



Human Fertilisation and Embryology Authority

Cromwell IVF and Fertility Centre, Darlington
(0075)

Date of the Inspection: 17th November 2005
Licence Committee Date: 8th February 2006

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Key facts about the centre

Centre name Cromwell IVF and Fertility Centre, Darlington

Centre address Woodlands Hospital
Morton Park
Darlington
Durham
DL1 4PL

Centre number 0075

Person responsible Kamal Ahuja

Nominal licensee Eric Simons

Activities of centre

		2004/05
Licensed treatment cycles	IVF	49
	ICSI	68
	FET	32
	Egg Sharing	110
	Other	9
Donor Insemination		10
Research	None	
Storage	Yes	

Focus of inspection General inspection to review the centre's licence.

Additional licence conditions None

Licence expires 31 March 2008

Summary

1. The centre has been licensed since 1992 but has only been based in its current premises since early 2003. The centre offers licensed treatment to private patients in Darlington and the surrounding area. The centre has a large egg sharing programme with satellite links with the Cromwell centre in London (0074) and Swansea (0059).
2. The centre is currently licensed to undertake Donor Insemination (DI), In Vitro Fertilisation (IVF), IVF with donor eggs, IVF with donor sperm. IVF with egg sharing, Intra Cytoplasmic Sperm Injection (ICSI), ICSI with donor sperm, Gamete Intra Fallopian Transfer (GIFT), GIFT with donor sperm, GIFT with donor eggs, storage of sperm, storage of embryos, storage of eggs, assisted hatching (mechanical) and storage of sperm within testicular tissue until 31 March 2008 with no additional conditions on the licence.
3. This was an interim inspection and focused on all aspects of the centre's services. The treatment data analysed (246 cycles) was from the period 1 May 2004 to 30 April 2005.
4. The inspection team made recommendations regarding the following areas
 - The centre should review its security arrangements to ensure that unauthorised entrance to rooms critical to service provision can not occur (see paragraph 35).
 - The centre should revise its witnessing arrangements to include two appropriate persons witnessing the storage of all material as in the Chair's Letter CH(02)06 (see paragraph 49 & 81). Since the inspection the centre has submitted a copy of the revised witnessing procedure.
 - The centre should clarify the patient information regarding counselling and when charges apply (see paragraph 72). Since the inspection the centre has submitted a revised version of the counselling service information.
5. A previous Licence Committee made six recommendations, and all have been complied with.
6. The inspection team recommends that the continuation of the centres licence.

Background to inspection

7. This interim inspection report covers the period from October 2004 to November 2005. The treatment data analysed (246 cycles) was from the period 1 May 2004 to 30 April 2005.
8. Patient questionnaires were distributed during xx eg December 2003.
9. A site visit took place on 17th November 2005 and lasted six hours. The most recent HFEA audit visit took place on 16 January 2004.
10. The report was reviewed by the centre in December 2005.

The centre's context

11. The centre has been licensed since 1992 and has been based at its current premises since 2003. Licensed treatment is offered to private patients in Darlington, the surrounding area (~80% of patients) and other parts of the UK such as Ireland and Scotland.
12. The PR confirmed approximately 50% of patients are GP/consultant or self referred.
13. The centre has a large egg sharing programme (110 cycles, 1 May 2004 to 30 April 2005).
14. The centre is open from 9am to 5pm Monday to Friday. Embryo transfers, egg collections and sperm retrieval are performed in the morning. Consultations, scans and IUI occur in the afternoon. Counselling sessions are held on Thursday afternoons and on other days if required. The average waiting list is around 6 to 12 weeks for a clinical consultation.
15. The accredited consultant stated that on rare occasions embryo transfers occur on Saturdays.
16. The centre is in the process of setting up marketing of their treatment services to attract more patients. The marketing plan was observed in the audit meeting minutes by the inspection team.

Type of work carried out

Licensed treatment

17. The centre carries out the following licensed treatments.
 - Donor Insemination (DI)
 - In Vitro Fertilisation (IVF)
 - IVF with donor eggs
 - IVF with donor sperm
 - IVF with egg sharing
 - Intra Cytoplasmic Sperm Injection (ICSI)

- ICSI with donor sperm
- ICSI with donor eggs
- Gamete Intra Fallopian Transfer (GIFT)
- GIFT with donor sperm
- GIFT with donor eggs
- Storage of sperm
- Storage of embryos
- Storage of eggs
- Assisted hatching (mechanical)
- Storage of sperm within testicular tissue

Treatments that do not need a licence

18. The centre carries out the following treatments that do not require a licence.

- GIFT
- IUI
- Ovulation Induction

Satellite/transport arrangements

19. The centre has a satellite arrangement with the Cromwell IVF Centres in London (0074) and Swansea (0059).

20. The PR stated that the satellite arrangement is used very infrequently and only for egg donation.

Staff

21. All staff interviewed were positive and knowledgeable about the centre's activities. The senior embryologists/laboratory manager joined the centre's team in July 2005. The second embryologist has returned from maternity leave and works four days a week. The other three embryologists on the staff list are now working at the Cromwell IVF Centre in London (0074). The Person Responsible and Nominal Licensee are both based in the London Cromwell centre (0074) but visit the centre for meetings. The Accredited Consultant at the centre has been based at the centre for around three years.

22. The centre can use embryologists from the Cromwell group to cover periods of annual leave or sickness.

23. If nurses are on annual or sickness leave, cover can be supplied by the local nursing agency. The agency can supply nurses who have worked at the centre before.

Staffing profile

Person responsible	Kamal Ahuja
Nominal licensee	Eric Simons
Accredited consultant	Eric Simons
Other medical staff	2 (both accredited consultants)
Embryologists	2 (2 senior)
ICSI practitioners	2
Nursing staff	3 (all RGN)
Independent counsellor	1
Complaints manager	Kamal Ahuja

24. The majority of staff are new to the centre, the staff numbers are appropriate for the number of cycles carried out each year and the working capacity within the centre e.g. size of the laboratory.

Professional registration and continuing professional development (CPD)

25. The two consultants are confirmed by website search to be members of the Royal College of Obstetricians and Gynaecologists.

26. All nurses at the centre are registered with the Nursing and Midwifery Council (NMC), confirmed by website search.

27. Both embryologists are confirmed to be Health Professionals Council (HPC) registered and are in the process of registering for the ACE (Association of Clinical Embryologists) CPD scheme.

28. The counsellors CV confirms membership to the British Infertility Counselling Association (BICA) and is BACP (British Association for Counselling and Psychotherapy) accredited.

29. The centre has a budget for allowing staff to attend relevant courses and conferences where necessary. The nurses have attended a British Fertility Society course on ultra sound scanning and are to start performing scanning duties at the centre.

30. Weekly team meetings between clinical, scientific and nursing staff occur to discuss potentially difficult cases. Minutes taken at these meetings were not observed by the inspection team.

31. The Person Responsible and nominal licensee attends multidisciplinary audit meetings held every four to six weeks. These meetings discuss recent success rates, changes to protocols and HFEA alerts. These meetings are minuted and then disseminated to all relevant staff. The inspection team observed the minutes of two recent audit meetings.

32. The unit coordinator confirmed that the counsellor will start attending the audit meetings in the near future.

The premises, equipment and other facilities

Premises

33. The premises were custom built when the centre relocated to the hospital in early 2003 and are well equipped and patient friendly.

Equipment

34. Since the last inspection the centre has obtained a cronus imaging system for the microscope, a new centrifuge and a spare dewar. The centre has maintenance contracts for the equipment and keeps records of all maintenance and inspections carried out, These were observed by the inspection team.

Security

35. The centre is a self contained unit within the hospital. There are three entrances to the centre which are not manned and do not have controlled access. The number lock on the laboratory door is not currently being used. The inspection team recommended that the centre staff review the security arrangements and ensure access to where the gametes and embryos are stored is controlled (section 9.5, HFEA Code of Practice 6th Ed.).

Confidentiality

36. Current patient records are kept in locked cabinets in the administration office. The office is locked at night and when it is unoccupied. Archive records are kept in a separate locked store room.

Arrangements for collecting sperm samples

37. The centre has a dedicated sperm production room. It has a lockable door, sink and chair and is comfortable and discreet.

Cryostore facilities, oxygen and dewar alarms

38. The centre has four dewars which are all linked to a low nitrogen level alarm. The alarms are linked to a monitor that constantly observes the temperature of each dewar. The temperature is recorded on daily reports which the centre staff check and file. The alarms are also linked to an autodialler system which contacts the on-call embryologists if the alarms sound outside of normal working hours. The centre tops up the dewars fortnightly or more frequently if necessary.

39. The centre has obtained a spare dewar fulfilling the recommendation of the Licence Committee held on the 20th January 2005.

40. The centre does not store any oncology samples and screens all patients for HIV and Hepatitis B/C as per the relevant Chair's letter and the 6th Code of Practice before gametes or embryos are stored.

41. The laboratory is equipped with a low oxygen level alarm.

Emergency facilities

42. The centre uses sedation instead of general anaesthetic for egg collection and an anaesthetic nurse is present during such procedures. There is also an emergency trolley located next to the theatre.
43. Patients at risk of OHSS are asked to stay locally. Any patient that does suffer from OHSS is referred to the private hospital in which the centre is based under the care of the centre's consultant.

Clinical, nursing and laboratory procedures

Clinical

44. The clinical protocols were considered to be satisfactory by the inspection team.

Nursing

45. The nursing protocols were observed at the licence renewal inspection in 2004 and considered appropriate.

46. The nurses carry out IUI and are being trained to carry out scans.

Laboratory

47. The laboratory protocols were observed by the inspection team and found to be satisfactory.

48. There are written standard operating procedures for filling vessels; securing vessels; freezing and thawing procedures and location and duration of storage.

49. A procedure is in place to double check identification and is documented in the patient records, observed by the inspection team. The staff do not double witness at the time of storing gametes and embryos as recommended in the Chair's Letter CH(02)06, "Two appropriate persons are expected to witness the storage of all material". The witnessing procedure and any relevant laboratory protocols should be updated accordingly and copies submitted to the HFEA.

50. The centre has changed the fertilisation check protocol to a scoring system of nucleoli size, number and their alignment to the pronuclei junction. This system is used to select the most suitable embryo/s for transfer.

51. The centre should submit to HFEA, ICSI survival rate data for each embryologist. Since the inspection the ICSI data has been submitted

Procedures for assessing clients and for assessing and screening donors

Welfare of the child

52. The centre has a documented process for conducting a welfare of the child assessment which takes into account:
- the commitment to raise children
 - ability to provide a stable and supportive environment for a child/children
 - immediate and family histories
 - age, health and ability to provide for the needs of a child/children
 - the risk of harm to children including inherited disorders (or transmissible diseases), multiple births, neglect or abuse, the effect of a new baby or babies upon any existing child of the family

Ethics committee

53. The centre has access to an ethics committee based in London which is the same committee used by the Cromwell, London (0074) centre. The centre has not referred any Darlington based cases to the ethic's committee.

Assessing and screening donors

54. Egg donors are recruited by open evenings/mornings, radio advertising, newspaper adverts and website.
55. The centre routinely screens all donors according to the relevant guidelines. The donors also complete and sign a donor medical history check list. The donor protocol and checklist were observed by the inspection team.
56. A log is kept of all donors and the recipients they were matched with, along with details of results, to track the live birth events.

Counselling process and facilities

Counselling protocols

57. The counselling protocols have not been seen. The centre has agreed to submit the counselling protocols to the HFEA.

Counselling referral arrangements

58. The centre's independent counsellor works five hours a week at the centre. Three hours on a Thursday and another two hours during the course of the week.

59. The centre offers two free sessions of counselling to patients.

60. Counselling is mandatory for egg donors and recipients.

61. The services provided include implication, therapeutic and support counselling.

Supervision and professional registration

62. The centre provides funding for the counsellor's continuous professional development.

63. The counsellor is a member of BICA and BACP and receives regular external supervision from a dedicated fertility counsellor supervisor.

64. The counsellor is to start attending the team meetings.

Counselling audit

65. The counsellor provided an audit of counselling uptake for the period July 2003 to June 2004 as shown below. The percentage uptake of counselling for the same period was 10.4%.

Referrals	120
Implications Counselling	67
Support Counselling	10
Therapeutic Counselling	33
DNA	6
Cancelled	4

66. The counsellor gives a counselling questionnaire to patients to help audit the service. The inspection team observed the questionnaire.

Location of counselling facilities

67. There is a dedicated counselling room which is considered to be pleasant, comfortable, and private by the inspection team. However, the centre acknowledged that the room requires further soundproofing to ensure patient confidentiality.

Patient experience

Patient feedback

68. There is currently no patient support group although the centre hopes to initiate one in the near future depending on demand.
69. The centre conducts its own patient surveys. The patient survey was observed by the inspection team. Responses are discussed amongst the centre staff and changes are considered and implemented where appropriate and practicable.
70. On the day of the visit the inspection team interviewed two patients. Both patients stated the staff were friendly and helpful and that they were very happy with treatment and the facilities.
71. The centre distributed HFEA patient questionnaires prior to the inspection. The HFEA received 58 responses. The responses indicated patients were satisfied with the service provided by the centre.

Patient information

72. The patient information was reviewed and the following points were fed back to the centre.
- There is a disparity in the patient information regarding whether counselling is free and when it is mandatory, this should be amended.
73. The centre invites patients to attend an open evening to discuss treatment services and answer any questions.

Record keeping procedures

74. The inspection team examined 13 patient records that covered a range of treatments offered by the centre.

Treatment type	Error	Breach of Code reference	Number of errors
IVF	No evidence of being informed of the Deceased Fathers Act 2003	Chair's Letter CH(04)03	1
Various	Patient copies of (00)6 not present	N/A	1
IVF	No evidence of being informed of the Deceased Fathers Act 2003	Chair's Letter CH(04)03	1
IVF	(00)7 form for donated eggs not present in egg share records	6.48 6 th Code of Practice	1

75. The inspection team discussed the findings of the patient record audit with the centre. A checklist is used to ensure that all relevant documentation is present. In the records examined the checklist was not being signed and dated. This could potentially cause an issue if the information needs to be provided again. It is recommended that the checklist is signed and dated in the spaces provided.

76. Since the inspection, the centre has informed the HFEA that a deceased father's consent form has been sent to the two patients above.

77. Since the inspection the centre has informed the HFEA that the missing (00)6 form has been located and was misfiled.

Three embryo transfer arrangements

78. The centre has not performed any three embryo transfers in the time period covered by the report.

Audit

Centre's own audit of stored material

79. The centre has conducted an audit of stored material within the last year. The audit of stored gametes and embryos was completed in April 2005. No discrepancies between the laboratory notebooks and stored material were found.

Spot check of tracking process for stored material

80. The following audit trails were observed.

- **Sperm** – One sample tracked from record to dewar, and one sample tracked from dewar to record.
- **Embryos** – one sample tracked from record to dewar, and one sample tracked from dewar to record.

81. The embryo being tracked from the patient's record to dewar could not be found. Upon further investigation the sample was found in the correct bucket in the dewar. The patient's initials on the cane had not been updated when reused for another patient's embryos. This occurred because the storage of material is not witnessed as required by the Chair's Letter CH(02)06 (see paragraph 80).

HFEA register

82. The most recent HFEA audit visit took place on 16 January 2004.

Clinical governance

83. The centre has its own clinical governance policies as it is a self contained unit within the hospital but also abides by the general clinical governance policies of the hospital.

Risk management

84. The centre has audit meetings every four to six weeks where recent HFEA alerts are discussed and any relevant changes made to protocols.

85. All HFEA alerts are disseminated to relevant staff as are the minutes of the audit meetings.

Complaints

86. The centre recorded one complaint since the last inspection, observed in the audit meeting minutes, and has been resolved.

Other matters

87. Due to the financial policies of the Cromwell group, the centre has consistently been overdue with payment of HFEA fees. At the time of inspection the October payment was over due. The PR contacted the finance team and assured the inspection team that the payment would arrive shortly. The delay was due to annual leave. The PR confirmed that the payment policy had been restructured so invoices would be processed within 30 days.

Breaches of the Code of Practice or Act

Compliance with previous conditions and recommendations

Conditions

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

Recommendations

89. The licence committee made 6 previous recommendations. They are listed below along with the centre's response.

Recommendation	Adopted by centre (Y/N)	Comment
1. All protocols should be version controlled	Y	
2. The centre should ensure that all relevant patients are written to regarding the Deceased Fathers Act in line with the Chair's letter (03)06.	Y	
3. The centre should develop a protocol to distinguish between assessment of patients and counselling. The protocol should explicitly document the distinction between the responsibilities of the staff involved.	Y	
4. It is expected that the embryologists should be registered with the Health Professions Council	Y	
5. A spare dewar should be acquired.	Y	
6. Minutes should be taken at team meetings.	Y	

Key points for the Licence Committee

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

Issues

91. The inspection team would like to draw the following points to the attention of the licence committee.

- The centre should review its security arrangements to ensure that unauthorised entrance to rooms critical to service provision can not occur (see paragraph 35).
- The centre should revise its witnessing arrangements to include two appropriate persons witnessing the storage of all material as in the Chair's Letter CH(02)06 (see paragraph 49 & 81). Since the inspection the centre has submitted a copy of the revised witnessing procedure.
- The centre should clarify the patient information regarding counselling and when charges apply (see paragraph 72). Since the inspection the centre has submitted a revised version of the counselling service information.

Appendix A The inspection team and staff interviewed

The inspection team

Elliot Lawrence	Chair, HFEA Inspector
Imogen Swann	HFEA Inspector

Centre staff attending meetings with the inspection team

The inspection interviewed the PR and six other members of staff.

Conflicts of interest

None declared.