Human Fertilisation and Embryology Authority

Report of a renewal inspection at

Centre for Assisted Reproduction, Gateshead (0170)

on

27th September 2005

Contents

Key facts about the centre

Centre name Centre for Assisted Reproduction, Gateshead

Centre address Gateshead Health NHS Foundation Trust
Queen Elizabeth Hospital, Sheriff Hill
Gateshead
Tyne & Wear NE9 6SX

Centre number 0170

Person responsible Ian Aird

Nominal licensee Chris Reed

Activities of centre

		April 2004 – March 2005
Licensed treatment cycles	IVF ICSI FET	141 49 23 (IVF) 8 (ICSI)
Donor Insemination		32
Unlicensed treatments	IUI Ovulation induction	
Research	None	
Storage	Yes	

Focus of inspection General

Additional licence conditions None

Licence expires 31 January 2006

Summary

1. The centre is part of the Gateshead Health NHS Foundation Trust and has provided licensed treatments since 1996. The unit offers self funded and NHS funded treatments to patients from the local geographical area. The centre provided 253 licensed treatment cycles between April 2004 and March 2005.

2. The centre has had a stable staffing structure in the time covered by this report. The workload at the centre increased by approximately 40% over the last year and an additional clinician is being recruited to the team in response. Staff reported good opportunities for induction, CPD and training although training and development for members of the nursing team has been hampered by Trust imposed restrictions.

3. The main pressure on the centre is the size of the premises in relation to its layout and the number of patients treated. On occasion, the patient waiting area and recovery room cannot reasonably accommodate the number of patients seen at the clinic. The unit is aware that space constraints may impact on the quality of service but has delayed refurbishment in anticipation of the implementation the EUTD. However, before the workload is further increased, the centre should develop an action plan detailing how additional patients can be accommodated. The plan should include information on how resources are to be provided and a review of staffing levels. This plan should be submitted to the HFEA before additional treatment cycles are provided.

4. A small number of minor issues were identified in the course of the inspection visit and these are summarised below.
   - Key pieces of laboratory equipment are not maintained routinely. The risk associated with this has been assessed and the assessment has been communicated to the Trust.
   - Not all patients have been provided with a signed copy of 00(6) or 00(7) consent forms. The centre agreed to adapt procedures to ensure that all patients are provided with a copy of their consent form.
   - Patient information does not fully comply with all of the requirements of the COP. A small number of omissions were discussed and the centre should submit revised information to the HFEA at the time of the next inspection.

5. The embryology laboratory is proactive in carrying out quality assurance and risk assessments and in auditing outcomes. On the day of the inspection, the team appeared well integrated and responded positively to discussions with inspectors. Patient feedback received by the HFEA was very positive, with 29 of 31 respondents having compliments about the treatment they had received. The inspection team support the renewal of the centre's licence for three years.

Background to inspection

6. This report covers the period from September 2004 to September 2005 and includes outcome data from April 2004 to March 2005.

7. Patient questionnaires were distributed in the six months preceding the inspection.

8. One site visit took place on 27 September 2005 and lasted 7 hours. The last operational audit visit was in October 2003.

9. The report was reviewed by the centre in November 2005.

The centre's context

10. The centre is part of the Gateshead Health NHS Foundation Trust and provided 253 treatment cycles to NHS and self funding patients from the local area. The centre is currently commissioned to provide 64 NHS treatments per year but this may rise as a result of the implementation of National Institute of Clinical Excellence (NICE) guidelines in the region.

11. The centre is open from Monday to Friday.

12. The main pressure on the centre is the size of the premises in relation to its layout and the number of patients treated. The patient waiting area has only two chairs and there are frequently more patients than can reasonably be accommodated. Patients can use a general waiting area in the main reception area but this area also services patients from the maternity and antenatal wards. Following egg collection or embryo transfer, patients pass through the waiting area to reach the recovery room. The recovery room can accommodate only two patients. On occasion up to four patients are treated in the clinic's theatre and two patients are moved to recovery rooms elsewhere in the hospital.

13. In feedback gathered by the HFEA from 31 patients who received treatment at the centre in the time covered by this report, eight respondents commented that the waiting area is not satisfactory. In text responses two respondents commented that waiting in the maternity area is distressing and two other respondents commented that the unit is "small" and cramped".

14. The unit is aware of that space constraints may impact on the quality of service but has delayed refurbishment in anticipation of the imposition of revised standards for IVF facilities as a result of the European Union Tissues and Cells Directive (EUTD). However recent information suggests that the finalisation of legislation may be further delayed. In the interim the centre should inform the HFEA if commissioning of additional cycles is confirmed. Before additional cycles are provided, the centre should develop an action plan detailing how additional patients can be accommodated. This plan should be submitted to the HFEA before additional treatment cycles are provided.

Type of work carried out

Licensed treatment

15. The centre carries out the following licensed treatments

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

Licensed treatments that are not currently provided

16. The centre has protocols and patient information for egg donation and egg share treatments but these have not been provided in the time covered by this report. These services may be provided in the future and the centre wishes to continue including these treatments on the centre's licence.

Treatments that do not need a licence

17. The centre offers intra uterine insemination and ovulation induction treatments.

Staff

Staffing profile

18.

Person Responsible	Mr Ian Aird
Nominal Licensee	Mr Chris Reed
Accredited consultant	Mr Ian Aird
Other medical staff	1 (associate specialist)
Embryologists	2 (senior)
ICSI practitioners	2 (senior)
Nursing staff	3 (1 acting nurse coordinator, 1 nurse coordinator on maternity leave, 1 temporary fertility nurse)
Healthcare assistant	1
Independent counsellor	1
Administration staff	1 (part time)
Complaints manager	Mr Chris Reed

19. The workload at the centre increased by approximately 40% in the time covered by this report. It is expected that there may be a further increase in the workload in the next year if the centre is commissioned to provide additional treatment funded by local primary care Trusts (PCTs).

20. The recruitment of an additional clinician to the team is at an advanced stage and this appointment will significantly increase the clinical input at the centre.

21. The unit has only three hours of administrative support per week although this was not reported as having an impact on the quality of the service offered. However, if the workload does increase in the next year, the provision of adequate staff in the administrative, nursing, embryology and counselling teams should be reviewed and the outcome of that review should be included in the action plan submitted to the HFEA (see paragraph 14).

Professional registration and continuing professional development (CPD)

22. All staff are recruited in accordance with the Trust recruitment and selection procedure. This process ensures that the character, qualifications, and experience of staff are appropriate. Staff are subject to criminal records bureau (CRB) checks on recruitment.

23. All clinical staff are registered with the General Medical Council. All nursing staff are registered with the Nursing and Midwifery Council. Members of the embryology team are registered with the Health Professions Council. The counsellor is registered as an accredited member of the British Association for Counselling and Psychotherapy.

24. All newly recruited staff take part in an induction programme. Staff attend meetings and conferences appropriate to their specialist roles and provide feedback on learning to the rest of the team.

25. Members of the clinical team reported good opportunities for CPD. The PR complies with Royal College of Obstetrics and Gynaecology (RCOG) requirements for continued medical education and the associate specialist reported being well supported in her RCOG training. Embryology staff take part in the Association of Clinical Embryologist's (ACE) CPD scheme. The counsellor attends BICA courses, study days and workshops and other relevant CPD events.

26. Opportunities for members of the nursing team to take part in CPD have been hampered by Trust imposed limitations despite the availability of funding for external training opportunities. One member of the nursing team has received Royal College of Radiologists accredited trans vaginal ultrasound training and a second member of the team has a higher level award in women's reproductive health (ENB N40). The centre should ensure that members of the nursing team receive adequate opportunities for CPD and training as required by sections 1.8 and 1.17 of the 6th Code of Practice.

27. Staff training records did not show evidence that all required mandatory training has been undertaken. The centre should ensure that all staff take part in and record the mandatory training provided by the Trust.

28. The laboratory collates monthly information on outcomes including fertilisation rates, embryo quality and pregnancy and implantation rates. This information is reviewed at monthly audit meetings.

29. The centre holds regular monthly multi-disciplinary team meetings which are attended by all members of the team including the counsellor.

The premises, equipment and other facilities

Premises

30. The premises have not changed since the last inspection and consist of a waiting area, a laboratory leading to a theatre area, a recovery room, a scanning room, a consultation room and an office.

Equipment

31. There have been no changes to the centre's equipment since the last inspection.

32. Embryo and gamete freezing equipment and the pressurised nitrogen storage tank are maintained under service contract and the flow hood is currently maintained under warranty. Other pieces of laboratory equipment, including incubators, are not routinely maintained. The embryology team have been proactive in assessing the risks associated with a lack of service contracts for key equipment and submitting risk assessments to the Trust. The centre should inform the HFEA of the outcome of the Trust's consideration of the risk assessments.

Security and Confidentiality

33. Access to the unit is controlled and current records are kept in locked filing cabinets in the centre's office. The office is locked when unoccupied. Archived records are kept in locked cabinets in other clinic areas.

Arrangements for collecting sperm samples

34. The centre has a document that is signed by patients on provision of a sperm sample. The document does not require patients to confirm the time that the sample was produced and that the sperm has not been subsequently interfered with. This was discussed with members of the embryology team who agreed to revise the document to comply with section 8.14 of the COP.

35. The centre's sperm production facilities are appropriate for purpose.

Cryostore facilities, oxygen and dewar alarms

36. Gametes and embryos are stored in the laboratory. Access the laboratory is keypad controlled and limited to licensed personnel only.

37. The cryostore facilities are adequate for the type and volume of activities currently carried out but laboratory space is limited and there can be no further expansion of facilities within the area.

38. The centre does not store samples for patients who have undergone treatment that could impair their fertility.

39. Cryopreservation dewars are fitted with low nitrogen level alarms and the two members of the embryology team operate a rota system for responding to an alarm.

40. The laboratory has a written protocol for responding to low nitrogen and low oxygen level alarms.

Emergency facilities

41. The centre is located within the Queen Elizabeth Hospital which can provide emergency resuscitation facilities.

42. The centre has resuscitation equipment within the clinic and clinical staff receive annual training in cardio pulmonary resuscitation. Resuscitation equipment in the fertility clinic is checked weekly and emergency drugs are checked by the pharmacy department. The Royal College of Anaesthetists[1] advises that it is best practice for equipment checks to be done daily. The centre should consider local guidance on resuscitation equipment checks and review the frequency of checks if required.

[1] Royal College of Anaesthetists, Raising the Standard, 2000

Clinical, nursing and laboratory procedures

43. The centre's documents are version controlled and show evidence of revision.

Clinical and Nursing

44. The centre's clinical and nursing protocols are combined. Protocols cover the key aspects of the centre's activities and staff report that they are informative and reflect current practice.

45. The protocol detailing the procedure for carrying out a welfare of the child assessment does not include information on the circumstances when an assessment should be repeated. The audit of patient records suggested that the centre is repeating the assessment when required but the centre should consider revising the protocol to reflect practice as detailed in section 3.5 of the COP.

46. The centre has appropriate protocols for the management of ovarian hyperstimulation syndrome (OHSS).

47. The nursing team perform initial IUI and DI treatments and have received in house training in these techniques. Staff feel well supported to provide this treatment.

Laboratory

48. The laboratory protocols are appropriate and staff reported that they are easy to follow and reflect current practice.

49. There are written standard operating procedures for filling vessels; location and duration of storage; freezing and thawing procedures. To fully comply with the requirements of section 2.16 of the COP the centre should consider the following;
    - protocols should be developed for the handling of contaminated samples;
    - protocols detailing the procedure for filling of cryopreservation dewars should be revised to describe the steps required for securing of vessels.

50. Procedures are in place to double check patient identification and for the witnessing of key laboratory and clinical stages. Witnessing steps are documented in patient records.

51. When cryopreserved material reaches the end of its consented storage period, patients are sent a standard letter explaining that embryos cannot be stored beyond the date of expiry of consent. Patients are advised that storage may be extended but the criteria for eligibility for prolonged storage and alternative options are not detailed. This was discussed with the embryology team who agreed to review the contents of the letter.

52. On inspection of patient records, it was noted that both the top and bottom copies of the HFEA 00(6) and 00(7) forms were present in some records

(see paragraph 78). Section 6.7 of the COP states that it is expected that a copy of the signed consent form will be provided for those who have given consent. This omission was discussed with the clinic team and it was explained that patients do not complete the sections of the forms that relate to freezing of embryos until it known whether there are suitable embryos for freezing. Where patients do not go on to freeze embryos, the top copy of the 00(6) or 00(7) forms remain in the patient files. The centre agreed to adapt procedures to ensure that in future, patients are supplied with a copy of their consent form.

53. Consent to storage of embryos is obtained either after the day 10 scan or at the time of embryo transfer. This practice was discussed at length during the inspection and the inspection team were satisfied that patients are given sufficient time to consider information before giving consent as information on the pros and cons of freezing is given to patients at the beginning of treatment.

Procedures for assessing clients and for assessing and screening donors

Welfare of the child

54. The centre has an appropriate procedure in place for conducting a welfare of the child (WOC) assessment. The assessment includes communication with the patients' GP and a self assessment questionnaire.

55. Information for patients receiving treatment with donated gametes addresses the issue of parental responsibility. However, the centre should consider revising consent forms to clarify that the unmarried partner of a woman receiving treatment with donor sperm will only have parental responsibility for any resulting child if his name is recorded on the child's birth certificate (section 111 of the Adoption and Children Act 2002).

Ethics committee

56. The centre has access to an ethics committee. It was noted during the inspection that the husband of a member of the IVF team sits on the ethics committee. The centre staff do not consider that this has led or is likely to lead to any conflict of interest.

57. Complex cases are referred to the ethics committee for review before treatment. Two cases have been referred to the ethics committee for review in the time covered by this report, with one referral resulting in a refusal to offer treatment.

Assessing and screening donors

58. The centre buys sperm supplies from a sperm bank.

59. The embryologists are alerted by the sperm supplying centre when a donor has achieved six live births and this notification is recorded in all relevant files and documentation. After the notification is received, sperm is only used after the supplying centre has been contacted to verify that the donor sperm has not been used to produce 10 live births.

60. The centre has not carried out any treatments with donated eggs or egg sharing in the time covered by this report however, these treatments may be offered in the future. The centre has an appropriate clinical protocol that details the screening tests that should be carried out before an egg donation is accepted.

Counselling process and facilities

61. The centre offers support, therapeutic and implications counselling. The counsellor can offer telephone appointments to patients unable to attend the clinic. No additional charge is made for counselling services.

62. In some cases the counsellor carries out pre-treatment assessment of clients. Her assessment role is clearly explained to clients and is distinct from counselling. Any information provided by the counsellor to the centre's multi disciplinary team or ethics committee is with the clients' prior knowledge and consent.

Counselling protocols

63. Counselling protocols are appropriate, up to date and version controlled and reflect current practice.

Counselling referral arrangements

64. Patients can be referred for counselling by members of the clinic's staff or can refer themselves directly to the counsellor.

65. Patient information addresses the availability of counselling and provides the name and a direct telephone contact number for the counsellor. The centre's web site includes information on contact details for other support agencies.

Supervision and professional registration

66. The counsellor has appropriate qualifications and experience, is a member of the British Infertility Counselling Association (BICA) and the British Association for Counselling & Psychotherapy (BACP) and adheres to the BACP Ethical Framework for Good Practice in Counselling and Psychotherapy. The counsellor has recently attained BACP accreditation. Professional supervision is provided by an independent counselling supervisor who also works within the BACP Ethical Framework. Funding for supervision is provided by the Trust.

Counselling audit

67. A counselling audit for the period October 2004 to September 2005 was provided on the day of the inspection. The counsellor offered a total of 110 sessions including 15 implications, 18 support, 37 therapeutic, 29 telephone, and 11 WOC assessment counselling sessions. This represents an approximately four fold increase in counselling activity compared to the previous year. In the time covered by this report, there has been no increase in the counsellors working hours which are currently 18.5 hours per week. In the course of the working week the counsellor provides a service to fertility, maternity and gynaecology patients and provides psychological support for staff.

68. The need for increased provision for counselling services, including the number of counselling hours dedicated to the centre, should be included in

any review of staffing that is carried out prior to increasing the centre's workload.

Location of counselling facilities

69. The centre provides a private and comfortable room for counselling which ensures confidentiality. The room is located in the hospital's centre for women's health where the waiting area is also used by patients attending antenatal clinic. The counsellor ensures that clients are aware of this and is able to offer an alternative room in the hospital's chaplaincy if clients wish. These arrangements are not ideal and this should be considered in any future development plans for the centre's premises.

70. Patient's counselling records are stored in locked filing cabinets and are accessible only by the counsellor. There are arrangements in place for access to records in the event of the counsellor's sudden incapacity.

Patient experience

Patient feedback

71. The centre plans to carry out a review of the counselling service in the next year. A patient questionnaire has been prepared that asks patients to comment on the service.

72. The HFEA received feedback from 31 patients who received treatment at the centre in the time covered by this report. The feedback was very positive with 29 respondents commenting that they have compliments about the treatment they received. Eight patients did comment that the waiting area is unsatisfactory and a further four respondents made similar comments in text responses (see paragraph 13).

Patient information

73. Information packs are sent to patients prior to their first appointment when additional verbal explanations and information are offered.

74. Patient information leaflets are clear and appropriate however, a number of minor omissions were discussed with the PR: these are summarised below.
    - Information on the risks of multiple pregnancy as required by section 5.5 (vi) of the COP is provided in leaflets intended for patients having treatment with donor eggs but is not included in other leaflets.
    - Issues relating to the statutory storage period for gametes and embryos, options in the event of death or mental incapacity, or the importance of keeping the treatment centre informed of treatment outcome are not addressed in patient information (COP sections 5.4 (vi), (vii) and 5.5 (x)).
    - Information for patients receiving treatment with donor gametes or for patients donating gametes does not reference all of the screening tests that are carried out or the scope and limitations of infectious diseases or genetic tests or that tests may reveal previously unsuspected conditions (COP sections 4.1 (ii), 4.13 to 4.18 and 5.7 (i) and (ii)).

The centre should review patient information to consider how this information can best be provided to patients. Revised or newly developed information should be submitted to the HFEA for review at the time of the next inspection.

75. Consent forms for patients providing or receiving donor gametes do not reflect that donors and recipients can consent to the exchange of non-identifying information on the outcome of treatment. The centre should revise egg recipient and donor sperm recipient consent forms to reflect that both donors and recipients can consent to the exchange of outcome information.

76. At present, patients undergoing treatment with donated gametes are given the non-identifying information provided by the donor. However, the donor registration forms introduced in June 2004 may contain more detailed information than was previously available to the recipients of donor gametes. Patient information should also be revised to inform patients about the non-identifying information that may be available to the recipients of donor gametes or children born as a result of treatment with donor gametes (chair's letter CH(04)07). It is expected that patients will approach centres for this non-identifying information in the first instance (see HFEA Update Issue 5, November 2004) and the centre should ensure that they have been provided with the necessary information by suppliers of donor sperm.

Record keeping procedures

77. A review of a thirty patient records was carried out on the day preceding the main inspection visit. The paperwork in 12 sets of records was found to be correctly completed and compatible with treatment.

78. The errors seen in patient records are summarised in the table below.

Error	Breach of Code reference	Number of errors
Both the top and bottom copy of the HFEA 00(6) and 00(7) forms present in patient record	Section 6.7 of the COP states that it is expected that a copy of the signed consent form will be provided to those who have given consent.	16 (see paragraph 52)
Patients indicated that embryos could be used in research in addition to treatment of self or self with named partner after death or in the event of mental incapacity.	These options cannot all be complied with and as such, consents would be invalid.	2

The centre agreed to ensure that in future, patients would be supplied with a copy of their consent form. The two sets of records that contained invalid posthumous consents were from patients who had not gone on to store embryos however, the centre should ensure that consents are reviewed to ensure that the options chosen by patients can be complied with.

Three embryo transfer arrangements

79. The centre has appropriate policy in place relating to three embryo transfers. Implementation of this policy was confirmed by inspection of patient records.

Audit

Centre's own audit of stored material

80. The centre completed an annual audit of cryopreserved material in June 2005 and a report of that audit was submitted with the renewal application. In the course of the audit one straw containing an embryo was found to be missing. This was reported to the HFEA. The dewar which should have contained the missing straw was emptied and the straw was found at the bottom of the dewar. It was assumed that the straw had "floated" out of the visitube. To prevent a reoccurrence of the incident the embryologists now attach an empty vial to the cane carrying the visitube, just above the position of the straw.

Spot check of tracking process for stored material

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

Clinical governance

82. The centre is part of the Gateshead Health NHS Foundation Trust and adopts the clinical governance policies of the Trust. The Nominal Licensee (NL) is the Chief Executive of the Trust and acts as a link between the centre and senior management. The 2003/4 clinical governance indicator places the Trust's clinical governance performance in band 5 (good) when compared to other NHS Trusts[2].

Risk management

83. Members of the embryology team have received training in risk assessment and aspects of the clinic's embryology services have been assessed.

84. The laboratory carries out internal quality assurance assessments and participates in the National External Quality Assessment Service (NEQAS) scheme for andrology. The laboratory has also carried out an internal assessment of evaluation of embryo quality and has participated in an ACE scheme piloting the assessment of embryo quality.

85. The centre has a written incidents policy. The centre reported one incident in the time covered by his report. The incident was reported, managed and investigated proactively and appropriate steps have been taken to minimise the possibility of a reoccurrence (see paragraph 80).

86. HFEA ALERTs are disseminated to the team as appropriate and any necessary review of practice or protocols is implemented as required.

Complaints

87. The centre has an appropriate written complaints policy. The centre received no complaints in the time covered by this report.

Breaches of the Code of Practice or Act

88. On inspection of patient records it was noted that a number of patients had not been given a copy of the signed 00(6) or 00(7) consent form as required by section 6.7 of the COP (see paragraphs 52 and 78).

89. A small number of omissions were noted in patient information and these are detailed in paragraphs 74 to 76.

Compliance with previous conditions and recommendations

90. The centre's current licence carries no additional conditions or recommendations.

[2] Gateshead Health NHS Performance Ratings 2003/2004, Health Care Commission

Key points for the Licence Committee

91. The inspection team supports the renewal of the centre's licence for treatments set out in paragraph 15 above.

Issues

92. The inspection team would like to draw the following points to the attention of the licence committee.
    - The main pressure on the centre is the size of the premises in relation to its layout and the number of patients treated. The unit is aware that space constraints may impact on the quality of service but has delayed refurbishment in anticipation of the implementation of the EUTD. Before workload is increased, the centre should develop an action plan detailing how additional patients can be accommodated. The plan should include information on how resources are to be provided and a review of staffing levels. This plan should be submitted to the HFEA before additional treatment cycles are provided.
    - Key pieces of laboratory equipment are not maintained routinely. The risk associated with this has been assessed and the assessment has been communicated to the Trust.
    - Not all patients have been routinely provided with a signed copy of 00(6) or 00(7) consent forms. The centre agreed to adapt the procedure to ensure that all patients are provided with a copy of their consent form.
    - Patient information does not fully comply with all of the requirements of the COP. A small number of omissions were discussed and the centre should submit revised information to the HFEA at the time of the next inspection.

Appendix A The inspection team and staff interviewed

The inspection team

Catherine Grieve	Social and ethical advisor
Chris Hall	Records audit advisor, HFEA executive
Debra Bloor	Inspection Chair, HFEA executive
Lynne Gallagher	Nursing advisor
Peter Brinsden	Clinical advisor

Centre staff interviewed

Ian Aird	Person responsible

Eight other members of the clinic's team also met with inspectors.

Conflicts of interest

None declared.