Licence Renewal Inspection Report for Treatment and Storage Centres

CRM London
0199

Date of Inspection: 6 September 2007
Date of Licence Committee: 5 December 2007

CENTRE DETAILS

Centre Address	Park Lorne 111 Park Road London NW8 7JL
Telephone Number	0207 616 6767
Type of Inspection	Renewal Treatment and Storage
Person Responsible	Robert Forman
Nominal Licensee	Nathalie Forman
Licence Number	L0199/6/a
Inspector(s)	Parvez Qureshi (Lead)
	Neelam Sood
	Andrew Leonard
	Sandra da Silva (Observer)
Fee Paid - date	To be invoiced
Licence expiry date	29 February 2008

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About the Inspection:
This inspection visit was carried out on 6 September 2007 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between October 2005 and August 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

The CRM London centre is privately owned and has been licensed since 2002. It has a good history of compliance with no previous conditions on its licence.

Over the past year more than 400 treatment cycles were carried out at the unit. Since the previous inspection no major changes have been made to the premises. CRM London has links with five satellite centres. An organisational chart is in place indicating key functions and lines of accountability.

Opening hours at the centre are between 8.30am and 6.00pm Monday to Friday and weekends as required**.**

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

Activities of the Centre

	01/01/2006 – 31/12/2006*
Licensed treatment cycles	391
Donor Insemination	20
Research	No
Storage	Yes

*HFEA unverified statistics

Summary for Licence Committee

Since the last inspection, some improvements have been made at the centre. However, further improvements are required to the service provided. In addition, a number of recommendations were made by the inspection team.

The inspection team recommends the renewal of the centre's licence for treatment with storage for 5 years without any additional conditions.

Risk Assessment

The current risk matrix score for the centre is 0%.

EUTD
The centre scored a low risk rating of 1% 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

Breach	Action required	Time scale
None.	None.	None.

Non-Compliance

Area for improvement	Action required	Time scale
Witnessing of all laboratory procedures.	Documenting of all steps.	Immediately.

Recommendations	Time scale
Counsellor to keep CPD up to date.	Ongoing.
Accuracy of treatment forms returned to the HFEA Registry need to be addressed.	Immediately.

Proposed licence variations

None.

Changes/ improvements since last inspection

Resolution of issues raised in last inspection.
Recruitment of additional staff to address increase in workload.
Appointment of a Quality Manager.
ISO 9001 accreditation.

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 submitted for the inspection. Key members of staff have extensive experience of working in the fertility field. A Quality Manager is 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. No major issues were raised in the recent application to vary the centre's licence to include intra-uterine insemination (IUI) treatment. Clinic meetings attended by all staff are held once or twice a year, however, regular departmental and management team meetings are held to discuss practice related issues. The minutes of these meetings are made available to all staff. Documented evidence for a number of recently held meetings was reviewed by the inspection team and considered to be satisfactory. Recently a risk assessment associated with laboratory processes at the centre was carried out by an external consultant. The findings showed that the overall level of risk was low and this was attributed to the current working procedures at the centre. Review of the complaints log showed that all complaints received by the centre since the last inspection had been resolved. The incidents log was also reviewed by the inspection team and was considered to be satisfactory, it indicated, that the HFEA had been informed of all the appropriate incidents. HFEA Alerts are discussed at Management meetings and the information is cascaded, where appropriate. This was evidenced from staff interviewed during the inspection. Any difficult cases at the centre are not dealt with by an ethics committee but are considered by the centre's Internal Review Committee (IRC). The PR stated that he does not see the

need to have external input, since the centre performs licensable activities. Therefore the IRC reviews the suitability and social implications of treatment, not the ethics. The PR stressed that he is always working within the HFE Act and as such 1/3 of the cases that are presented to the IRC are not taken on for treatment.

In the event of an emergency, there are mutual contingency arrangements in place with the London Fertility Centre.

Regular audits of practice, patient feedback and of records are conducted by staff and any areas of concern are addressed accordingly. Evidence of this was seen during the inspection.

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

Areas for improvement
None.

Executive recommendations for Licence Committee
None.

Areas not covered on this inspection
All areas covered.

Evaluation
No 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:

- 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 is higher than national average. The FET for the age groups 40-42 and 38-39 is above national average. For age groups 35-37 and below 35 is lower than national average. The DI for all age groups is above national average.
Areas of firm compliance
Review of the documentation submitted for the inspection and discussions held with the staff confirmed that 'Welfare of Child' assessment procedures are in place. Patients' confidentiality is well maintained and evidence of this was seen during the visit. All treatment notes are stored in lockable filing cabinets in a secure area with only members of staff having access to them. Consultations with the patients are held in private rooms and any resulting treatment is documented in their notes. A couple were interviewed during the inspection and made complimentary comments about their experience at the centre. A total of 17 patient questionnaires were returned to the HFEA and majority of the responses were positive regarding the quality of service they had received. Counselling at the unit is offered by two counsellors who are members of the British Infertility Counselling Association (BICA). Patients are made aware of the counselling service at their initial consultation. Both counsellors receive regular supervision from their mentors and attend the centre's Internal Review Committee meetings. Patients can contact the counsellors via the staff or directly. An additional charge is not made

for the service and currently there is no waiting list. The counselling sessions take place in a dedicated room at the centre or alternatively at the counsellors' private practice. If required, telephone counselling is available. A reference is made in the patients' notes regarding uptake of the service. However, the counselling notes are kept separately in a secure place.

The counselling audit submitted for inspection confirmed that there were a total of 98 referrals from April 2006 to March 2007. Referral data show that counselling sessions for patients who were involved in the egg sharing programme being the most frequent.

Areas for improvement

The counsellor interviewed during the inspection stated that her continuous professional development (CPD) was not up to date. Measures need to be put in place to ensure that CPD is kept up to date.

Executive recommendations for Licence Committee

None.

Areas not covered on this inspection

Donor selection.
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
There is controlled access to the centre with an intercom and a closed circuit television in operation. All areas seen during the inspection were found to be clean and well presented. Since the last inspection no major changes have been made to the premises. However, the PR stated that expansion of the centre was being considered and he was in negotiations with the landlord for acquiring the floor above the centre. The current cryostore facilities are adequate for the volume of work carried out. All dewars are alarmed and linked to an auto dialler. A spare dewar is also kept full for emergency storage purposes. The facilities are fitted with a low oxygen monitoring system and there are adequate procedures in place for responding to alarms. Air quality is checked by settle plates bimonthly, and particle counts every 6 months when the air flow cabinets are serviced. The lead embryologist stated that the air quality was easily compliant with the requirements of the EUTD. All consumables used in the laboratory are CE marked (80%) or tested for impact on sperm motility (20%). Batch numbers and dates of changeover to new batches are recorded for all consumables used in a log book for traceability purposes. Since the last inspection, a number of changes have been made to the equipment. For example the centre has acquired an additional ICSI work station and an ultrasound scanner to meet the increase in workload. 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 by the inspection team and considered to be well organised. In the event of a power failure the centre has access to an uninterrupted power supply.
Areas for improvement
None.
Executive recommendations for Licence Committee
None.

Areas not covered on this inspection
All areas covered.
Evaluation
No improvement 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
Fifteen patient records were reviewed during the inspection for different treatments. The notes were found to be well organised with relevant documents being in place. However, some errors were identified and these were discussed with the centre's staff.
Areas of firm compliance
The information management system seen during the inspection was considered to be well organised. The server is backed up nightly and a monthly backup is archived to a secure storage site. An exercise was performed early in the year and the centre staff considered that their recovery measures worked effectively. All treatment related information is stored in locked filing cabinets in a secure area. The patient information submitted for the inspection was reviewed and was found to be satisfactory. The following information was also seen during the course of the inspection: The Centre's treatment licence and complaints procedure. Centre's information on various treatments. Counselling services and HFEA leaflets. Forms to the HFEA Registry are sent within the required timescale.
Areas for improvement
Accuracy of treatment forms returned to the HFEA Registry need to be addressed.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
All areas covered.
Evaluation
Some 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:

- 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	3
HPC registered scientists	1
Scientists working towards registration	3
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. Some errors were identified in the data entry records and were rectified by the laboratory staff accordingly.
Summary of spot check of stored material
An audit of 2 sperm samples from dewar to records and 3 vice versa was carried out. No discrepancy was found for the former samples. In the case of the latter 3 samples, one sample was not found in the dewar. The reason for this was that the missing sample had been transferred but the associated paperwork was left in the storage folder rather than being moved to the transfer folder.
Areas of firm compliance
There are policies are in place for assessment of patients seeking treatments and for screening of patients. This was evident from the information submitted for inspection and discussions held with staff. 3 embryo transfer (3ET) is only carried out for patients who are above 40 years old. Since the last inspection a total of 58 were performed, only 2 resulted in ongoing twin pregnancies. Age as a justification for 3ET is referenced in the patients' notes. Centre offers PGS for 9 chromosomes, 19 cases have been done since last inspection.

Overall the centre has a comprehensive witnessing procedure in place and this was evident from the documents reviewed during the inspection.

The PR stated that the satellite centres linked to CRM London use the same SOPs and protocols, with the exception of the stimulation protocol. The doctors at the satellite centres are vetted by the PR to ensure and ascertain their experience. The reason for this is to ensure that the CRM London's success rates are not affected. Patients from satellite centres are treated the same as those attending CRM London. The satellite centres' doctors have clinical responsibility but the patients are provided with the CRM London emergency contact details.

Staff recruitment is done in accordance to the needs of each department manager. However, all new staff are also interviewed by the centre's directors. Backgrounds including CRB are checked for all staff.

CPD requirements are reviewed annually and budgeted for. The PR was considered by staff to be very supportive of CPD, due to it being a requirement of the recently acquired ISO accreditation.

For new staff, the centre has a thorough induction programme in place. The induction schedule is proposed by the managers and tailored to the job, evidence of this was seen during the inspection. The staff turn over at the centre is low.

Areas for improvement
It was noted on the embryo processing and main witnessing forms that the disposal of embryos was not witnessed.

Executive recommendations for Licence Committee
None.

Areas not covered on this inspection
All areas covered.

Evaluation
Some improvements required.

Report compiled by:

Name……..Parvez Qureshi…….

Designation…Inspector…….

Date……12 October 2007……

Appendix A: Centre Staff interviewed

The PR and six other members of staff.

Appendix B: Licence history for previous 3 years

2007

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 10th April 2006
The Committee agreed that the centre's licence should continue with no additional conditions.

2005

Licence Committee 20th January 2005
The Committee agreed to renew the centre's licence for three years with no additional conditions and made two recommendations.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……199……

Name of PR……..Robert Forman……..…….

Date of Inspection……6th September 2007……....

Date of Response……15th November 2007……

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

(Comments taken from PR response received)

Accuracy of treatment forms returned to the HFEA Registry need to be addressed.
This issue relates to communication problems between our database and the HFEA registry using EDI. Our IT consultant, laboratory manager and the HFEA IT department have addressed this issue and we now believe that we have identified and cured nearly all the "bugs"

It was noted on the embryo processing and main witnessing forms that the disposal of embryos was not witnessed.
This step is now witnessed

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

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

Name……Robert Forman……..……..…….

Date……..15 November 2007……

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

5 December 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

CRM London (0199)
Licence Renewal

Members of the Committee:

Emily Jackson, Lay Member – Chair
Anna Carragher, Lay Member
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary
Roger Neuberg, Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary
William Ledger, Professor of Obstetrics and Gynaecology, University of Sheffield

In Attendance:

Stephanie Sullivan, Interim Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice:
Mary Timms, Field Fisher Waterhouse

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 (38 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 is privately owned and has been licensed since 2002. The centre has a good history of regulatory compliance and a risk score of 0%. Mr Qureshi informed the Committee that this renewal inspection visit took place on 6 September, and identified a number of areas for improvement.

2. The Committee noted with concern the finding that the centre has been failing to witness the disposal of embryos, in breach of guidelines. The Committee considered the response to the report by the Person Responsible (at page 20 of the inspection papers). In particular, they noted that the Person Responsible has

confirmed that this issue has now been addressed, along with the accuracy of treatment forms.

3. The Committee noted the recommendations in relation to the need to update the Counsellor's CPD. The Committee requested that this is checked by the Executive at the time of the next inspection of the centre.

4. The Committee agreed that they were satisfied as to the suitability of the Person Responsible, the centre premises and the use of suitable practices at the centre. The Committee further agreed that it was satisfied that it had sufficient and satisfactory information on which to make a decision.

5. The Committee decided to renew the centre's licence for a period of five years, although the new licence will not be issued until the licence fee has been received.

Signed…… … Date……..
Emily Jackson (Chair)