

Human Fertilisation and Embryology Authority

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Human Fertilisation and Embryology Authority

Report of an interim inspection at

CRM London (0199)

Date of Inspection 24th October 2005

Date of Licence Committee 10th April 2006

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Key facts about the centre

Centre name CRM London

Centre address Park Lorne
111 Park Road
London
NW8 7JL

Centre number 0199

Person responsible Robert Forman

Nominal licensee Nathalie Forman

Activities of centre

		2004 to 2005
Licensed treatment cycles	IVF	83
	ICSI	66
	FET	48
	Egg sharing	82
	Other	06
Donor Insemination		67
Research	None	
Storage	Yes	

Focus of inspection General

Additional licence Conditions None

Licence expires 29 February 2008
All payments to the HFEA are up to date.

Summary

1. The centre has been licensed since 2002 and is privately owned with a good history of compliance.
2. The current licence for treatment with storage is due to expire on 29 February 2008, there are no conditions on it and the two recommendations made by the previous licence committee have been addressed.
3. The centre is currently licensed for:
 - Donor insemination (DI), in vitro fertilisation (IVF), IVF with donor eggs, IVF with donor sperm, intra cytoplasmic sperm injection (ICSI), storage of patient sperm, storage of embryos, assisted hatching (chemical), storage of sperm within testicular tissue, gamete intrafallopian transfer (GIFT) with donor eggs, GIFT with donor sperm, zygote intrafallopian transfer (ZIFT), preimplantation genetic screening for aneuploidy (PGS)
4. This interim inspection was undertaken on 24 October 2005. Currently the centre is carrying out around 400 treatments per year.
5. The inspection team would like to draw the following points to the attention of the licence committee.
 - Issues which were identified during the last inspection have been addressed.
 - No breaches of the HFE Act were observed during the inspection.
6. The inspection team supports the continuation of the centre's licence for treatment with storage.

Background to inspection

7. This report covers the period from October 2004 to October 2005. It includes an analysis of treatment data from 1 June 2004 to 31 May 2005.
8. The site visit took place on 24th October 2005.
9. Since September 2004 the centre has been in the process of a major overhaul of all of its documentation and working practices with the aim of achieving International Organisation for Standardisation (ISO) 9001 certification in 2006.
10. The report was reviewed by the centre in March 2006.

The centre's context

11. Patients are referred to the centre by medical consultants and private general practitioners, both from within the United Kingdom (UK) and from overseas, about 70% are self-referrals.
12. Many of the overseas referrals are egg sharing recipients. This is due to restrictions on egg donation overseas and incentives for egg sharing donors in the UK. The egg share donors receive IVF treatment free of charge including free drugs. However, they need to pay for the HFEA fee, intracytoplasmic sperm injection (ICSI) and freezing of embryos if required. The centre advertises for egg sharers and egg donors in national newspapers and magazines.
13. The current premises are adequate for the number of treatment cycles being performed per year. However, the centre has the potential to expand the premises by taking up office space on the floor above.

Type of work carried out

Licensed treatment

14. The centre carries out the following licensed treatments:
 - Donor insemination (DI)
 - *In vitro* fertilisation (IVF)
 - IVF with donor eggs
 - IVF with donor sperm
 - ICSI
 - Storage of patient sperm
 - Storage of embryos
 - Assisted hatching (chemical)
 - Storage of sperm within testicular tissue
 - Gamete intrafallopian transfer (GIFT) with donor eggs
 - GIFT with donor sperm
 - Zygote intrafallopian transfer (ZIFT)
 - Preimplantation genetic screening of aneuploidy (PGS)

Treatments that do not need a licence

15. The centre offers ovulation induction, intrauterine insemination (IUI) Gamete intrafallopian transfer (GIFT), reproductive surgery and surrogacy.

Satellite/transport arrangements

16. The centre provides satellite IVF services for the following three private clinics in London:

Dr Dickinson B Cowan
Docktime
The Portland Hospital
214 Great Portland Street
London W1W 5QN

Mr Talha Shawaf
Consultant Gynaecologist
Viveka
27A Queens Terrace
London NW8 6EA

Mr Colin Davis
149 Harley Street
London W1G 6DE

Staff

17. The PR informed the inspection team that since the last inspection, one member of staff has left the practice and four new members have been recruited. The inspection team considered that the current staffing level was adequate for the service provided by the centre.

Staffing profile

Person responsible	Robert Forman
Nominal licensee	Nathalie Forman
Accredited consultant	Robert Forman
Other medical staff	2
Embryologists	4
ICSI practitioner	3
Embryo biopsy practitioners	2
Nursing staff	3
Independent counsellors	2
Complaints manager	Deborah Evans

Professional registration and continuing professional development (CPD)

18. Documentation sent to the HFEA and the information obtained during the site visit confirmed that the staff at the centre are registered with the appropriate professional bodies.
19. The inspection team was informed by the PR that all staff have access to appropriate CPD, documented evidence was seen during the inspection.
20. Regular multi-disciplinary team meetings are held by staff to discuss clinical issues. The minutes of the meetings are available to all staff; an example of them was made available for inspection.

The premises, equipment and other facilities

Premises

21. The PR informed the inspection team that the premises have not changed since the last inspection. Positive pressure filtered air systems are in operation in main areas of the centre. All patient areas were found to be clean and comfortably furnished.
22. The centre's current licence and complaints procedure were seen during the inspection. However, they were displayed in two different locations. The centre's staff were advised by the inspection team to have them displayed in a common place, ideally near the reception.

Equipment

23. The centre's staff informed the inspection team that over the last year no significant changes have been made to the equipment. Maintenance contracts are in place to ensure that equipment is kept in good working order. These were seen during the inspection.

Other facilities

24. The centre has access to facilities at the nearby Portland Hospital for procedures which cannot be carried out at the centre. However, the centre does not rely on either the personnel or the equipment from the Portland Hospital.

Security

25. Access to the centre is controlled via an intercom system. A closed circuit television system is also in operation. All areas within the centre are alarmed and doors are locked when not in use. Access to all departments is via keypad locks.

Confidentiality

26. The inspection team noted that all patient records are stored in secure filing cabinets in the administration area. Only members of staff who are on the centre's licence have access to patients notes. The inspection team was informed by the PR that on a regular basis the data from the centre's computer system is automatically encrypted and stored in a secure place. On completion of the ISO 9001 accreditation a new database will be setup. This will further improve the flow of information within the centre.

Arrangements for collecting sperm samples

27. The men's production room was seen during the inspection and was found to be suitably equipped. However, it was noted during the last inspection that a second room was being used for sperm production and for carrying out preimplantation genetic screening (PGS) procedure. The PR informed the inspection team that now the second room is used for PGS purposes only.

28. Although not common, if a man finds it difficult to produce a sample on site then he may produce it at home. However, this is at the embryologist's discretion. Before the sample is handed over to the laboratory staff, the sample producer has to verify the label on the specimen container.

Cryostore facilities, oxygen and dewar alarms

29. The inspection team noted that all dewars are fitted with low nitrogen level alarms and are linked to an auto dial system. In the event of an alarm becoming activated then a dedicated member of staff responds accordingly. The liquid nitrogen level for each dewar is checked on a regular basis and topped up if required, a log of this procedure was made available for the inspection team.

30. The storage area housing the dewars is also fitted with a low oxygen level alarm.

Emergency facilities

31. Resuscitation equipment was seen during the inspection and was found to be satisfactory. The nursing staff informed the inspection team that staff at the centre have received basic life support training. Patients attending the centre are given mobile telephone numbers of staff for out of hours contact.

Clinical, nursing and laboratory procedures

Clinical

32. As the centre is in the process of acquiring ISO 9001 accreditation, all protocols used at the centre are being incorporated into a new quality management system. Draft copies made available for the inspection reflect the services being offered by the centre.

33. A protocol for the management of complications resulting from Ovarian Hyper Stimulation Syndrome (OHSS) has been developed by centre's staff. If a patient develops symptoms of OHSS they can contact the centre to discuss the situation with a clinician. If required, the patient can either visit the centre or their local hospital. In a case where a patient visits a hospital then the centre's staff contact the hospital to ensure that the patient receives appropriate treatment.

Nursing

34. The nursing protocols are linked to the clinical ones and they encompass distinct roles for nurses, including witnessing duties and information given to patients.

Laboratory

35. Copies of the laboratory protocols being developed for centre's ISO 9001 accreditation were made available for the inspection team. They were found to be satisfactory.

36. All patients are screened for HIV, Hepatitis B and C. Those patients who test positive for Hepatitis C can receive treatment but their sperm and/or embryos are not frozen. However, with respect to the 'Welfare of the Child', treatment may be declined to those patients who test positive.

Three embryo transfer arrangements

37. The inspection team checked the 'three embryo log' and noted that fourteen three embryo transfers had been undertaken at the centre for patients over the age of 40.

Procedures for assessing clients and for assessing and screening donors

Welfare of the child

38. Protocols for the 'Welfare of the Child' were seen by the inspection team and were found to be satisfactory. The assessment includes the obtaining of a detailed medical and social history of the patients seeking treatment. However, the protocols will require reviewing to reflect the recent changes made to the 'Welfare of the Child' policy.

Ethics committee

39. There is no ethics committee at the centre; instead it has an Internal Review Committee (IRC) for making decisions on difficult cases. The PR informed the inspection team that the IRC meets as and when required and considers approximately 15 cases per year.

Assessing and screening donors

40. No donors are recruited by the centre. Donor sperm is purchased from sperm banks. On receiving notification from a sperm bank that a specific donor has reached six pregnancies the centre's staff contact the sperm bank before any more samples are used.
41. The PR informed the inspection team that the centre recruits its own egg donors and runs an egg sharing programme. Separate information for altruistic egg donors and egg share donors is available which explains the investigations and tests which need to be carried out, the implications, the associated risks and the legal issues.

Counselling process and facilities

Counselling protocols

42. The counsellor carries out both support and implication counselling for donors. The nurses provide the patients with information. There is no separate charge for counselling sessions.

Counselling referral arrangements

43. Counselling is compulsory for patients involved in the egg sharing programme and is recommended for altruistic egg donors.
44. Any patient who requires genetics counselling is referred by the centre's clinicians to genetic counsellors.

Supervision and professional registration

45. Documentation seen by the inspection team showed that the counsellor is a member of the British Psychological Society (BPS), the British Association for Counselling and Psychotherapy (BACP) and the British Infertility Counselling Association (BICA). The counsellor receives regular supervision and her CPD is supported by the centre's management.

Counselling audit

46. The counselling data supplied to the inspection team confirmed that a total of 48 patients were seen by the counsellor between October 2004 and October 2005. Counselling sessions occurred for many of the treatments offered by the centre.

Location of counselling facilities

47. Counselling is provided in a comfortable and dedicated room within the centre. The notes are kept in a secure cabinet.

Patient experience

Patient feedback

48. Patients are given a questionnaire to provide their opinion on the quality of service they receive at the centre. Information seen during the inspection showed a very positive feedback. The PR informed the inspection team that as a result of the patient feedback many improvements have been made to the service offered to the patients.
49. A total of 21 completed questionnaires were returned to the HFEA. Overall the comments received from the patients were positive. During the inspection, the findings of the patient questionnaires were discussed with the centre's staff.

Patient information

50. As a part of the centre's ISO 9001 accreditation, draft copies of the patient information and advice about the treatments offered by the centre were made available for the inspection. The information was reviewed by the inspection team and was found to be satisfactory.

Record keeping procedures

51. A total of twenty patient records were reviewed during the inspection without any errors being noted.

Audit

Centre's own audit of stored material

52. Since the last inspection, an audit of stored samples has been undertaken by the centre's laboratory staff, without any discrepancies.
53. During the last inspection it was noted that laboratory records and database system were used for locating and verifying the identity of stored material. However, the patients clinical notes were not checked as part of the audit process. This matter was raised with the PR who informed the inspection team that by duplicating paperwork there would be an increased chance of errors occurring. To resolve this issue, the centre is in the process of purchasing a new database that will integrate laboratory and clinical records.

Spot check of tracking process for stored material

54. A spot check of one embryo from the laboratory records to a dewar and one embryo from a dewar to the laboratory records was undertaken. The procedure was repeated for stored sperm samples. There were no discrepancies.

HFEA register

55. During the inspection no issues were raised concerning the register.

Clinical governance

56. Regular multi-disciplinary team meetings are held at the centre. Any clinical issues are discussed as appropriate.

Risk management

57. The centre has a 'near miss' log for potential incidents which was seen by the inspection team and was found to be satisfactory.

58. Staff are aware of the alert system initiated by the HFEA.

59. Incidents or alerts are discussed at staff meetings and any appropriate action is taken by the relevant staff.

Complaints

60. Since the last inspection three complaints have been received by the centre, two have been resolved. The outstanding complaint involves a patient who has refused to pay for donor insemination treatment.

61. A log of verbal complaints was seen by the inspection team and it showed that appropriate action had been taken for each complaint.

Breaches of the Code of Practice or Act

62. No breaches of the HFE Act were observed during the inspection.

Compliance with previous conditions and recommendations

Conditions

63. There are no conditions on centre's current licence.

Recommendations

64. The previous licence committee made two recommendations and these have been addressed.

Key points for the Licence Committee

65. The inspection team supports the continuation of the centre's licence for treatments set out in paragraph 14 above.

Issues

66. The inspection team would like to draw the following points to the attention of the licence committee.
- Currently there are no conditions on centre's licence. Two recommendations made by the previous licence committee have been addressed.
 - No breaches of the HFE Act were observed during the inspection.

Appendix A The inspection team and staff interviewed

The inspection team

Parvez Qureshi	Chair, HFEA inspector
Neelam Sood	HFEA inspector

Centre staff interviewed

Meetings were held with person responsible and four other members of the staff.

Conflicts of interest

None declared.

Appendix B Sources of evidence

1. Previous licence committee minutes
2. Previous inspection reports
3. Relevant correspondence between the centre and the HFEA
4. Application form
5. Staff CVs
6. Outcome data from licensed treatments
7. Patient information
8. Consent forms
9. Treatment forms
10. Standard operating procedures and protocols
11. Audits of stored material and counselling practice
12. Interviews with centre staff
13. Feedback questionnaires from patients (centre's own)