Human Fertilisation and Embryology Authority

| | |
|---|---|
| Centre Name: | University of Aberdeen |
| Document Type: | Report of a Renewal Inspection |
| Date: | January 2005 |

Human Fertilisation and Embryology Authority

Report of a renewal inspection at

# Aberdeen Fertility Centre, Assisted Reproduction Unit, University of Aberdeen (0019)

January 2005

# Contents

## Key facts about the centre

**Centre name**
University of Aberdeen
Assisted Reproduction Unit

**Centre address**
Department of Obstetrics & Gynaecology
Aberdeen Maternity Hospital
Foresterhill
Aberdeen
AB25 2ZD

**Centre number**
0019

**Person responsible**
Mark Hamilton

**Nominal licensee**
Alison McTavish

**Activities of centre**

| | | 2002/03 |
|---|---|---|
| Licensed Treatment Cycles | IVF<br>ICSI<br>FET<br>Egg Donation<br>Egg recipient<br>Donor Insemination<br>Other | 242<br>128<br>200<br>21<br><br>34<br><br>177<br><br>0 |
| Unlicensed Treatments | GIFT<br>IUI | |
| Research | Yes | |
| Storage | Yes | |

**Focus of inspection**
Full renewal inspection

**Additional licence conditions**
One

**Licence expires**
31 January 2005

## Summary

1. This centre has requested that their HFEA registered name be amended to Aberdeen Fertility Centre. The address remains as the Assisted Reproduction Unit, University of Aberdeen.

2. This centre has been licensed since 1992 and offers a comprehensive range of treatment and storage services. It is currently licensed to 31 January 2005 with one additional licence condition related to a clinical trial. They have complied with this condition.

3. The centre currently treats around 500 NHS patients (IVF/ICSI) per year including around 50 who participate in egg donor/recipient arrangements. They centre serves a large catchment area covering the Highlands and Islands of Scotland so many patients have to travel a considerable distance for treatment.

4. This was a full renewal inspection however a clinical inspector had to cancel attendance and clinical aspects of the service have yet to be formally reviewed. Consideration was given to compliance with the changes introduced in the 6th Code of Practice and recent Directions. Several members of staff were interviewed as well as three individual patients and two couples. A tour of the facilities took place and the inspectors reviewed a sample of 19 patient records and conducted a spot check of stored material.

5. The centre has applied to add storage of eggs to their licence and the appropriate protocol and patient information and consent were reviewed with modifications agreed. Revised versions are to be submitted.

6. A new person responsible was appointed in July 2004 however as he has been in a clinical post for several years there has been a smooth transition. Staff were found to be well informed and appropriately qualified and registered with professional bodies.

7. Premises, equipment and facilities were reviewed and found to be satisfactory. It was noted however that the low level nitrogen alarms are not yet on an autodial out 24 hour alert system. This is being considered by the centre and they are to prepare a protocol for dealing with being called out of hours in emergencies.

8. The inspection found that provision for witnessing at weekends needs to be reviewed; that the welfare of the child assessment should be more formally documented and that the centre should recording the attendance of the partner when appropriate. A few instances of incorrect or inconsistent completion of consent forms were identified.

9. The centre was not aware that they should be conducting welfare of the child assessments for IUI patients as required to be in compliance with the HF& E Act.

10. During the spot check of stored material it was noted that copies of consent forms are not referred to at time of audit and this was not considered good practice.

11. Overall, the inspection team supports the continuation of the centre's licence.

# Background to inspection

12. This report covers the period from the previous inspection to date, i.e. June 2003 to November 2004. It includes an analysis of treatment data from April 2002 to March 2003.

13. One site visit took place on 8 September 2004 and lasted 9 hours. The HFEA auditors have not visited the centre since the previous inspection.

14. The centre has recently had an International Organisation for Standardization (ISO) inspection. No formal report is issued for this.

15. The report was reviewed by the centre in October 2004.

# The centre's context

16. This is the only licensed fertility centre in the region, so patients may have to travel long distances to receive treatment here. The centre receives referrals from the Grampian, Highland, Orkney and Shetland Health Boards. The centre also treats privately funded patients. The centre will treat single-sex couples if they are referred.

17. The centre plans egg collections so that procedures take place during the week, but some weekend work is required. This can cause problems for witnessing as fewer members of staff are available.

## Type of work carried out

### *Licensed treatment*

18. 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
- Storage of embryos
- Assisted hatching (chemical and mechanical)

19. The centre has kept assisted hatching on its licence to keep this option available if it is required. The staff team will meet to discuss if they wish this to be included on the new licence (within a week of the inspection).

### *Licensed treatments that are not currently provided*

20. The centre has applied to have storage of patient and donor eggs added to its licence. The HFEA Executive has reviewed the application and issued the centre with a number of amendments for the documentation. The centre has agreed to amend the documentation and has requested that the application is considered with the licence renewal.

21. The centre has previously applied for egg sharing, but is not currently seeking approval.

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

22. The centre carries out the following non-licensable treatments:

- Superovulation and Intrauterine Insemination (IUI)
- Ovulation induction
- Surrogacy

### *Satellite/transport arrangements*

23. The centre is not providing transport or satellite IVF services for other assisted conception units.

## Staff

### *Staffing profile*

| | |
|---|---|
| Person Responsible | Mark Hamilton |
| Nominal Licensee | Alison McTavish |
| Accredited Consultant | Mark Hamilton |
| Other medical staff | 5 |
| Embryologists | 6 |
| ICSI practitioner | 3 |
| Andrologist | 3 |
| Nursing staff | 15 |
| Independent Counsellor | 1 |
| Complaints Managers | Mrs May Vobes,<br>Directorate of Obstetrics & Gynaecology<br><br>Mr Alec Cumming,<br>Chairman of Grampian Health Board |

24. The person responsible was appointed to the role in July 2004. He was already playing a large part in the running of the centre and so there has been a smooth transition into his new role. The previous person responsible continues to run clinics at the centre and may be contacted for advice.

25. The nominal licensee also takes a major part in the running of the centre as nurse manager. Her role is mainly in management.

26. The counsellor attends staff meetings when she can, but these can clash with patient's appointments. The counsellor shares an office with the nurses which assists communication with the staff.

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

27. Five of the six embryologists are registered with both the Association of Clinical Embryologists (ACE) and the Health Professions Council. The sixth embryologist is studying for the ACE diploma.

28. The nurse manager keeps files for all nurses in locked cabinets in her office. The files contain records of the nurses' registration numbers and training.

## The premises, equipment and other facilities

### *Premises*

29. The centre is located on the first and second floors of the Aberdeen Maternity Hospital.

30. The entrance to the unit is on the first floor, which has a reception desk. The first floor premises comprise two waiting areas (one general, one for IVF patients), eight offices, two scan rooms, a counselling room, a staff cloakroom, a kitchen and a laboratory (used for thawing donor sperm samples).

31. The second floor premises comprise two offices, a consulting room (which can be used for patient recovery), a sperm sample production room with shower room next door, a patient recovery room, a procedures room, an andrology laboratory (which now has a viewing window), an embryology laboratory and an ICSI laboratory (now with a solid floor). There is no dedicated research laboratory.

### *Equipment*

32. Both scan rooms have a couch with stirrups, a scan machine and a sink.

33. The counselling room has four chairs and a telephone (for counselling patients living a long distance from the centre).

34. The ICSI apparatus is on an anti-vibration table.

35. The procedures room has a treatment couch, a television (linked to a camera in the laboratory), heated stages, a sink, a telephone with a list of contact numbers and a cupboard containing the preliminary drugs needed for resuscitation. The crash recovery equipment is kept on the first floor.

36. The recovery room has four beds and a buzzer to call staff.

### *Security*

37. There is a reception desk at the main entrance to the centre. Access by all other entrances is restricted by doors with keypad locks.

### *Confidentiality*

38. The patient notes for DI are kept in locked cabinets in a room with a lockable door on the first floor. The patient notes for IVF are kept in locked cabinets in the nurses' office.

39. The nurse manager has keys for the cabinet in which the counselling records are kept but a coding system is used for identifying the patients.

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

40. The dewars have low level liquid nitrogen alarms but are not linked to a telephone system. However the centre is considering connecting the alarms to a telephone system and is looking at the options for this.

41. The laboratory where the dewars are stored is fitted with an oxygen depletion alarm which sounds in the corridor outside.

## Clinical, nursing and laboratory procedures

### *Clinical*

42. The centre plans egg collections to take place on Mondays, Tuesdays and Wednesdays so that embryos transfers can take place two days later on Wednesdays, Thursdays and Fridays. This is to reduce the need for staff to work at weekends, although egg collections may need to take place at weekends on occasion.

43. Patients are given a mobile telephone number to contact one of the clinicians if they show symptoms of Ovarian Hyperstimulation Syndrome (OHSS).

### *Nursing*

44. Nurses carry out the scanning.

45. A nurse is always allocated to monitor the recovery room. Patients are usually awake and ready to leave the centre within an hour of their treatment.

### *Laboratory*

46. The centre does not carry out assisted hatching. It has previously requested for this to appear on its licence in case a patient asks for this procedure.

47. When sperm samples for oncology patients are placed in storage they are split between dewars to reduce the risk of losing all of the samples. This is a new policy and the centre is in the process of rearranging samples currently in storage, which is a large task.

48. Screened and unscreened samples are stored in separate dewars.

49. Patients meet the embryologists approximately one week before their egg collection to discuss embryo storage. This meeting last between 30 and 45 minutes. The patient is given an information pack and an embryologist goes through the consent forms with the patient. The patient is then left for 15 minutes to complete the consent forms. If the patient is consenting to allow their embryos to be used for research, they are given a copy of the consent form for the clinical trial which involves varying the concentration of sucrose in the centre's freezing medium. When the embryologists returns, if the patient has any queries the embryologist discusses these with the patient. If not, the embryologist checks the consent forms are correct and witnesses the patient signing them.

50. To make the (00)6 form easier for the patient to complete, the embryologists cross out the section for storing sperm, as the embryologists do not carry this out. If sperm is to be frozen, a second (00)6 form is kept by the andrologists.

51. The centre should not use two (00)6 forms on which the patient has expressed different wishes, as this could cause ambiguity and the more recent of the two forms may supersede the other. The inspection team suggested that the staff photocopy the consent form if it is to be kept in two separate files, and that all crossings out should be initialled and dated by the person who has done this.

52. Although egg collections are planned to take place at the start of the week, they may on occasion take place at weekends. There is not always a member of staff available for witnessing laboratory procedures at weekends. If there is no witness available, the embryologist will record the reason why and will record when only one patient's material has been processed.

53. The inspection team informed the centre that witnessing should be routinely done at weekends and that there should be no exceptional circumstances. However the witness does not need to be a trained embryologist.

54. The centre would benefit from the use of a signature log, in case the identity of a witness needs to be verified at a later date.

55. The centre should consider preparing a protocol for 24 hour call-out in the event of a low level nitrogen alarm.

## *Three embryo transfer arrangements*

56. Since the regulations changed with the sixth code of practice, the centre has not carried out any three embryo transfers. The information for how many embryos have been transferred in a treatment cycle is recorded on laboratory record sheets. There is no master book containing information on how many embryos have been transferred in each treatment cycle.

57. The centre is due to take part in a trial on single embryo transfers, starting in January 2005 and scheduled to last for three years. This will involve several other centres in the UK, with this centre acting as the co-ordinating centre.

58. This centre has carried out a feasibility study to find out if patients would accept single embryo transfers. Patients are made aware of the risks of multiple births and are given literature about the associated hazards.

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

### *Welfare of the child*

59. The centre does not assess the welfare of the child for unlicensed IUI. The inspection team informed the centre that the welfare for the child should be considered for all patients receiving treatment at a licensed centre.

60. Patients undergoing licensed treatments are given an information leaflet on the welfare of the child. A similar leaflet is given to the patient's GP, with a form for the GP to complete and return. Patients may not receive treatment until a completed form has been received from the GP.

61. If the patient does not know the GP or does not want their GP to be contacted, this is discussed with the patient and with the staff team and documented in the patient notes.

62. If the centre does not receive a response from the patient's GP or the GP raises issues about the patient's treatment, a nurse telephones the GP to discuss this. The case will then be taken to the staff team meeting to decide if treatment should go ahead.

63. The centre does not have an internal questionnaire to document assessment of the welfare of the child (staff do have copies of questionnaires used by other centres). The clinician who sees the patients for their consultation will discuss the welfare of the child with the patient and place a tick in the clinical notes to indicate that this has been discussed. The centre was informed to review this procedure as the inspection team deemed it inadequate.

64. The welfare of the child assessment is repeated if it is more than two years since the patient last received treatment, if the patient has had a child or if there has been a change the patient's circumstances.

65. A patient must be re-referred to return to the centre. However the centre does not document when the male partner has attended with the female patient, so the centre would not know if the female patient is with the same partner.

66. The person responsible stated that patients have had a lot of interaction with various health professionals by the time the welfare of the child is being

assessed and that this builds up the centre's knowledge of the patient. He considers that the welfare of the child is being fully assessed but it is just not being documented, and that how it should be documented is down to an interpretation of the code of practice.

### *Ethics committee*

67. The centre has an ethics committee with a membership of 17. The committee is available to give advice and guidance to the staff team when there is uncertainty regarding specific treatments or clinical protocol design.

## Counselling process and facilities

### *Counselling protocols*

68. The nurses provide the implications counselling for DI patients. A significant proportion of counselling is by telephone as patients may live a long way from the centre.

### *Counselling referral arrangements*

69. Counselling is offered for DI patients but is not compulsory. Counselling is compulsory for surrogacy cases.

### *Supervision and professional registration*

70. The counsellor receives one hour of supervision once a fortnight. She also provides supervision for another counsellor.

71. The counsellor established the Scottish Infertility Counselling Group and is its current chair.

### *Counselling audit*

72. The counselling audit data does not differentiate between treatment types. Donors and surrogates are listed separately as different issues are raised.

### *Location of counselling facilities*

73. There is a dedicated room for counselling on the first floor of the centre. For patients who live a long way from the centre, counselling may take place over the telephone.

## Patient experience

### *Patient feedback*

74. The inspection team interviewed three individual patients and two couples during the visit.

75. The main issues raised by patients were a lack of continuity in the clinicians and nurses who they see and the distance some of them have to travel. Patients generally consider the centre to have a good staff team and like the telephone counselling service.

### *Patient information*

76. The information for egg sharer recipients states that the donor may withdraw their consent. The information for egg sharer donors does not mention that they may withdraw their consent to donate.

77. The HFEA address and telephone number need to be updated in the patient information leaflet on the welfare of the child. The centre began adding labels to these leaflets with the new contact details during the inspection.

78. The general waiting area has a 'touch screen' information system, with a headset to listen to it. Both waiting areas have a range of information leaflets on fertility services and support groups.

## Record keeping procedures

79. The inspection team examined 19 patient records.

| Treatment type | Error | Breach of Code reference | Number of errors | Comments |
|---|---|---|---|---|
| IVF | On (00)7, ticked 'no' to treatment with partner, but named one | 6.18 | 1 | |
| IVF/ICSI | No/insufficient welfare of the child assessment | 3.1, 3.3, 3.12 | 7 | |
| ICSI | No consent to embryo replacement | 6.18, 8.19 | 1 | |
| IVF | Posthumous consent incomplete | 6.21 | 3 | Potential breach |

80. The majority of the (00)6 and (00)7 consent forms had sections crossed out instead of being annotated with "n/a" or having the boxes ticked to say "no". There were three of these forms where sections were incomplete. This was raised with the embryologists, who explain the forms to the patients (see 50 to 52).

81. In addition to the section of the consent to treatment form indicating how many embryos are to be transferred, patients also complete a separate embryo transfer form. This form was missing in one record. The person responsible explained that this form is completed on the day of embryo transfer and that all of this patient's embryos were frozen.

82. The patient records lacked documentation to show that a thorough welfare of the child assessment had been carried out (see 59 to 66).

83. The centre does not actively document when the male partner has attended the centre (as required by the 6th Code of practice). The only indication of his attendance is that the follow-up letters will say “she” or “the couple” when referring to their appointment.

# Audit

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

84. The centre reported its most recent audits in the application form. The most recent audit of the embryos currently in storage was carried out between January and April 2004. The most recent audit of sperm samples currently in storage was carried out between January and December 2003. For both audits, all straws were present and accounted for. The audit for sperm samples for 2004 began in January.

85. The centre’s database flags up samples which are approaching the end of the consented storage period. Patients consent for (up to) five years initially and can extend this to ten if required.

86. When embryos are to be frozen, the embryologist checks the (00)6 and (00)7 consent forms and signs a sheet to confirm that these have been completed correctly. Once this is done, the embryologists do not return to the patient records again unless something needs clarifying.

87. When the audit is carried out, the embryologist checks the consent check sheet and does not refer back to the patient records. The embryologists do not keep copies of the consent forms in the laboratory as this would cause an increase in paperwork and photocopying. The inspection team found a number of errors on the consent forms which were not picked up on the summary sheets, so this system may not be sufficient for storage review.

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

88. Two patients’ embryos and two patients’ sperm samples were traced from the patients’ files to the dewars. The samples were located satisfactorily, but one patient had incomplete consent forms.

89. Two patients’ embryos and two patients’ sperm samples were traced from the dewars to the patients’ files. The samples, paperwork and consents were satisfactory.

# HFEA register

90. There were no register or audit issues. The last HFEA audit took place between 27 and 29 November 2002. Patients must pay in advance of their treatment so the centre does not need to chase up fees.

# Clinical governance

91. The centre has unsuccessfully attempted to get trust personnel involved with patient complaints.

### *Risk management*

92. The centre has not reported any incidents. The centre's good practice guidelines say that incidents should be reported through the person responsible.

93. Internally, any member of staff may report an incident. A sheet giving the criteria for an incident is completed and handed to the nominal licensee, who takes it to a monthly meeting. A written report with all of the points discussed is held on computer and any member of staff may access these. Minutes of two of these meetings were reviewed by the HFEA's Head of Clinical Governance and Patient Safety and the centre has been advised that four of these cases should have been reported to the HFEA as incidents.

94. The person responsible receives Alerts by email. These are then distributed to staff by email and discussed amongst the relevant staff team. A response is prepared and taken to the team meetings on Fridays. This is kept on file and the discussions during the meeting are minuted.

95. The centre is in the process of arranging a "quality team". This will include a core management team from the centre staff and the centre plans to recruit a quality manager by the end of September. The centre will invite researchers into the team for specific issues. The team will meet monthly and review its work every six months. Staff teams will have the opportunity to give input for improvements.

## Breaches of the Code of Practice or Act

96. Laboratory procedures taking place without a witness – see paragraph 52. This is a breach of section 15 (general) of the Code of Practice and a breach of Directions 2004/4.

97. Insufficient assessment of the welfare of the child – see paragraphs 59 to 66. This is a breach of sections 3.1, 3.3 and 3.12 of the Code of Practice.

98. Incomplete or missing consent forms – see paragraphs 79 to 81. This is a breach of sections 6.18, 8.19 and (potentially) 6.21 of the Code of Practice.

## Compliance with previous conditions and recommendations

### *Conditions*

| ***Conditions*** | ***Adopted by centre (Y/N)*** | ***Comment*** |
|---|---|---|
| The centre must submit a progress review of the clinical trial being conducted which involves varying the concentration of sucrose in the centre's freezing medium. This report should be | Yes. | |

| | | |
|---|---|---|
| included in the papers submitted for the next annual inspection. | | |

### *Recommendations*

99. The licence committee made no previous recommendations.

## Key points for the Licence Committee

100. The inspection team supports the renewal of the centre's licence for treatments set out in paragraph 8 above for a period of three years. The team also support the addition of storage of eggs to the licence.

### *Issues*

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

- The patient records do not have sufficient documentation to show that the welfare of the child has been considered thoroughly. There is no internal assessment and they do not document when the male partner has attended.

- Laboratory procedures are taking place at weekends when there is no witness available.

- The embryologists use summary sheets to record patient consent which are used to audit stored material. The inspection team found a number of discrepancies between the consent forms in the patient records and the summary sheets used by the laboratory staff. A full annual audit of consents is required.

# Appendix A Staff interviewed

## *Centre staff attending meetings with the inspection team*

| | |
|---|---|
| Mark Hamilton | Person Responsible |
| Alison McTavish | Nominal Licensee |

2 further members of staff were interviewed by the inspection team.

## *Conflicts of interest*

None declared.