvements are required to the quality of service being provided.

The inspection team recommends the renewal of the centre's treatment and storage licence for three years.

Risk Assessment

The current risk matrix score for centre is 11%.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	x	

Evaluations from the inspection

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

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
None.	None	None

Non-Compliance

Area for improvement	Action required	Time scale
Review of centre's documents.	Signing off of completed tasks and inclusion of review dates for new documents.	Within a month from report being presented to the Licence Committee.
Information on the centre's success rate for DI.	To be provided in writing.	Within a month**.**
Confirming identity of patients seeking treatment.	Development of a procedure for verifying patients' identity.	Immediately.
Feedback from patients.	Need to develop one.	As soon as possible.

Recommendations	Time scale
The PR needs to ensure that measures are in place for premises and equipment to meet with the EUTD requirements.	As soon as possible.

Proposed licence variations

None

Changes/ improvements since last inspection

Development of new Quality Management documents for the unit.
New risk management procedure in place.
Establishment of a donor bank.
Clinical Pathology Accreditation (CPA).

Additional licence conditions and actions taken by centre since last inspection

C	None.
A	None.

Report of Inspection findings

1. **Organisation**

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

Summary of findings from inspection
Evidence is drawn from:

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

Areas of firm compliance
Documentation including an organisational chart showing main functions and lines of accountability within the unit were supplied for the inspection. Key members of the staff have extensive experience of working in the fertility field and also have been at the unit for a considerable time. All staff interviewed during the inspection stated that they were well supported by the PR in all aspects of their work. The PR stated that requirements highlighted in the last inspection have been addressed. The centre has a Quality Manager in place and the PR confirmed that he was aware of the new HFEA Standards and the requirements of the EU Tissue and Cells Directive. Since the last inspection the laboratory has acquired Clinical Pathology Accreditation (CPA) and has developed a Total Quality Management system. Currently the centre's documents are arranged manually. However, the inspection team was informed by staff that they will be changing over to a new document control system in the near future. Minutes of multi-disciplinary team meetings held at the centre to discuss practice related issues were seen during the inspection and were found to be satisfactory. Complaints and incidents logs together with evidence of risk assessments being carried out at the unit were made available for the inspection. All staff are made aware of the HFEA alerts and this was evident from the staff interviewed. The unit has access to NURTURE centre 0076 ethics committee. However, since the last inspection no referrals have been made to it.

Contingency arrangements are in place, with NURTURE centre 0076, in the event of an emergency.

The PR stated that the centre uses the Trust's clinical governance policies. Regular audits of practice, results, patient feedback and of records are carried out by staff. Incident reporting and complaints management procedures are in place and these were discussed during the inspection.

Information from the HFEA finance department showed that there were no issues with the centre over the payment of treatment fees.

Areas for improvement

Additional details need to be added to the organisational chart.

The PR anticipates an increase in the centre's workload within the next year and stated that the availability of extra funds for recruitment of additional staff were limited.

Executive recommendations for Licence Committee

None.

Areas not covered on this inspection

All areas covered.

Evaluation

Some improvements required.

2. Quality of service

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

Summary of findings from inspection:

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

Live Birth Rates

Summary of the donor insemination (DI) information from the HFEA Success Rate Assessment (31st March 2002 – 1st April 2005):

For the age group 40-42 and 35-39 the success rates are lower than national average.

For age band below 35 the success rate is higher than national average.

Areas of firm compliance

Discussions held with staff and a review of the documentation submitted for the inspection showed that 'Welfare of Child' assessment procedures are in place.

The centre has a robust confidentiality procedure in place. All patients' medical records are stored in secure areas with only members of the staff having access to them. Consultations with the patients are held in private rooms and any treatment offered is documented in their notes.

A total of three patient questionnaires were returned to the HFEA. Overall the responses were positive and these were discussed with the centre's staff. There is a suggestion box placed in the centre for seeking patients' views on the quality of service provided to them. Any suggestions made are discussed by staff and where possible improvements are made.

There is an on call rota system in place for outside working hours and patients are provided with all the relevant contact numbers.

The centre's complaints procedure was seen during the inspection and the PR stated that since the last inspection no complaints have been made by the patients.

The counsellor has been associated with the centre for three years and also provides a counselling service at the NURTURE centre 0076. She is a member of the British Infertility Counselling Association (BICA) and stated that her CPD, which is both self and centre funded, was up to date. Evidence of this was provided during the inspection. The counsellor receives regular supervision from a mentor. She stated that she is unable to attend centre's MDT meetings. However, she does have access to the minutes of the meetings and is able to raise any problems with the PR as and when required.

Counselling sessions take place in a dedicated room within the centre and the notes are kept separately from the patients' treatment notes in a secure place.

The counselling audit supplied to the inspection team confirmed that there were a total of 117 referrals between January and December 2006. The uptake rate for counselling is relatively high for the number of patients seeking treatment. Referral data show that supportive/ therapeutic counselling is the most frequently attended, followed by implications and sperm donors.

A sperm donor bank has been set up at the centre. All donors receive counselling and are thoroughly screened before donation. The arrangement for recruitment of donors was found to be satisfactory.

Areas for improvement

Referrals to the centre are made by GPs. However, there is no formal procedure in place for verifying the identity of the patients seeking treatment, other than their national health number.

Executive recommendations for Licence Committee

None.

Areas not covered on this inspection

Egg sharing and surrogacy.
Protection of children arrangements (for patients under 18yrs).

Evaluation

Some improvements required.

3. Premises and Equipment

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

Summary of findings from inspection:

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

Areas of firm compliance
Access to the centre is via a key pad operated system. Since the last inspection no major changes have been made to the premises. All areas seen during the inspection were found to be clean and well presented. The inspection team considered the current cryostore facilities at the unit to be adequate for the volume of work being carried out. There is controlled access to the cryostore area which is fitted with a low oxygen monitoring system. All dewars are alarmed and linked to an autodialler system. The inspection team considered that the procedures for responding to alarms were satisfactory. Since the last inspection, no significant changes have been made to the equipment. The unit is in the process of acquiring two new vapour phase refrigerators for storage of samples. Maintenance contracts are in place for key pieces of equipment in the laboratory and evidence of this was made available. Logs of activities carried out in the laboratory are kept and these were seen during the visit. In the event of a power failure the centre has access to a back up generator.
Areas for improvement
None
Executive recommendations for Licence Committee
The PR needs to ensure that measures are in place for premises and equipment to meet with the EUTD requirements.
Areas not covered on this inspection
All areas covered

Evaluation
No improvements required.

4. Information

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

Summary of findings from inspection:

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

Outcome of audit of records
A total of ten patient records were reviewed by the inspection team. The notes were found to be well organised with all the relevant documents being in place. However, some errors were identified and these were discussed with the centre's staff.
Areas of firm compliance
The centre's information management system seen during the inspection was considered to be satisfactory. All treatment related information is stored in secure areas. The centre has a robust system for tracking live birth events via use of DI and donor databases. Once the donor has reached 7-8 pregnancies then samples are stored for siblings use only. During the inspection an example of this procedure was seen. The patient information submitted for the inspection was reviewed and was found to be of a good standard. The following information also was seen during the course of the inspection: Centre's treatment licence. Complaints procedure. HFEA leaflets. Counselling services. No issues were raised by the HFEA Registry regarding return of treatment forms by the centre.
Areas for improvement
Signing off of completed projects and inclusion of review dates for new documents. The centre's success rate for DI is not included in patient information. The centre has no system in place for patient feedback on the quality of service being provided.

Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
All areas covered.

Evaluation
Some improvements required.

5. Laboratory and Clinical Practice

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

Summary of findings from inspection:

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

Full time equivalent staff

GMC registered doctors	2
NMC registered nurses	2
HPC registered scientists	
Andrologist	3
Scientists working towards registration	--
Support staff (receptionists, record managers, quality and risk managers etc)	5

Summary of laboratory audit
A recent laboratory audit of stored samples was made available during the inspection. No discrepancies were found.
Summary of spot check of stored material
An audit of two samples from notes to dewars and vice versa was carried out. No discrepancies were found.
Areas of firm compliance
The unit has 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 has a thorough witnessing procedure in place. Evidence of this was seen in the laboratory documents and in the patients' notes reviewed. The PR stated that CPD for staff is addressed through internal and external training and courses. This was evident from the discussions held with staff.

Staff meetings are held every alternate month and formal departmental meetings are held once a month. The outcomes from these meetings are circulated to all staff, even if they were absent from the meetings.
A corporate policy is in place for the recruitment of staff and their suitability to work in the centre. However, the PR does have some input into the recruitment procedure. The staff turnover is very low.

Areas for improvement

None.

Executive recommendations for Licence Committee

None.

Areas not covered on this inspection

PGD/ PGS.

Evaluation

No improvements required.

Report compiled by:

Name……Parvez Qureshi…….

Designation……Inspector…….

Date……13 March 2007……

Appendix A: Centre Staff interviewed

The PR and five other members of staff.

Appendix B: Licence history for previous 3 years

2006

Licence Committee 8 June 2006
Licence continued with one condition and no recommendations.

2005

Licence Committee 11 April 2005
Licence continued with no condition and no recommendations.

2004

Licence Committee 13 May 2004
The committee agreed to renew the centre's licence for 3 years with one condition and six recommendations.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……0162……

Name of PR……..James Hopkisson……

Date of Inspection……8th February 2007……...

Date of Response……8th May 2007……

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

Quality manual has been placed into an organisational computer programme.

Air quality – monitored.

Patient and user feedback Questionnaire in place.

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

Signed…A signed hardcopy received from PR……

Name……

Date……

2. Correction of factual inaccuracies

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

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

23 May 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 3

Queens Medical Centre (0162)
Licence Renewal

Members:
Sharmila Nebhrajani, Lay Member – Chair
Emily Jackson, Lay Member
Anna Carragher, Lay Member
Richard Harries, Lay Member
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary

In Attendance:
Frances Clift, Legal Adviser
Chris O'Toole, Head of Research Regulation
Claudia Lally, Committee Secretary

Clinical Adviser to the Committee:
William Ledger, Professor of Obstetrics and Gynaecology, University of Sheffield

Conflicts of interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- papers for Licence Committee (35 pages)
- no papers were tabled.

1. The papers for this item were presented by Parvez Qureshi, HFEA Inspector. Mr Qureshi informed the Committee that this centre has been licensed since 1992 and has a good history of regulatory compliance. The centre offers a combination of NHS and self-funded treatments and carried out only 30 treatment cycles last year. Its risk score currently stands at 11%. The inspection visit found that some improvements have been made since the time of the last inspection, such as the establishment of a quality management system. The centre has also set up a donor bank which has had some success and is hoping to recruit more donors in the future.

2. Mr Qureshi informed the Committee that the Person Responsible for the centre has assured him that all of the improvements identified in the inspection report have now been addressed.

3. The Committee agreed to renew the centre's licence for a period of five years with no additional conditions.

Signed…… … Date……..
Sharmila Nebhrajani (Chair)