Interim Inspection Report

London Women's Clinic
0105

Date of Inspection: 13 December 2007
Date of Licence Committee: 6 March 2008

CENTRE DETAILS

Centre Address	113-115 Harley Street London W1G 6AP
Telephone Number	0207 487 5050
Type of Inspection	Interim Inspection
Person Responsible	Geetha Venkat
Nominal Licensee	Kamal Ahuja
Licence Number	L0105/17/a
Inspector(s)	Parvez Qureshi (Lead)
	Steve Lynch (External)
Fee Paid - date	Not due
Licence expiry date	28 February 2009

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About the Inspection:
This inspection visit was carried out on 13 December 2007 and lasted for 6 hours. The report covers the pre-inspection analysis, the visit and information received between March and December 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 interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the 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

The London Women's Clinic has been licensed since 1992. Currently there are no conditions on its licence The centre is privately owned and currently is carrying out over 1000 treatments per year.

The premises have undergone further refurbishment since the last inspection. An organisational chart is in place indicating key functions and lines of accountability.

The centre is open for business Monday to Friday from 8.00 am to 5.30 pm and Saturday morning.

The Person Responsible (PR) has completed the PR Entry Programme and is appropriately qualified to discharge her duties.

Activities of the Centre

	01/01/2006 – 31/12/2006
Licensed treatment cycles	N/A*
Donor Insemination	526
Storage	Yes

* Only DIs carried out between 01/01/2006 – 31/12/2006

Summary for Licence Committee

Since the last inspection a number of improvements have been made at the centre. However, additional improvements are required in some areas of the service. Overall the centre appears to be well organised.

An inspection by the Healthcare Commission was also conducted on the same day as the HFEA visit. However, both organisations inspected against different aspect of the service provided by the centre.

A number of Breaches of the Act or Code of Practice were identified. The weight to be attached to these reported breaches is a matter for the Licence Committee to determine.

The inspection team recommends the continuation of the centre's licence for treatment with storage.

Risk Assessment

The current risk matrix score for centre is 16%
EUTD - The centre scored a low risk rating of 12% with regard to compliance with the requirements of the EUTD.

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 The table below sets out matter which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and or Code of Practice. The weight to be given to any breaches of the Act, Standard Licence Conditions or Code of Practice is matter for the Licence Committee

Breach	Action required	Time scale
Establishment and review of contracts with third parties and transport. **(S.4.2.10)**	All third party agreements need to be formalised.	Within three months from report being presented to a (LC).
Quality Management System (QMS) not in place. **(S.5.1, S.5.2, S.2.6)** **Directive 2004/23/EC, Art.16**	Development of a comprehensive QMS.	Within three months from report being presented to a (LC).
Air Quality. **(S 7.8.5)** **(G9.4.1)**	Monitoring of air quality in the laboratory.	Within three months from report being presented to a LC.
Continuing education and professional development (CPD). **(S.6.2.8, S.6.2.11)** **G.1.2**	Addressing of CPD for staff.	On-going.

Non-Compliance

Area for improvement	Action required	Time scale
Improvements in the quality of forms being returned to the HFEA.	Auditing of forms prior to submission to the HFEA.	Immediately.

Recommendations	Time scale
Departmental meetings.	On-going.
Review of security for the room housing the medical notes.	As soon as possible.
Review of out of hours on call system.	As soon as possible.

Proposed licence variations

None.

Changes/ improvements since last inspection

Further refurbishment of the premises.
Recruitment of additional staff to meet increase workload.
Resolution of issues raised in last inspection and areas highlighted in the EUTCD application.

Additional licence conditions and actions taken by centre since last inspection

C	Not applicable.
A	Not applicable.

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
An organisational chart showing main functions and lines of accountability within the unit was submitted for the inspection. The majority of staff have extensive experience of working in the fertility field and have been at the centre for a considerable time. Staff interviewed during the inspection stated that they were well supported by the management team. A Quality Manager has been appointed to ensure that the centre complies with the new HFEA Standards and the requirements of the EU Tissue and Cells Directive. Issues highlighted in the recent application to vary the centre's licence to include intra-uterine insemination (IUI) treatment have been addressed or are in the process of being actioned. As noticed during the last inspection, regular multi-disciplinary team meetings are held at the centre and the outcomes are circulated to all staff. The minutes of three recently held meetings were reviewed by the inspection team and considered to be satisfactory. On the day of the inspection a multi-disciplinary team meeting was held at the centre and the inspectorate had the opportunity to attend this and found it to be informative. There are arrangements in place for risk management and these are carried out as and when required, evidence of a number of risk assessments conducted since the last visit were seen during the inspection. The unit has an incidents log in place and this was reviewed and considered to be satisfactory. Incident log entries showed that the HFEA had been informed of all appropriate incidents. The PR informed the inspection team that staff are made aware of the HFEA alerts and any action required is taken by the appropriate s personnel. This was further confirmed by the discussions held with members of staff. Review of the complaints log showed that since the last inspection the centre had received six complaints and all of them had been resolved.

The centre has access to an ethics committee. However, the PR confirmed that over the past year no case has been referred to it. In the event of an emergency, contingency arrangements are in place with other centres within the London Women's Clinic group.

There are procedures in place for conducting regular audits of practice including patient feedback and centre's success rates, any areas of concern are addressed accordingly.

No issues have been raised by the HFEA finance department regarding payment of treatment fees.

Areas for improvement

It was noticed by the inspectorate that the centre has numerous third party agreements in place. However, not all have been formally signed off.

The unit has only basics of a Quality Management System (QMS) in place. The Quality Manager needs to develop the QMS and its application rapidly to have full compliance with the Code of Practice 7th Edition.

Currently no documented laboratory meetings are held.

Executive recommendations for Licence Committee

All third party agreements need to be formalised.

Development of a comprehensive QMS.

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
The information from the HFEA Success Rate Assessment (31st March 2002 – 1st April 2005) can be summarised as follows: The IVF/ICSI for all age groups lower than national average. The FET except for the age groups 40-42 higher than national average. The DI for all age groups except for 40-42 lower than national average.
Areas of firm compliance
Staff interviewed and a review of the documentation submitted for the inspection showed that 'Welfare of Child' assessment procedures are in place. Medical records are stored in secure areas with only members of the staff having access to them. Patients' confidentiality is well maintained and evidence of this was seen during the visit. All consultations are held in private rooms. A patient interviewed during the inspection made complimentary comments about the quality service she had received at the centre. A total of 43 patient questionnaires were returned to the HFEA and the majority of the responses made by the patients were positive regarding their experience at the unit. The counsellor stated that patients are made aware of the counselling service through the patient information and at their initial consultation. Those involved in the egg sharing programme have to seek counselling prior to commencing their treatment. The counsellor is a member of the British Infertility Counselling Association (BICA). Her continuous professional development (CPD) is well maintained. She receives regular supervision from a mentor and attends the centre's open evening events held for prospective patients.

All counselling sessions take place in a dedicated room located within the centre and the notes are kept in a secure place. Appointments can be booked via the administration staff or by contacting the counsellor directly. Currently there is a two to four weeks waiting list and no additional charge is made for counselling.

The counselling audit submitted for the inspection confirmed that 607 referrals were made between January 2007 and December 2007, indicating a good uptake rate for the number of patients seeking treatment**.** Referral data show that implications counselling was the most frequently attended.

Areas for improvement
Access to the room housing the medical notes was considered to be adequate. However, additional measures could be considered to make the room more secure.

Executive recommendations for Licence Committee
None.

Areas not covered on this inspection
Surrogacy. Protection of children arrangements (for patients under 18yrs).

Evaluation
No 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:

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

Areas of firm compliance
Since the last inspection no major changes have been made to the premises other than some ongoing refurbishment. All areas seen during the visit were found to be clean and well presented. There is a controlled access to both the IVF and the donor bank areas, with each having a dedicated entrance. The current cryostore facilities are adequate for the volume of work carried out. All dewars containing patient's material are locked and fitted with alarms linked to an auto dial out system and monitored remotely The cryostore facilities are fitted with a low oxygen monitoring system and there are adequate procedures in place for responding to alarms. A spare dewar for storage of sperm and embryos is available in cases of an emergency. Since the last inspection, no major changes have been made to the equipment other than the centre acquiring two additional Laminar hoods. Maintenance contracts are in place for key pieces of equipment and evidence of this was seen during the visit. Logs of activities carried out in the laboratory are kept and these were seen during the inspection and considered to be well maintained.
Areas for improvement
The background air quality in the laboratory area is compliant with the requirements of the EUTD, not all key processes take place in an environment of at least grade C air quality.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
All areas covered.
Evaluation
Some 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
Ten patient records were reviewed during the inspection for different treatments. The notes were found to be well organised with relevant documents being in place.
Areas of firm compliance
The centre's information management system seen during the inspection was considered to be well organised. All treatment related information is stored in a secure area which is only accessed by staff. The patient information submitted for the inspection was reviewed and found to be of a good standard. The following information was also seen during the course of the visit: The Centre's treatment licence. Complaints procedure and Counselling services. Details of various treatments offered at the centre. HFEA leaflets. Treatment forms are sent to the HFEA Registry within the required timescale.
Areas for improvement
Concerns were raised by the HFEA Registry Department regarding the return of incomplete treatment forms by the centre. The PR needs to put measures in place to address the quality of forms being returned to the HFEA.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
All area 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	2.9
NMC registered nurses	7
HPC registered scientists	2
Scientists working towards registration	4
Support staff (receptionists, record managers, quality and risk managers etc)	8

Summary of laboratory audit
A copy of a recent laboratory audit of stored samples was submitted for the inspection. No discrepancies were identified.
Summary of spot check of stored material
An audit of 2 embryos and 2 sperm samples was carried out. No discrepancies were found.
Areas of firm compliance
There are policies in place for assessment of patients seeking treatments and for screening of patients. These were evident from the documentation submitted for inspection and from the staff interviewed. Key protocols reviewed by the inspectorate do reflect the quality of service being offered at the centre. The centre has a comprehensive witnessing procedure in place for processes carried out in the laboratory. This was evident from the review of documents and discussions held with the laboratory staff. Since the last inspection, staff have undergone mandatory training including fire, infection control and manual handling. Documented evidence of this was made available for the inspection.

Review of the 3 embryo transfer (3ET) log showed that a total of 28 were carried out between January and September 2007. All these 3ET were for patients who were above 40 years of age.

The suitability of staff to work within the centre is the responsibility of the London Women's Clinic Group's management team. An induction programme is in place for new staff and a documented example of this was seen by the inspectorate.

Areas for improvement

CPD for the majority of the staff is well maintained and documented evidence of this was made available for the inspection team. However, due to the current workload, CPD for some of the laboratory staff is not being fully addressed. This was evident from the discussions held with the laboratory staff.

The centre's out of hours on call system needs to be reviewed to ensure that only specified laboratory staff are on call at any one time rather than the entire team.

Executive recommendations for Licence Committee

None.

Areas not covered on this inspection

PGD/ PGS.

Evaluation

Some improvements required.

Report compiled by:

Name……..…Parvez Qureshi…….

Designation……Inspector……...

Date…….25 01.2008……

Appendix A: Centre Staff interviewed

The PR and six other members of staff

Appendix B: Licence history for previous 3 years

2007

Licence Committee 23rd May 2007
The Committee agreed that the centre's licence should continue with no additional conditions.

Licence Committee 26th April 2007
The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

2006

Licence Committee 22nd November 2006
The Committee was satisfied that the premises were suitable for IVF and ICSI and agreed to vary the centre's licence to add IVF and ICSI, subject to a follow up visit being undertaken before any such treatment commences.

Licence Committee 27th February 2006
The Committee decided to grant the centre a licence to store embryos and sperm and to carry out donor insemination. This licence is for three years and with no additional conditions.

2005

Licence Committee 19th December 2005
The Committee agreed to issue a 12 month storage licence to the centre.

Licence Committee 30th November 2005
The Licence Committee agreed to recognise Dr Geetha Venkat as the new Person Responsible.
The Licence Committee agreed that the concerns raised in the inspection report were serious enough to justify the non-renewal of the centre's licence for donor insemination. The centre agreed to withdraw their application for a treatment licence and re-submit an application for a storage licence only.

Licence Committee 22nd June 2005
The Licence Committee agreed to the renewal of the licence for six months, for the storage of gametes and embryos, and carrying out donor insemination.

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Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number…....0105……

Name of PR……...Geetha Venkat…..……

Date of Inspection…13 December 2007……

Date of Response….7 February 2008……

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

Breach	**Action required**	**Time scale**	**PR Response**
Establishment and review of contracts with third parties and transport. **(S.4.2.10)**	All third party agreements need to be formalised.	Within three months from report being presented to a (LC).	All agreement completed.
Quality Management System (QMS) not in place. **(S.5.1, S.5.2, S.2.6) Directive 2004/23/EC, Art.16**	Development of a comprehensive QMS.	Within three months from report being presented to a (LC).	We are currently improving and working towards a comprehensive QMS.
Air Quality. **(S 7.8.5) (G9.4.1)**	Monitoring of air quality in the laboratory.	Within three months from report being presented to a LC.	Air quality maintained and assessed daily with protocol and log in place.
Continuing education and professional development (CPD). **(S.6.2.8, S.6.2.11) G.1.2**	Addressing of CPD for staff.	On going.	Active CPD program ongoing for all staff.

Non-Compliance

Area for improvement	Action required	Time scale	PR Response
Improvements in the quality of forms being returned to the HFEA.	Auditing of forms prior to submission to the HFEA.	Immediately.	Further to a meeting with the HFEA on 17th January 2008, it has been confirmed that there has been an EDI computer system error effecting the treatment returns. The HFEA is taking corrective actions.

Recommendations

	Time scale	PR Response
Departmental meetings.	On-going.	Agreed – Currently we have the following meeting as routine: - Clinical Governance –Monthly - Nurses – Weekly - Embryology – Weekly - Donor Bank – Fortnightly - QMS – Monthly - Clinical /Full team – Monthly Minutes and Agendas are available for all staff on the computer system.
Review of security for the room housing the medical notes	As soon as possible	Key pad lock installed on 4th February 2008.
Review of out of hours on call system.	As soon as possible.	Under review.

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

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

Name……Geetha Venkat……..

Date……7 February 2008……..…

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

6 March 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

London Women's Clinic (0105)
Interim Inspection

Members of the Committee:
Clare Brown, Lay Member – Chair
Ruth Fasht, Lay Member
Sue Price, Consultant in Clinical Genetics, Oxford Regional Genetics Service
Chris Barrett, Head of Reproductive and Developmental Biology, University of Dundee

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

Providing Legal Advice to the Committee:
Graham Miles, Morgan Cole Solicitors

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 (28 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 privately owned centre currently carries out in the region of 1,000 cycles per year. The premises have undergone further refurbishment since the last inspection visit and the centre appears to be well organised. Mr Qureshi informed the Committee that a number of breaches of the Code of Practice were identified at the inspection visit and these are summarised at page 7 of the report. The breaches, and further areas for improvement identified at the inspection, have all either been addressed by the centre or are close to completion.

2. The Committee reminded the Person Responsible that the requirement to establish a Quality Management System (QMS) is also a condition on all licences. The Committee noted that the QMS is being discussed at department meetings and agreed that they would like the QMS to be completed within three months (i.e. by 6 June 2008).

3. The Committee agreed that the centre's licence should continue with no additional conditions.

Signed…… … Date……..
Clare Brown (Chair)