Human Fertilisation and Embryology Authority

Report of an interim inspection at

Centre for Reproductive Medicine and Fertility, Sheffield (0196)

Date of Inspection: 24 March 2006
Date of Licence Committee: 8 June 2006

Contents

Key facts about the centre

Centre name Centre for Reproductive Medicine and Fertility, Sheffield

Centre address Jessop Wing
Sheffield Teaching Hospitals NHS Trust
Tree Root Walk
Sheffield
S10 2SF

Centre number 0196

Person responsible William Ledger

Nominal licensee Gill Guest

Activities of centre

		2004/05
Licensed treatment cycles	IVF ICSI FET Egg Donation	168 139 108 16
Donor Insemination		101
Unlicensed treatments	GIFT IUI Ovulation induction	
Research	No	
Storage	Yes	

Focus of inspection General

Additional licence Conditions None

Licence expires 30 September 2007

Summary

1. The Centre for Reproductive Medicine and Fertility is a purpose built dedicated centre offering a range of assisted conception treatments for NHS and self funding patients. The unit is managed by the Sheffield Teaching Hospital NHS Trust as a non-profit making service.

2. This centre was first licensed in 2001 and has a good history of compliance. The unit carried out over 500 treatment cycles in the period covered by this report.

3. Since the last inspection the centre has undergone major refurbishment. Staff report that there has been no reduction in pregnancy rates during or after the refurbishment.

4. The procedures and protocols have been revised in line with the requirements for ISO accreditation. All the critical equipment in the laboratory is continually monitored and connected to the autodialler system. The system alarms in the 24 hour manned control room. Staff there then notify ACU staff.

5. The following issue was noted by the inspection team:

    - The team recommend that the centre should perform risk assessments as necessary for procedures carried out at the centre.

6. The inspection team supports the continuation of the centre's licence.

Background to inspection

7. This inspection report covers the period from the last inspection in March 2005 to March 2006 and includes outcome data from December 2004 to November 2005.

8. One site visit took place on 24 March 2006 and lasted 5 hours. The last operational audit was carried out on 21-22 January 2004.

9. The report was reviewed by the centre in April 2006.

The centre's context

10. The Centre for Reproductive Medicine and Fertility is a purpose built dedicated centre offering a range of assisted conception treatments for NHS and self funding patients. The unit is managed by the Sheffield Teaching Hospital NHS Trust as a non-profit making service.

11. The centre opens between 0800 and 1700 Monday to Saturday and between 0800 until 1400 for the provision of embryology services on Sundays. Clinical staff are available 24 hours a day on a rota basis. Other staff operate a rota to provide weekend cover.

12. The centre has recently carried out a major refurbishment to upgrade the facilities to good manufacturing practice standard. This refurbishment should ensure compliance with the European Tissue Directive. Treatments have been provided in the new facilities since November 2005 and there has been no reduction in pregnancy rate since this time.

13. Patients from 11 Primary Care Trusts (PCTs) receive treatment at the centre. The Person Responsible (PR) informed the team that the criteria for treatment have recently been relaxed by the PCTs.

14. In discussion, the PR reported that NHS patients can expect to receive treatment within 1 year of being placed on the waiting list. There is currently approximately a 2 year waiting list for treatment with donor eggs.

15. Due to the period when the laboratories were being refurbished the workload at the centre decreased in 2004/5 when compared to 2003/4.

Type of work carried out

Licensed treatment carried out

- Donor insemination (DI)
- In vitro fertilisation (IVF)
- Intra cytoplasmic sperm injection (ICSI)
- Treatment with donor gametes

- Storage of sperm
- Storage of embryos
- Assisted hatching (chemical)
- Zygote intra-fallopian transfer (ZIFT)
- Preimplantation genetic diagnosis (PGD)

Treatments carried out that do not need a licence

- Gamete intra-fallopian transfer (GIFT)
- Intra-uterine insemination with partner sperm (IUI)
- Ovulation induction

Staff

Staffing profile

Person responsible	William Ledger
Nominal licensee	Gill Guest
Accredited consultant	Jonathan Skull
Other medical staff	11 (3 consultant, 8 junior)
Embryologists	4 (2 senior, 2 qualified)
ICSI practitioner	3
Andrologist	3 (1 senior, 1 qualified, 1 trainee)
Nursing staff	8 (1 matron, 1 H grade, 2 F grades, 3 E grades, 1 support)
Independent counsellor	1
Administration and Management	12
Complaints manager	Valerie Kitcheman

16. Four staff have resigned since the last inspection (2 medical staff, 1 counsellor, 1 clerical officer) an four staff have joined the centre (4 medical staff). It was reported to the team that the centre will be advertising for another Counsellor in the near future.

17. The Head of Embryology and one of the embryologists were on maternity leave at the time of the inspection.

Professional registration and continuing professional development (CPD)

18. All of the staff at the centre are NHS employees and their recruitment is carried out in accordance with the Sheffield Teaching Hospital NHS Trust recruitment policy.

19. All staff interviewed reported good opportunities and support for training and CPD.

20. The inspection team confirmed that the PR is registered with the General Medical Council (GMC). The other member of the medical team who was interviewed confirmed that they were also registered with the GMC.

21. The team were provided with the CV for the Nurse Co-ordinator which stated that she is registered with the Nursing and Midwifery Council (NMC).

22. The nominal heads of both the Andrology and Embryology laboratories are not registered with the Health Professions Council (HPC). The HPC does not currently recognise or register andrologists and the Head of Embryology is an academic embryologist rather than a practising Clinical Embryologist and is therefore ineligible for registration. Both scientists are extremely well qualified, are experienced in their respective fields and hold lectureships within the University of Sheffield. Their role in the centre is to provide specialist expertise and neither plays an active role in the laboratory.

23. The CV for the Senior Embryologist was provided to the inspection team. This confirmed that she is registered with the Health Professions Council (HPC).

24. The Counsellor is a past Chair of the British Infertility Counselling Association (BICA). She informed the team that she supports herself in terms of CPD.

25. Staff keep a record of training and appraisals and examples of these records were seen on the day of inspection. Clinical staff have an annual allocation of funds for training and a trust fund is available to fund other staff members' attendance at meetings and conferences.

26. The centre holds a daily meeting to review the patient treatment schedule. Weekly multidisciplinary meetings are held and a copy of the minutes of one of these meetings was provided to the team on the day of the inspection. A copy of the minutes of a recent embryology team meeting was also provided to the team.

The premises, equipment and other facilities

Premises

27. The inspection team saw the HFEA licence and the complaints notice displayed in the waiting room.

28. The laboratory area has undergone complete refurbishment since the last inspection. This is to meet the requirements of the EU Tissue Directive particularly in relation to the requirements for the procurement and culture of stem cells.

29. The unit has a dedicated entrance into a reception area with a reception desk and patient toilets. This area leads to an office for administration staff which in turn leads to a secure records store.

30. The clinical suite comprises an additional waiting room (used for patients who require additional privacy), two clinical rooms, two scanning rooms, a counselling room, four single bedded recovery rooms (with emergency alarms) and two theatres. Both theatres link to the laboratory.

31. The embryology suite comprises a dedicated ICSI laboratory, an embryology laboratory, a research laboratory, a further laboratory and a cryostore. There is a double change area prior to entry into the embryology suite. The embryology suite operates as closely as is reasonably practicable to clean room standards.

Equipment

32. All handling of gametes and embryos is performed in class II cabinets. This was observed by the inspection team.

33. There is continual monitoring of the incubators, fridges, flow hoods, dewars, low oxygen alarm and CO2 cylinders. Evidence of this was seen by the team. If the monitoring system detects problems with any of the equipment the autodialler will call the hospital control room who will then call the appropriate member of staff. There is also a visual and audible alarm in the corridor of the embryology suite; the light is green if the equipment is working correctly and red if a non-compliance or fault is detected.

Security

34. Entry to the embryology facilities and theatres is controlled by proximity cards to restrict access. Evidence of this was seen by the team.

35. The team was informed that there is CCTV surveillance in the area outside the centre and that there is an intruder alarm within the clinic.

36. The team noted that there was a sign on the doors to the office areas stating that this was a restricted access area but the doors were not locked. It was suggested that the centre staff may wish to consider having access through this area controlled by proximity cards or some similar system for their own safety and security. The inspection team did not consider this to be a risk to patient safety or confidentiality.

Confidentiality

37. Patient records are kept in a locked store off the main administration office. This was observed by the inspection team.

Arrangements for collecting sperm samples

38. The sperm production rooms are spacious and well presented. The rooms are located away from the main clinical suite to ensure privacy.

Cryostore facilities, oxygen and dewar alarms

39. Gametes and embryos are stored in a designated security area with controlled access. This was seen by the inspection team.

40. The team considered the cryostore facilities to be adequate for the type and volume of activities carried out.

41. There are appropriate emergency procedures in place to respond to damage to storage vessels and failures in storage systems. These were provided to the inspection team prior to the visit.

42. Cryopreservation dewars are fitted with low nitrogen level alarms and these are connected to an auto-dialler system linked to the hospital control room. If the alarms are activated, the switchboard contacts a designated member of the unit staff. This is documented in a protocol.

43. The cryostore has a low oxygen level alarm that is connected to the auto-dialler system.

Emergency facilities

44. Documents provided to the inspection team prior to the inspection visit state that links with the feto-maternal unit and emergency gynaecological assessment unit enable prompt and efficient management of treatment or pregnancy related complications.

45. Full details of the emergency facilities were not submitted as this was an interim inspection.

Clinical, nursing and laboratory procedures

Clinical

46. Clinical protocols were not submitted for this inspection as it was an interim inspection and the protocols had not changed.

47. In discussion, one of the clinicians interviewed demonstrated that she was familiar with the clinic's SOPs.

Nursing

48. Nursing protocols were not submitted for this inspection as it was an interim inspection.

49. The centre staff informed the inspection team that they intend to incorporate the nursing protocols into the multi disciplinary protocols as part of the ISO review process.

50. Nursing sisters carry out embryo transfers and ultrasound scanning and the Nurse Co-ordinator informed the team that the nurses were willing to extend their role further.

51. Two nurses have received accredited training in ultrasound scanning procedures. The centre is now accredited to train nursing staff in embryo transfer.

Laboratory

52. Laboratory protocols were provided to the inspection team. They have been revised to meet the requirements of ISO accreditation.

53. The Senior Embryologist informed the team that all consumables and equipment are CE marked and they do not therefore perform their own QA checks on these items.

54. Laboratory equipment is serviced annually and service agreements for a random selection of items of equipment were seen by the inspection team.

55. There is a training log for each item of equipment to document that staff members have been trained in their use. This was seen by the team.

56. The team was informed that all samples of stored material are stored in two separate locations and this was evidenced during the audit trail.

Procedures for assessing clients and for assessing and screening donors

Welfare of the child

57. The centre has a procedure for assessing the 'welfare of the child'. The inspection team were provided with an updated protocol prior to the inspection visit. These documents were considered to be adequate and fulfil the requirements of the HFEA.

Ethics committee

58. The centre has access to an ethics committee. The application form submitted by the centre states that the role of the ethics committee has not changed since the last inspection.

Assessing and screening donors

59. The centre buys donor sperm supplies from a sperm bank and does not recruit its own donors.

60. Treatment with donor eggs is provided at the centre and counselling is offered to all potential egg donors.

Counselling process and facilities

Counselling protocols

61. Counselling protocols were provided to the inspection team. They have recently been updated in line with ISO requirements.

Counselling referral arrangements

62. The centre provides implications, therapeutic and support counselling.

63. The Counsellor informed the team that patients can telephone her directly to book an appointment.

64. Patients are not charged additional fees for counselling services.

Supervision and professional registration

65. The Counsellor informed the team that she is an accredited member of the British Association for Counselling and Psychotherapy (BACP) and the British Infertility Counselling Association (BICA).

66. Documentation provided to the inspection team states that the counsellor receives regular supervision in line with the BACP Ethical Framework recommendations. This takes place within working hours and the costs are met by the Unit.

Counselling audit

67. A detailed and comprehensive audit of counselling for the period January to December 2005 was provided to the HFEA. A total of 337 sessions were attended. Some of these sessions took place when there was a second counsellor is post who has now left the employment of the centre.

68. In discussion, the counsellor reported that approximately 30% of patients take up the counselling services which is comparable with national statistics.

Location of counselling facilities

69. The centre provides private and comfortable rooms for counselling. These were seen by the team on the day of the visit.

Patient experience

Patient feedback

70. The centre has not conducted its own survey of patient experience in the last year but staff informed the team that they plan to do so in the coming year.

71. A total of 35 responses to the HFEA questionnaires have been received. The responses were generally favourable. Very few negative responses were received. The most significant of the negative responses was made by nine patients who commented that counselling services were not made easily accessible. Five patients also reported that their appointments had been cancelled or delayed.

Patient information

72. Updated patient information was provided to the inspection team. This included information on complaints and 'welfare of the child'. These documents have been revised in the format required for ISO accreditation.

73. Not all patient information was supplied to the inspection team as this was an interim inspection.

Record keeping procedures

74. A review of the records of ten patients was carried out on the day of the inspection. No discrepancies were noted in the records.

Three embryo transfer arrangements

75. One patient had received a three embryo transfer in the reporting period. She was aged 43 at the time of the transfer.

76. In discussion with the PR it was apparent that he is keen to move towards single embryo transfer in appropriate patients. He informed that team that the centre is applying to take part in a multi-centre randomised controlled trial investigating single embryo transfer in young patients. He is also aware of the difficulty that this trial will face as many patients are reluctant to receive a single embryo transfer.

Audit

Centre's own audit of stored material

77. The audit of samples stored in the embryology laboratory was last performed in January 2006. No discrepancies were found and a copy of this report was provided to the inspection team.

78. The audit of samples stored in the andrology laboratory was performed in March 2006. Four minor discrepancies were detected; these were all for samples that had been used in treatment but the medical records had not been updated. The embryology records were checked for these samples to confirm that the errors were due to failure to update the paperwork after use. These discrepancies have now been resolved. A copy of the audit report was provided to the inspection team.

Spot check of tracking process for stored material

79. A spot check of four embryo samples (two from tank to records, two from records to tank), and two sperm samples (from records to tank) was carried out. All samples were tracked successfully.

HFEA register

80. The last HFEA audit was carried out in January 2004.

Clinical governance

81. The unit is managed by the Sheffield Teaching Hospital NHS Trust and adopts the clinical governance policies of the Trust.

82. The PR explained that there is a monthly board meeting of the senior staff at the centre relating to clinical governance. The results of this meeting are passed via the Management Team for the Jessop Wing to the Hospital Board.

83. The Nominal Licensee (NL) is the general manager of the directorate that incorporates the Centre for Reproductive Medicine and Fertility. The NL therefore provides a direct link with the trust's clinical governance structure.

Risk management

84. In line with ISO requirements the centre has produced a quality manual outlining the purpose of the Centre, responsibilities and quality checks performed.

85. The laboratory carries out a comprehensive series of quality assurance checks to monitor equipment and outcomes. The procedures for these were provided to the team.

86. COSHH form records for substances used within the clinic were seen by the inspection team on the day of the visit.

87. In discussion the clinician interviewed demonstrated that she was familiar with the incident reporting policy and was aware of the HFEA alerts.

88. The team recommended that the centre should perform risk assessments as necessary for procedures carried out at the centre.

Complaints

89. The centre has a written complaints procedure which was provided to the team. Patients are initially asked to direct their complaint to the Centre's Complaints Officer. If the patient is still dissatisfied then they can take the complaint to the Chief Executive of the hospital.

90. The centre has received two complaints in the last year, one of which remains unresolved.

91. The HFEA has received one complaint about this centre in the last year. This complaint has been investigated and closed.

Breaches of the Code of Practice or Act

92. No breaches of the Code of Practice or Act were detected during the inspection.

Compliance with previous conditions and recommendations

Conditions

93. The centre's licence carries no additional conditions.

Recommendations

94. The previous Licence Committee made one recommendation as below:

Recommendation	***Adopted by centre (Y/N)***	***Comment***
1. That the centre should amend it's written protocol for 'Welfare of the Child' and submit it to the HFEA.	Y	

Key points for the Licence Committee

95. The inspection team supports the continuation of the centre's licence for the treatments listed above.

Issues

96. The Inspector would like to draw the following point to the attention of the licence committee.

- The team recommend that the centre should perform risk assessments as necessary for procedures carried out at the centre.

Appendix A: The inspection team and staff interviewed

The inspection team

Dr Vicki Lamb	Inspector, HFEA, Chair
Dr Neelam Sood	Inspector, HFEA

Centre staff interviewed

William Ledger	Person Responsible
Four	Other members of staff

Conflicts of interest

None declared.