



Human Fertilisation and Embryology Authority

Report of an interim inspection at

IVF Hammersmith Hospital  
(0078)

Date of inspection 26<sup>th</sup> July 2005

Date of Licence Committee 30<sup>th</sup> November  
2005

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## Key facts about the centre

**Centre name** IVF Hammersmith

**Centre address** Wolfson Family Clinic  
Du Cane Road  
London  
W12 OHS

**Centre number** 0078

**Person responsible** Mr Stuart Lavery

**Nominal licensee** Mr Geoffrey Trew

**Activities of centre**

	01.01.04- 31.12.04	
Licensed treatment cycles	IVF ICSI FET Egg sharing	559 400 224 0
Donor Insemination		105
Unlicensed treatments	GIFT IUI	
Research	Yes	
Storage	Yes	

**Focus of inspection** General

**Additional licence conditions** None

**Licence expires** 31 December 2007

## Summary

1. The centre has been licensed since July 1992 for treatment and storage. Its current three year licence expires on 31 December 2007.
2. The centre is currently licensed for storage of eggs, storage of eggs within ovarian tissue, storage of sperm, storage of sperm within testicular tissue, storage of embryos, donor insemination (DI), in vitro fertilisation (IVF), IVF with donor eggs, IVF with donor sperm, zona drilling, intra-cytoplasmic sperm injection (ICSI), chemical assisted hatching, preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS).
3. The centre carried out 1288 licensed treatment cycles between 1 January 2004 and 31 December 2004.
4. The centre is currently undergoing ISO9001 accreditation process.
5. Following the last renewal inspection the previous Licence Committee added a condition to the centre's licence:
  - PGD or PGS must not be carried out until the centre has shown that they have a competent person in place to perform them and have resubmitted their protocols to a Licence Committee for a review, as well as undergoing a visit to inspect their suitability to offer these services.
6. This condition was removed following a Representations hearing when the Committee agreed that they were satisfied that the centre had a competent embryo biopsy practitioner on its staff.
7. The Committee also agreed to modify the requirement made by a Licence Committee which asked the centre to submit, on a monthly basis, information about all embryo transfers which have taken place. The Committee advised the centre that it should limit the information to the number of three embryo transfers carried out along with the age of the patient concerned and any relevant circumstances.
8. The centre has carried out three embryo transfers to women under forty on five occasions.
9. No other breaches of the Code of Practice or Act were identified during the inspection.
10. The inspection team support the continuation of the centre's licence.

## **Background to inspection**

11. This was an interim inspection and covers the period from the last renewal inspection in August 2004 to July 2005. The report includes analysis of outcome data from 1 January 2004 to 31 December 2004.
12. One site visit took place on 26 July 2005 and lasted six and a half hours.
13. The last audit visit to take place at the centre was 25 July 2005.
14. The report was reviewed by the centre in October 2005.

## **The centre's context**

15. The centre treats both NHS and private patients and also sees private patients from overseas. The centre does not provide any transport or satellite IVF services for other assisted conception units.
16. The centre is currently undergoing ISO9001 accreditation process.

## **Type of work carried out**

### ***Licensed treatment***

17. The centre carries out the following licensed treatments
  - Storage of eggs (patient)
  - Storage of eggs (donor)
  - Storage of eggs within ovarian tissue
  - Storage of sperm (patient)
  - Storage of sperm (donor)
  - Storage of testicular tissue
  - Storage of embryos
  - Donor insemination
  - IVF
  - IVF with donor eggs
  - IVF with donor sperm
  - SUZI
  - ICSI
  - Chemical assisted hatching
  - PGD
  - PGS

## ***Treatments that do not need a licence***

18. The centre carries out comprehensive fertility services offering a full range of treatments to men and women.

## **Staff**

### ***Staffing profile***

Person responsible	Mr Stuart Lavery
Nominal licensee	Mr Geoffrey Trew
Accredited consultant	Mr Raul Margara
Other medical staff	2 Consultant anaesthetists 8 Research fellows
Embryologists	9 (3 senior, 2 qualified, 4 trainee)
ICSI practitioner	7
Andrologist	2
Nursing staff	10 (one head nurse, eight qualified nurses and one health care assistant)
Independent counsellor	2
Complaints manager	Jenny Jackson (trusts complaints officer) and Debbie Clarke (IVF complaints officer)

### ***Professional registration and continuing professional development (CPD)***

19. The person responsible ensures that the character, qualifications and experience of staff are appropriate. He liaises with the hospital human resources department who check applicant's qualifications and criminal records when they are offered a position at the centre.
20. There have been no changes to senior staff since the last inspection. All nursing staff are registered by the Nursing and Midwifery Council and their Personal Identification Numbers (PIN) were provided for the previous inspection. The person responsible and nominal licensee are both members of the General Medical Council (GMC) and the Royal College of Obstetrics and Gynaecology (RCOG).
21. The senior counsellor is a member of the British Association for Counselling and Psychotherapy (BACP), the British Infertility Counselling Association (BICA) and the British Fertility Society (BFS).

22. All staff, where appropriate, are either registered with the Health Professions Council (HPC) or are working towards registration.
23. All staff have access to continuing professional general and specialist education.
24. They have the opportunity to attend conferences for example: BFS, Insights and study days.
25. The nursing team have an in depth induction programme following the patient pathway.
26. There are regular staff meetings in each discipline, for example weekly team meetings within the embryology and nursing teams. These meetings are minuted and the key decisions from them are passed on to all staff. Multi-disciplinary staff meetings are also held monthly to make staff aware of the activity in other disciplines.
27. A clinical meeting is held every day at the centre to discuss all the patients attending during the week and the stage they are up to in their treatment cycles. This meeting will include a doctor and an embryologist who will go through patient's scan and blood results and discuss the resources needed for treatment. Unlicensed treatments and patient queries are also discussed at these meetings. The Doctors inform the patients of the outcomes of these meetings.

## **The premises, equipment and other facilities**

### ***Premises***

28. There have been no changes to the premises since the last inspection. It was noted by the inspection team how clean, tidy and well presented the clinic was. The Person Responsible explained that the introduction of ISO 9002 involved giving members of the team "ownership" of specified areas and responsibility for their appearance and upkeep. This has had a positive effect on the pleasant appearance of patient areas.
29. The centre is split over two floors within the Wolfson family clinic. There is a large patient waiting area on the ground floor as well as two men's rooms, three scan rooms, two rooms where blood can be taken and the record storage room. In addition there is a dedicated theatre for egg collections adjacent to a laboratory. There is also a large recovery room and a viral positive laboratory.
30. The second floor houses the main, larger laboratory where all embryology work is carried out. This is adjacent to an embryo transfer room. There is also a smaller recovery room, an ICSI laboratory and a patient waiting area. The laboratories are temperature controlled, have an air conditioning system and power back-ups for the incubators and freezing machines.

### ***Equipment***

31. Previous inspectors were informed that the centre were awaiting the delivery of a new class II hood and incubator. These have been delivered and are installed. All incubators are monitored 24 hours a day through an alarm system that has a call out function when the alarm is triggered.

### ***Security***

32. Access to all laboratories, treatment and consulting rooms are by swipe card and a numerical keypad. The PIN number to access these rooms is provided only to staff working at the centre.

### ***Confidentiality***

33. Patient records are stored in a room accessed by a swipe card and numerical keypad. Only members of staff working at the centre have access to them. Patient records for patients with samples in storage, for donor insemination patients or MESA/TESA patients are kept in the embryologist's office that is locked when unoccupied.

34. In some instances the patients files are "shared with" the Hammersmith hospital. In these circumstances the patients sign a consent allowing the notes to be accessed by other departments within the hospital.

### ***Arrangements for collecting sperm samples***

35. Producing a semen sample off-site is actively discouraged by the centre. If a man does produce off-site he must arrange it in advance and sign a form stating that the sample is his when he delivers it to the centre.

36. There are two production rooms containing a bed in each room. These are adjacent to two toilets and are in a private and secluded suite distanced from the main clinic area.

### ***Cryostore facilities, oxygen and dewar alarms***

37. The dewars are stored in a room within the clinic that is controlled by swipe card access. There is an extractor fan in the room and two oxygen depletion alarms. The dewars have low nitrogen level alarms linked internally and externally and all dewars are locked. The dewars are all fitted with temperature probes and there is a spare dewar for use in the event of another dewar failure.

38. Screened and unsorted sperm, embryos, testicular tissue and ovarian tissue are all stored in separate dewars.

39. The centre hopes in future to offer freezing for high risk groups of patients, for example those screening positive for HIV and Hep C.
40. The centre do offer freezing to patients who are positive to hepatitis B and have a separate freezing machine and storage designated for their use.

### ***Emergency facilities***

41. Clinical staff are trained in basic resuscitation techniques and have annual updates of this training. All nursing staff have ALS training. Resuscitation equipment is available in the egg collection theatre that is located on the ground floor of the centre along with the recovery room, this equipment is checked daily.
42. Should a patient require admission to hospital they are admitted to the Hammersmith and are cared for by the centre's team.

### **Clinical, nursing and laboratory procedures**

43. The centre is currently undergoing ISO9001 accreditation process therefore many of the management and document protocols are in the process of being formulated or revised.
44. The centre's protocols were seen on the last renewal inspection and were said to be detailed, clear and easy to follow.
45. Protocols that were provided with the inspection papers show that errors noted in the last renewal inspection have been addressed and corrected.

### ***Nursing***

46. The nursing staff co-ordinate treatment cycles and specific treatment programmes such as egg donation and PGD. They carry out IUI's but do not perform embryo transfers.

### ***Laboratory***

47. The laboratory protocols submitted with the inspection papers were satisfactory.
48. A protocol for witnessing was seen at the last inspection and found to be adequate.

49. The centre has links with the andrology unit at the Hammersmith (centre 0080) which stores pre-chemotherapy samples. Any correspondence dealing with renewal or expiry is dealt with through centre 0078.
50. At the last inspection it was noted that the centre used a home made freezing media. They were finding it difficult to change to a standard media because of their high frozen embryo cycle pregnancy rate. Following a project to assess freezing media the centre now use a standard media.
51. At the last inspection it was noted that male partners are given a prescription of doxycycline during the females treatment cycle. The centre have now discontinued this practice.

## **Procedures for assessing clients and for assessing and screening donors**

### ***Welfare of the child***

52. At the previous inspection it was established that there was a clear written protocol for assessment of the welfare of the child.

### ***Ethics committee***

53. Ethical and social dilemmas meetings are held every 6 weeks. These are open to all members of the IVF team to attend and refer cases or issues for discussion. These meetings are minuted and the minutes are e-mailed to all members of the team.
54. Following these meetings patients are informed of the outcome of decisions in writing by the consultant responsible for their care. They will also be offered an opportunity to discuss this decision with the consultant.

### ***Assessing and screening donors***

55. As discussed at the last inspection the centre has developed a protocol for importing donor sperm and for using sperm from a known donor. The centre also buys samples from several donor banks in London.

## **Counselling process and facilities**

### ***Counselling protocols***

56. Counselling protocols were supplied with the inspection papers, they are clear and comprehensive.
57. Patient information regarding counselling was also supplied with the inspection papers. The information was clear and patient friendly.

58. The counsellors are experienced and integrate well into the team.
59. Counselling is free to all patients and they can be seen at the centre or Queen Charlottes.
60. The counsellors are able to call upon translators should they be required.

### ***Counselling referral arrangements***

61. Patients can either be referred by centre staff or self refer.
62. Any referrals to external counsellors are for specialist cases.
63. Patients requiring genetics counselling are referred to the pre-natal service at the Hammersmith Hospital which deals with pre-natal diagnosis but will also counsel couples from the centre.

### ***Supervision and professional registration***

64. The senior counsellor is a member of the British Association for Counselling and Psychotherapy (BACP), the British Infertility Counselling Association (BICA) and the British Fertility Society (BFS). She has had 20 years experience in infertility counselling at the centre and has adequate supervision and training.

### ***Counselling audit***

65. An audit of the counselling facilities at the centre for the period 1 April 2004 to 31 March 2005 was provided in the inspection papers. A total of 305 patients were seen in 874 counselling sessions. Introductory sessions were also provided to 171 patients during this time. There were a total of 1,045 counselling sessions. Of these patients attending counselling 35% were NHS patients and 68% private. The centre staff team referred 56% of these patients for counselling and the remaining 44% were self referrals. The type of treatments patients were undergoing was as follows:

- IVF - 45%
- ICSI - 7%
- Infertility - 8%
- Known egg donor - 14%
- Anon egg donor - 1%
- Egg recipient - 11%
- Donor Sperm - 15%
- Psychosexual - 1%
- Surrogacy - 4%
- Other - 3%

## ***Location of counselling facilities***

66. Patients can be seen at the centre or Queen Charlottes. The room at the centre is both comfortable and private. Confidential records maintained by the counsellors are kept in a secure filing cabinet in the counsellor's room and the key is held only by the counsellors.

## **Patient experience**

### ***Patient feedback***

67. The centre obtains patient feedback both formally, through surveys to improve service quality, and informally through comments boxes placed in patient waiting areas. As a direct response to patient's comments the centre have made several changes:

- They have limited the amount of baby pictures displayed within the unit and are more sensitive to their location.
- They have provided bags for the male partner to put his pots into following sperm production.

### ***Patient information***

68. Patient information was discussed at the previous inspection. Information submitted with this inspection was satisfactory.

## **Record keeping procedures**

69. 30 patient records were reviewed by the HFEA auditor on 25<sup>th</sup> July.

70. The notes were found to be in good order.

71. All consent to treat were found without exception.

72. Five files had missing Welfare of the Child assessments these were patients attending from abroad.

73. Two files had welfare of the child completed by the ART Consultant as the patients had not registered with a GP.

74. All patients are asked to complete consent to storage when embryos are available for freezing, posthumous consent is also completed at this time.

75. No errors were found on HFEA OO6/OO7 only failure to tick "no" boxes around "yes" boxes. For completeness all boxes should be ticked.

## **Three embryo transfer arrangements**

76. A copy of the three embryo transfer log was sent to the authority. The centre have carried out three embryo transfers to women under forty on five occasions. This is a breach of the HFEA Code of Practice 8.20 (i).

## **Audit**

### ***Centre's own audit of stored material***

77. An annual audit of stored material was carried out between December 2004 and February 2005. The findings were as follows:

- Frozen embryos - all sets of embryos except one case were found to be in the correct locations with the expected number of straws and ampoules as noted on the logging in sheets. Administration errors were found and corrected.
- Frozen Sperm 34 patients – All samples were found in correct locations and paperwork matched. Minor administration errors were found and corrected.
- Frozen Mesa/Tesa samples - 185 patients – All samples were found in correct location and paperwork matched. Minor administration errors were corrected
- Frozen Oocytes - 5 patients – No errors found

### ***Spot check of tracking process for stored material***

78. A spot check of stored material was carried out by the head of IVF laboratories and overseen by the scientific inspector. Three samples were tracked from patient notes and laboratory paperwork to the dewars. No discrepancies were found.

## **HFEA register**

79. There were no problems reported from the registry.

## **Clinical governance**

80. The centre links into the trust's clinical governance structure and have a good frame work with both Hammersmith and Queen Charlotte hospital.

81. Staff use a standard set of protocols for completing forms to report issues and incidents. These are considered by risk management committee and all consultants are debriefed if there is to be a change of policy or change to a protocol. The service manager and head nurse both attend the Trust's risk management meetings and report back to relevant centre staff.

82. HFEA alerts are disseminated to all relevant staff by the Person Responsible's secretary. The alerts are discussed at the unit meetings. They are also placed on the notice board in the embryology office and all staff have to sign to indicate that they have read them.

### ***Complaints***

83. The centre uses the Trusts complaints policy so complaints will be reported to the patient advice and liaison service. Complaints are also discussed at staff meetings.

84. The centre reported one complaint this year which has been resolved.

### **Breaches of the Code of Practice or Act**

85. The centre have carried out three embryo transfers to women under forty on five occasions.

86. There were no other breaches of the Code of Practice or Act identified during the inspection.

### **Compliance with previous conditions and recommendations**

#### ***Conditions***

87. The centre has no additional conditions on its current licence.

#### ***Recommendations***

88. The centre has no recommendations on its current licence.

### **Key points for the Licence Committee**

89. The inspection team supports the continuation of the centre's licence for treatments set out in paragraph 17 above.

#### ***Issues***

90. The centre are currently undergoing ISO9001 accreditation.

91. The centre now use a standard media in their freezing programme.

92. Patients do not complete HFEA 006/007 consent to store or posthumous consent until it is known if there are any gametes/embryos to store.

93. Welfare of the child assessments were missing from five of the files reviewed. These were however from patients attending from abroad.

## **Appendix A The inspection team and staff interviewed.**

Janet Kirkland	Lead inspector HFEA
Paul Knaggs	Scientific inspector
Parvis Qureshi	HFEA observing

### ***Centre staff interviewed***

Mr Stuart Lavery	Person responsible
Mr Geoffrey Trew	Nominal licensee
5 Staff members	

### ***Conflicts of interest***

None declared.