Human Fertilisation and Embryology Authority

Name of Centre: Edinburgh Assisted Conception Unit

Document Type: Renewal Inspection Report

Date: January 2006

Human Fertilisation and Embryology Authority

Report of a renewal inspection at

The Edinburgh Fertility and Reproductive Endocrine Centre Assisted Conception Programme (0201)

Date of Inspection: 4 November 2005
LC January 2006

Contents

Key facts about the centre

Centre name The Edinburgh Fertility and Reproductive Endocrine Centre

Centre address Royal Infirmary of Edinburgh
51 Little France
Edinburgh
EH16 4SA

Centre number 0201

Person responsible Dr K J Thong

Nominal licensee Ms S Mair

Activities of centre

		April 04 to March 05
Licensed treatment cycles	IVF ICSI FET Egg donation (provider) (recipient)	272 137 123 9 7
Donor Insemination		288
Research	None	
Storage	Yes	

Focus of inspection General

Additional licence conditions None

Licence expires 28 February 2006

Summary

1. The centre has been licensed since 1992 and moved to its present site in 2002.

2. The centre has a medium level of activity and carried out 548 treatment cycles between April 2004 and March 2005.

3. The centre treats both NHS and self-funding patients.

4. This report covers the period from December 2004 to November 2005 and was a renewal inspection. There was no specific focus assigned by the previous licence committee.

5. An external review of the centre's management structure and other matters affecting the running of the centre was completed in December 2004. Relevant issues from the review have been included in the inspection report.

6. The key issues for this inspection for LC are as follows.

    - The inspection team recommended that the centre review the NICE guidance on DI which promotes IUI over ICI as it is shown to have more favourable outcome for patients (see paragraphs 43 & 44).

    - The waiting time for commencement of treatment after the initial consultation for self-funding patients is around 10 months and for NHS patients 18 months. The centre is actively seeking ways of reducing the waiting times (see paragraphs 17 & 18).

    - Historical divisions of work within the nursing department remain despite efforts to combine the management of the department. We recommended that the centre consider ways of developing a team ethos that would assist the nursing team in moving forward as one cohesive group (see paragraphs 48 & 49).

    - The centre is working towards ISO accreditation.

    - The centre would like to have ICSI with donor sperm added to the licence.

7. The inspection team supports the renewal of the centre's licence.

Background to inspection

8. This was a renewal inspection and covers the period December 2004 to November 2005.

9. Patient questionnaires were distributed during the above period.

10. One site visit took place on 4 November 2005 and lasted 7 hours.

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

The centre's context

12. The centre has been at its current site since 2002. The centre sees patients from the Lothian, Borders and Forth Valley regions.

13. Patients are referred to the centre by their GP or by a consultant.

14. The centre sees both NHS and self-funding patients; approximately 40% are NHS patients.

15. The centre has increased its level of treatment cycles by around 27% in the last twelve months. The number of staff has increased in proportion to the number of treatment cycles and the premises and facilities are adequate for the increasing numbers of cycles.

16. The waiting time for commencement of treatment after the initial consultation for self-funding patients is around 10 months and for NHS patients 18 months.

17. The centre is actively seeking ways of reducing the waiting times. A clinical consultant has been appointed to work at the centre part time for five sessions a week – he has been in post since the end of October. The centre anticipates that his appointment will in due course start to have a positive impact on the waiting lists.

18. The nominal licensee is currently working on a business plan to acquire funding so that resources can be channelled into developing systems that will improve the waiting times.

19. The centre is open Monday to Friday from 8am to 5pm. The centre carries out some procedures at the weekend such as embryo transfers, egg collections, freezing and fertility checks.

20. In 2004 the nominal licensee on behalf of the Trust commissioned a report from an external consultancy company to examine the functioning of the centre: various aspects of the report are included throughout this report.

Type of work carried out

Licensed treatment

21. The centre carries out the following licensed treatments

- Donor Insemination (DI)
- In Vitro Fertilisation (IVF)
- IVF with donor eggs
- IVF with donor sperm
- Intra Cytoplasmic Sperm Injection (ICSI)
- Storage of sperm (patient & donor)
- Storage of embryos
- Storage of sperm within testicular tissue

Treatments that do not need a licence

22. Intrauterine insemination, ovulation induction and tubal surgery.

Satellite/transport arrangements

23. The centre does not have any satellite or transport arrangements.

Staff

24. We found the centre to be adequately staffed for the increasing levels of activity. In the last year a part-time consultant and staff grade have joined the clinical team. The centre has also recruited an additional E grade nurse, and a MLSO. The centre is in the process of recruiting a consultant embryologist.

Staffing profile

Person responsible	Joo Thong
Nominal licensee	Sandra Mair
Accredited consultant	Joo Thong
Other medical staff	1 part-time consultant, 1 Staff grade & 2 research fellows
Embryologists	5 (2 senior, 3 qualified, 1 trainee)
ICSI practitioner	4 (grades)
Andrologists	4 (1 senior biochemist, 1senior MLSO & 2 MLSO1)
Nursing staff	13 (2 G , 3 F & 8 E grades & 3 auxiliaries)
Independent counsellor	1 (with additional back up available)
Complaints manager	Dorothy Hanley

Professional registration and continuing professional development (CPD)

25. Staff registrations have been checked and relevant staff are registered with the appropriate statutory bodies.

26. Continuing professional development (CPD) is funded centrally by the Trust, with additional funds being provided by various endowments.

27. CPD for nurses was found to be well-structured and resourced. Nurses attend conferences such as BFS, ESHRE and HFEA as well as attending in-house study days and seminars. The embryologists, andrologists and MLSO's all undertake CPD, however there was some feedback from this staff group that CPD opportunities had been curtailed due the increasing workload. This situation should be eased with the appointment of a consultant embryologist and the additional MLSO who is already in place. The clinicians all follow appropriate CPD pathways.

28. The centre carries out regular audits of outcomes and practices including monthly audits of embryo transfers, practitioner outcomes, and fertilisation rates: laboratory staff participate in external quality control by NEQAS.

29. The centre holds regular multi-disciplinary team meetings. The meetings occur weekly except in the summer when staff holidays arrangements make weekly meetings less practical. The meetings are used to discuss patients' treatments, difficult cases and any other issues that are current e.g. the shortage of donor sperm. All staff are expected to attend and the meetings are minuted.

30. Individual disciplines hold regular staff meetings.

The premises, equipment and other facilities

Premises

31. The centre is situated within the main hospital. The premises are modern, designed for purpose, well equipped and can comfortably accommodate the increasing workload. The centre comprises a large waiting area, an overflow waiting area and a sub-waiting area for known donors. There are two sperm production rooms, four consulting rooms (two extra if needed), three scanning rooms, two cryostores, two theatres adjoined by the laboratory, semen analysis and preparation rooms, a six bedded recovery area and a research room for scientific staff.

Equipment

32. Since the last inspection the centre has purchased a new centrifuge, a second ICSI rig, two Toshiba scanners, a microscope, an additional incubator and one new dewar.

Security

33. Access to the centre is restricted with the use of swipe cards.

Confidentiality

34. Patient records are kept in a dedicated storage room with a keypad entry system. The centre has started to archive off some of the older records at an off-site location.

Arrangements for collecting sperm samples

35. The centre has two sperm production rooms that are adequate for purpose.

Cryostore facilities, oxygen and dewar alarms

36. Gametes and embryos are stored in a designated security area with controlled access.

37. The cryostore facilities are adequate for the type and volume of activities carried out.

38. There are appropriate emergency procedures to respond to damage to storage vessels and failures in storage systems.

39. The dewars are alarmed and linked to an auto-dialler.

Emergency facilities

40. The centre is situated within the main hospital and has access to all the hospital’s emergency facilities.

Clinical, nursing and laboratory procedures

41. The centre's documents are version controlled and dated.

Clinical

42. The centre's clinical pregnancy rate for DI for the period April 2004 to March 2005 was 2% for all treatment cycles initiated. This was discussed with the centre. The centre informed us that they have been performing unstimulated ICI/D.

43. The inspection team recommended that the centre review the NICE guidance on DI which promotes IUI over ICI as it is shown to have a more favourable outcome for patients.

44. Since the inspection the centre has reviewed the NICE guidance on IUI and has stated that the centre is unlikely to receive NHS funding for IUI for patients undergoing DI.

45. The protocols for ovarian hyperstimulation syndrome (OHSS) were considered to be appropriate.

46. The centre has recruited a part-time consultant (five sessions a week). This satisfies one of the recommendations of the external review.

Nursing

47. Historically the nursing department was separated into two distinct groups. One team of nurses, led by a G grade nurse looked after the ACU and a second team also led by a G grade supported the ovulation induction (OI), donor insemination and research projects. An internal management review led to a decision to appoint one of the G grades as overall manager of the nursing department, with the other G grade responsible for staff training needs and dealing with HFEA matters. The intention underpinning the restructuring was to create a single cohesive nursing team.

48. The external review found the nursing staff had reverted or continued to work within the historic divisions. On the day of the inspection interviews with nursing staff revealed that the situation remains the same and that there is some dissatisfaction with the present situation. The evidence gathered on the day indicates that the continued divisive management of the nurses results in poor communication and management.

49. We recommended that the centre consider ways of developing a team ethos that would assist the nursing team in moving forward as one cohesive group.

50. It is clear that to date the divisions within the nursing teams have not affected the high quality nursing care that patients receive at this centre.

However, the inspection team considered that if the situation was not resolved patient care could be adversely affected in the future.

51. The external review proposed that nurses should be given the opportunity to develop their skills in areas such as ultrasound, OI and embryo transfers.

52. Currently, some of the nurses are being trained to scan and it is intended to train up some nurses so that they can prescribe.

53. The nurses we interviewed said that they would welcome the opportunity to develop further skills such as carrying out embryo transfers.

Laboratory

54. The inspection team was satisfied with the laboratory protocols.

55. There are written standard operating procedures for: cleaning vessels; filling vessels; securing vessels; freezing and thawing procedures; location and duration of storage; handling of contaminated samples.

56. The witnessing arrangements were inspected and found to be compliant with regulatory requirements.

57. Future development plans may include developing a PGD service.

58. The external review proposed that consideration should be given to aligning the management of the andrology and embryology laboratories under the remit of one senior clinical embryologist. The centre will consider this proposal further once the appointment of a senior clinical embryologist has been made.

59. The andrology laboratory is CPA accredited.

60. The embryology laboratory has the air quality assessed on a regular basis. Recent testing demonstrated that the air quality was grade A in the flow hoods with grade C in the background. The embryology laboratory has a HEPA filter positive pressure air flow.

Procedures for assessing clients and for assessing and screening donors

Welfare of the child

61. The centre's process for conducting a welfare of the child assessment takes into account the following.
    a. the commitment to raise children
    b. ability to provide a stable and supportive environment for a child/children
    c. immediate and family histories
    d. age, health and ability to provide for the needs of a child/children
    e. 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

62. The centre takes reasonable steps to determine who will have parental responsibility for the child or children which may be born as a result of treatment.

63. Evidence was seen in the patient records that the centre follows its welfare of the child protocols.

64. The centre in assessing the welfare of the child, contacts the patients' GPs and also asks patients to fill out a self-assessment form.

65. The recent Chairs letter CH (05) 04 issuing guidance on welfare of the child assessments was discussed with the centre. The guidance is perceived by the centre as being proportionate and simple to implement.

Ethics committee

66. The centre does have access to an ethics committee but has not had cause to refer any issues to it during the last year.

67. If difficult issues do arise the centre discusses them at team meetings so that all the staff can be involved in the decision-making process.

Assessing and screening donors

68. The centre buys in supplies from a sperm bank but is finding it increasingly difficult to find sufficient suitable samples.

69. The centre runs an egg donation scheme that is co-ordinated by a senior fertility nurse.

70. All egg donors are screened according to regulatory and professional guidelines.

71. Potential egg donors are expected to see the counsellor on at least one occasion but may see the counsellor as many times as they wish.

Counselling process and facilities

Counselling protocols

72. We were not provided with any counselling protocols.

73. We recommended that the counsellor develop counselling protocols so that counselling procedures and issues to be covered are clearly identified.

74. Since the inspection the PR has informed us that the counselling protocols were inadvertently omitted from the inspection papers and a set of protocols will be submitted in due course.

Counselling referral arrangements

75. The counsellor works at the centre for approximately ten hours per week.

76. Patients are referred to the counsellor by a nurse or consultant or by self-referral.

77. Counselling is free and patients may see the counsellor as many times as they wish.

78. The waiting time to see the counsellor is around two weeks but the counsellor will ensure that patients requiring a more immediate appointment are seen sooner.

79. The centre is considering the recruitment of a back-up counsellor.

80. Patients who require the services of a genetic counsellor are referred to a specialist counsellor.

Supervision and professional registration

81. The counsellor meets with her supervisor once a month and can consult by phone in between visits.

82. The counsellor is a member of the British Infertility Counselling Association (BICA) and the Confederation of Scottish Counselling Agencies.

83. The counsellor attends relevant study days and conferences.

Counselling audit

84. We were provided with an audit of counselling for the period January 2005 to July 2005.

85. The audit shows that during the above period 89 patients were referred to the centre and 165 sessions were attended.

86. The audit shows that the majority of patients received implications counselling, only slightly fewer patients received support counselling and a minority of patients required therapeutic counselling.

Location of counselling facilities

87. The centre provides a private and comfortable room for counselling which ensures confidentiality.

Patient experience

Patient feedback

88. The centre does not at present have a patient feedback mechanism.

89. One hundred patient questionnaires were distributed and we received 30 responses. The majority of the feedback was very favourable with many patients commenting on the high level of service and support provided by the nurses at the centre.

90. We interviewed two patients on the day of the visit. Both patients reported that they felt positive about the treatment that they were receiving. The patients were informed about the counselling service and who to contact in case of emergencies. The patients stated that the staff were friendly and had time to answer their queries.

Patient information

91. Patients are provided with an initial patient information pack and then receive more specific information at different stages of their treatment. Before treatment begins patients spend two hours with a nurse who explains the different treatments, drugs and consent forms.

92. The patient information covers the following issues.

- Consent issues
- Patient information for specific treatments
- OHSS/other emergencies
- Donor issues
- Complaints process

93. We reviewed the patient literature and found it to be comprehensive, informative and up to date.

Record keeping procedures

94. An HFEA auditor reviewed 30 patient records. The records were found to be in good order and contained all the necessary paperwork.

Three embryo transfer arrangements

95. The centre does not carry out three embryo transfers.

Audit

Centre's own audit of stored material

96. An embryo and sperm audit has been carried out during the last twelve months. Both audits involved physically checking the location and quantity of embryos and sperm in storage the findings of which are then checked

against the database and the patients' records. The audits revealed minor discrepancies in consents that did not affect the validity of the storage: the relevant patients were contacted to revise their consents. There were no discrepancies of gametes/embryos in storage.

Spot check of tracking process for stored material

97. We tracked one embryo from tank to records and another from records to tank. One chemotherapy sperm sample was tracked from records to two separate tanks and one sperm sample was tracked from a tank to the records. There were no irregularities.

HFEA register

98. Registry have reported that there are no current registry issues.

Clinical governance

99. The PR attends Clinical Improvement Programme meetings with the Trust every two to three months. The Nominal Licensee is also the hospital's Director of Performance manager and thereby provides a direct link to the hospitals governance structure.

Risk management

100. The hospital's risk assessment officer inspects the centre on a regular basis.

101. The centre circulates HFEA Alerts to all staff and revises protocols as and when necessary in light of an Alert.

102. We reviewed the centre's incident policy and found it to be comprehensive and appropriate. All the staff we interviewed were aware of what constituted an incident and the mechanism for reporting one.

103. The centre reported a couple of incidents involving the loss of embryos during difficult transfers. The centre has changed certain protocols as a result including the practice of carrying out a dummy transfer where difficulties are anticipated.

Complaints

104. The centre has a clear complaints procedure and the complaints process is displayed on view in the patient reception area.

105. The centre received four complaints between December 2004 and August 2005. All complaints have been resolved.

Breaches of the Code of Practice or Act

106. We did not find any breaches of the Code of Practice or the HF&E Act.

Compliance with previous conditions and recommendations

107. The centre does not have any conditions or recommendations on its licence.

Key points for the Licence Committee

108. The inspection team supports the continuation of the centre's licence for treatments set out in paragraph 23 above.

Issues

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

- The inspection team recommended that the centre review the NICE guidance on DI which promotes IUI over ICI as it is shown to have more favourable outcome for patients (see paragraphs 43 & 44).

- The waiting time for commencement of treatment after the initial consultation for self-funding patients is around 10 months and for NHS patients 18 months. The centre is actively seeking ways of reducing the waiting times (see paragraphs 17 & 18).

- Historical divisions of work within the nursing department remain despite efforts to combine the management of the department. We recommended that the centre consider ways of developing a team ethos that would assist the nursing team in moving forward as one cohesive group (see paragraphs 48 & 49).

- The centre is working towards ISO accreditation.

- The centre would like to have ICSI with donor sperm added to the licence.

Appendix A The inspection team and staff interviewed

The inspection team

Peter Brinsden	External Advisor
Geraldine Hartshorne	External Advisor
Linda Koncewicz	External Advisor
Vicky Lamb	Observer, HFEA Inspector
Imogen Swann	Chair, Inspector, HFEA

Centre staff interviewed

We interviewed twelve members of staff including the Person Responsible and the Nominal Licensee.

Conflicts of interest

None declared.

Human Fertilisation and Embryology Authority

Centre Name : Edinburgh Assisted Conception Unit

Document Type: Licence Committee Minutes

Date : January 2006

Licence Committee Meeting

19 January 2006
21 Bloomsbury Street London WC1B 3HF

MINUTES item 4

Centre: Edinburgh Assisted Conception Unit (0201)
Licence Renewal

Members:
Clare Brown, Lay Member – Chair
Suzi Leather, Lay Member
Ivor Brecker, Lay Member
Chris Barratt, Scientific Director, Birmingham Women's Health Care Assisted Conception Unit
David Barlow, Executive Dean of Medicine, University of Glasgow

In attendance:
Trish Davies, Director of Regulation and Deputy Chief Executive
Frances Clift, Legal Adviser
Marion Witton, Head of Inspections
Claudia Lally, Secretary to the Committee

Conflicts of Interest: members of the Committee declared no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- papers for Licence Committee (45 pages)
- no papers were tabled.

1. The papers for this item were presented by Imogen Swann, HFEA Inspector. Ms Swann informed the Committee that the centre was of a medium size, offering a full range of treatments to patients. One of the inspection team's chief concerns had been the waiting times experienced by patients. However, the centre has secured additional funding to address the problems which are creating long waiting times and have been able to recruit a part time Clinical Consultant and a Senior Embryologist which should help with this problem. A recently commissioned external review has lead the centre to rearrange the way in which their nursing department is managed. In particular the centre is moving to one management structure for all nursing staff. Ms Swann added that the centre is working towards ISO accreditation. The Centre has now submitted the counselling protocols which had not been submitted prior to the inspection. The centre has applied to carry out Intra Cytoplasmic Sperm Injection (ICSI), and all the associated protocols and patient information have been received and reviewed by the Executive who found them to be satisfactory.

2. The Committee noted that the inspection team had recommended that the centre reviews the NICE guidance on DI which promotes IUI over ICI as it is shown to have more favourable outcome for patients. Ms Swann informed the Committee that the centre was not currently offering donor insemination to patients because of a shortage of donor sperm. The Committee noted the data sheet at page 43 of the Committee papers and in particular noticed that the centre achieved a 2% clinical pregnancy rate for cycles with donor gametes. The Committee endorsed the view that the centre should take the NICE guidelines into consideration. However, the Committee also agreed that a 2% clinical pregnancy rate is still considerably lower that would be expected, even for ICI. The Committee therefore decided to add a condition to the centre's licence in order to require the centre to obtain advice about what they could do to address their low success rates. The Committee also agreed that a clinical inspector should be involved in the next inspection to the centre.

3. The Committee decided to add ICSI to the centre's licence. However, members of the Committee agreed that it was important that couples are not advised to have IVF with ICSI just because success rates with ICI are low.

4. The Committee agreed to renew the centre's licence for a period of three years with the following additional condition:

- The Person Responsible must invite an appropriately qualified person to carry out a review of the centre's donor insemination practices. A report of the external review must be submitted to the HFEA by the end of May 2006.

Signed…… … Date……..
Clare Brown (Chair)