Human Fertilisation and Embryology Authority

Name of Centre:	Assisted Reproduction and Gynaecology Centre
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Report of an interim inspection at

Assisted Reproduction and Gynaecology Centre, London (0157)

Date of inspection: 8 February 2006
Date of Licence Committee: 24 May 2006

Contents

Key facts about the centre

Centre name	Assisted Reproduction and Gynaecology Centre
Centre address	13 Upper Wimpole Street London W1G 6LP
Centre number	0157
Person responsible	Mohamed Taranissi

Activities of centre

		January – December 2005
Licensed treatment cycles	IVF ICSI FET	124 445 55
Donor Insemination		
Unlicensed treatments	GIFT IUI Ovulation induction Surrogacy	
Research	None	
Storage	Yes	

Focus of inspection	General
Additional licence conditions	None
Licence expires	June 2007

Summary

1. The Assisted Reproduction and Gynaecology Centre is privately owned and has been licensed to provide fertility treatments since 1995. The PR reported that the centre provided 624 IVF and ICSI treatments to self funded patients from the UK and overseas in the time covered by this report.

2. An HFEA operational audit conducted in January 2006 concluded that the centre does not give sufficient importance to ensuring that treatments are reported within the requirements of Directions 1999/1. The audit team found that in a sample of treatments provided between September 2004 and August 2005 82% had not been reported to the HFEA within 15 weeks of treatment. Of these 18% were still outstanding at the audit date. The PR reports that the outstanding forms have been sent to the Authority. The Authority's Registry Department separately reports that they have not received the forms. The audit team found completed copies of all outstanding forms on file at the centre and a completed copy of the associated batch header.

3. Of the 1322 IVF treatments reported to the HFEA during the period 01/01/04 to 31/12/05, 70% were not reported to the HFEA within 15 weeks of treatment. The audit team did note that there is a high degree of accuracy in forms returned to the HFEA.

4. During the inspection a staff signature list and ICSI practitioner statistics were provided to the inspection team. These documents included the names of staff who do not appear on the HFEA centre's database. This suggests that there may have been staff changes at the centre of which the Authority has not been informed. This means that members of staff not included on the centre's licence have had access to confidential identifying information about patients. In the absence of a complete and up to date staff list it has not been possible to monitor professional registration of all laboratory or nursing staff.

5. A number of other regulatory issues were identified in the course of the inspection and these are summarised below:
   - Cryopreservation dewars are not fitted with low nitrogen level alarms or auto dial systems;
   - In two of three sets of patient records reviewed, witnessing sheets were absent or not complete;
   - Eight three embryo transfers were carried out in women less than 40 years old. Examination of patient records showed all of these patients to have had previous failed cycles and to be aged between 38 and 39 years old. The PR reported that he considered the transfer of three embryos clinically appropriate in these patients;
   - Information from the HFEA register suggests that three embryo transfers may have been carried out in three patients whose ages were 29 years, 30 years and 23 years. The records for these patients were requested but were not made available on the day of the inspection and it was not possible to confirm the information from the register;

- Errors in consent forms and welfare of the child assessments were observed in five of the nine sets of patient records reviewed;
- The 2005 interim inspection report recommended that the centre develop standard operating procedures for the assessment and screening of donors but no protocols have been submitted to the HFEA;
- No report of the findings of the annual audit of cryopreserved material was included at section 12 of the interim application;
- There are a number of omissions in patient information previously submitted to the HFEA.

6. The inspection team were able to gather evidence demonstrating the centres clear compliance with the requirements of the Act and COP for the provision of counselling services.

7. The HFEA received very positive feedback from six patients who received treatment at the centre in the time covered by this report.

8. The live birth rates per cycle of treatment started for IVF and ICSI treatments for 2005[1] that are achieved by the centre are significantly higher than the national average rates reported in the 2005/6 HFEA Guide to Infertility.[2]

9. The inspection team would recommend the continuation of the centre's licence but would ask the Licence Committee to consider what, if any, regulatory action should be taken to address the issues of concern highlighted in this report.

[1] Information extracted from the HFEA register has not been validated at the time of writing
[2] Information from the HFEA Guide to Infertility and Directory of Clinics refers to national average figures for all clinics for the period 01/04/02 – 21/03/03.

Focus of the inspection

10. Taking into account information from the previous report and from the audit and register departments of the HFEA, the inspection focused on the following aspects of the centre's practice:
    - Staff training, induction and continued professional development (CPD);
    - Patient information, particularly in relation to revisions introduced as a result of changes in donor anonymity;
    - Implementation of recommendations from the 2004 renewal report and 2005 interim report;
    - Provision of counselling services and review of counselling audit;
    - Implementation of clinical governance strategies;
    - Complaints management;
    - Pre implantation genetic screening (PGS).

11. A routine laboratory inspection was also carried out in the course of the inspection.

12. Aspects of the centre's procedures and practices which have not changed in the time covered by the report and were considered appropriate at the time of the previous renewal and interim inspections were not reviewed in the course of the inspection.

Background to inspection

13. This report covers the period from May 2005 to February 2006 and includes consideration of outcome data from January to December 2005.

14. A site visit took place on 8 February and lasted 7 hours. An operational audit was carried out between the 16th and 18th January 2006.

15. The report was sent to the PR for review on 5 April 2006 but no comments on the draft report had been received at the time of collating Licence Committee papers on 9 May 2006.

The centre's context

16. The centre offers self funded treatments to patients from the UK and overseas. Approximately 5%, of the patients treated are from overseas. Some patients are able to secure NHS funding for treatment on a case by case basis. The PR reported that a small number (estimated at three) of PGD cycles were provided in the time covered by this report. A report of annual embryo biopsy practice should be submitted for each of the centre's embryo biopsy practitioners and reports of the PGD treatments carried out should be submitted to the HFEA as required by Directions D 2004/6.[3]

17. The centre offers flexible opening hours.

[3] Directions on information to be recorded about pre implantation testing procedures

18. Staff employed at centre 0157 also work at centre 0206. The PR of centre 0157 is also the PR of centre 0206.

Type of work carried out

Licensed treatment

19. The centre carries out the following licensed treatments

- In vitro fertilisation (IVF)
- Intra cytoplasmic sperm injection (ICSI)
- Gamete intra fallopian transfer (GIFT) with donor gametes
- Treatment with donor gametes
- Assisted hatching (mechanical)
- Storage of sperm
- Storage of eggs
- Storage of embryos
- Pre implantation genetic screening (PGS)
- Pre implantation genetic diagnosis (PGD)

Treatments that do not need a licence

20. The centre also provides GIFT, intrauterine insemination (IUI), ovulation induction and surrogacy treatments.

Staff

21. The PR has reported that key staff have been in post for many years. Curriculum vitae (CVs) for key staff and sections 8.2 and 8.3 (which ask for information about staff members who have joined the centre or have resigned from the centre) were not submitted with the interim application.

22. The counsellor provided the inspection team with a copy of her CV in the course of the inspection. Copies of CVs for the PR, nurse co-ordinator and senior embryologist retrieved from the HFEA archive confirm that these individuals have appropriate training and experience.

Staffing profile

23.

Person responsible	Mohamed Taranissi
Accredited consultant	1
Other medical staff	1
Embryologists	9 (7 full time, 2 part time)
ICSI practitioner	6
Nursing staff	8
Independent counsellor	1
Complaints manager	Elly Fincham

24. A staff signature list and ICSI practitioner statistics were provided to the inspection team on the day of the inspection. Some of the staff listed in these documents do not appear on the HFEA centre's database suggesting that there may have been changes in staff which have not been reported to the HFEA. Failure to notify the Authority of individuals who may have access to confidential information is a breach of the guidelines outlined in Chair's letter CH(01)08.

25. The PR should provide the HFEA with a complete list of staff who work at the centre and who have access to confidential, identifying information about patients, donors and their treatment. This list should include members of the administration team and all clinicians who have been awarded practising privileges at the centre or who work on a long term temporary basis. The list should include relevant professional body personal identification numbers (PINs) for members of the clinical, nursing and embryology teams to allow registration to be confirmed and monitored by the HFEA.

Professional registration and continuing professional development (CPD)

26. Despite the absence of PINs it has been possible to confirm that six members of the embryology team are registered with the Health Professions Council. It has not been possible to confirm the registration status of three members of the embryology team. Section 1.10 of the Sixth Code of Practice states that all clinical scientists working in HFEA licensed centres are expected to be registered or show evidence of working towards registration with the Health Professions Council.

27. The PR and the clinician expected to join the team shortly are both registered with the General Medical Council.

28. It has not been possible to confirm the ongoing registration of members of the nursing team with the Nursing and Midwifery Council although inspection of a human resources file for a recently appointed member of staff showed evidence that registration of employees is confirmed and monitored by the nurse co-ordinator. Section 1.8 of the COP states that all nursing and midwifery staff are expected to be appropriately qualified and registered by the Nursing and Midwifery Council.

29. The centre should provide the HFEA with evidence that the requirements of sections 1.8 and 1.10 of the COP have been met and with evidence (in the form of PINs) of registration with relevant professional bodies.

30. The senior embryologist participates in the Association of Clinical Embryologists CPD scheme and demonstrated evidence of completion of a cycle of training in the course of inspection. The senior embryologist also provided a copy of a document that is used to monitor induction of new members of the embryology team.

31. The PR reported that he undertakes CPD in compliance with the requirements of the Royal College of Obstetrics and Gynaecology. No evidence of this was made available to the inspection team.

32. The nurse coordinator provided evidence of an in house training programme and confirmed that relevant staff receive annual life support training.

33. Staff should consider keeping a formal record of training and CPD, including mandatory health and safety training.

34. The PR reported that outcomes are audited annually. The PR also reported that he meets and talks to laboratory staff every day and that he monitors results and looks for variations daily. No evidence of the annual audit was provided to the inspection team.

The premises, equipment and other facilities

Premises and Equipment

35. Section 11 of the interim application, which asks for information on any changes that have been made to the premises or facilities, was not included with the form submitted to the HFEA. However, staff interviewed on the day of the inspection reported that there have been no changes to premises or equipment since the last inspection.

36. Evidence of annual maintenance of key pieces of laboratory equipment was seen in the course of the inspection. If a key piece of equipment failed, there is sufficient spare capacity to accommodate processing of samples using existing equipment.

Confidentiality

37. Patient records are kept securely.

Arrangements for collecting sperm samples

38. The clinic was busy on the day of the inspection and it was not possible to access the sperm production room.

39. The senior embryologist reported that most sperm production is on site but on the rare occasions that a sample is produced off site, the patient is asked to sign a form that confirms the provenance of the sample.

Cryostore facilities, oxygen and dewar alarms

40. Gametes and embryos are stored in the embryology laboratory which has controlled access.

41. Cryopreservation dewars are not fitted with low nitrogen level alarms or auto dial systems. The senior embryologist reported that the site has been surveyed and suitable equipment identified but at the time of the inspection, the purchase of the equipment had not been completed. This is a breach of Chair's Letter CH(04)03.

42. The centre should advise the HFEA of the anticipated timescale for compliance with the requirements of Chair's Letter CH(04)03. Following installation of alarms, the centre should also develop written protocols for responding to dewar alarms and these should be submitted to the HFEA.

43. The centre is still in the process of contacting patients with sperm in storage to advise then of changes in the law as a result of the Human Fertilisation and Embryology (Deceased Fathers) Act 2003. A copy of the letter template used to communicate with patients was provided in the course of the inspection. A member of the embryology team has been assigned the task of completing the process. The PR should advise the HFEA of the anticipated timescale for the completion of the process.

44. The PR reported that no samples are stored at centre 0157 for patients who have had treatment that may have impaired their fertility.

Clinical, nursing and laboratory procedures

45. No revised standard operating procedures or patient information documents were submitted with the interim application. Documents previously submitted to the HFEA were collated, paginated and bound and a copy of this documentation (termed "the bundle") was provided to the PR in September 2005. The PR was asked to clarify which of the documents in the bundle are currently in use at the centre. The PR reported that all of the documents are current.

46. Subsequent to the inspection, a review of the documentation in the bundle was carried out. The results of the review are referenced in the text of this report with relevant page numbers shown in parentheses.

Clinical

47. Clinical protocols in the bundle do not show evidence of revision or version control: documents should be revised to incorporate a suitable system of version control and to show evidence of the revision date.

48. The bundle contains clinical protocols for relevant aspects of the centre's clinical practice with the following exceptions:
    - There are no protocols for the treatment or assessment of patients undergoing embryo donation, pre implantation genetic screening (PGS), PGD or egg freezing;
    - Screening requirements for gamete donors are not referenced in egg donation protocols (page 10);
    - DI protocols (page 16) require revision to reflect the changes in donor anonymity introduced in April 2005;
    - Welfare of the child (WOC) assessment protocols should be reviewed following recent changes in HFEA guidelines.

    The requirement for omitted documentation should be reviewed and existing documentation should be revised as appropriate. Revised or newly developed documentation should be submitted to the HFEA.

49. The protocol for intrauterine insemination (IUI) states that patients with more than three failed cycles should be encouraged to have IVF treatment. The protocols also suggest that patients receive ovarian stimulation prior to IUI although the nature of the stimulation is not specified. Guidelines from the National Institute of Clinical Excellence[4] (NICE) make the following recommendations:
    - Couples with mild male factor fertility problems, unexplained fertility problems or minimal to mild endometriosis should be offered up to six cycles of IUI because this increases the chance of pregnancy;
    - Where IUI is used to manage male factor fertility problems, ovarian stimulation should not be offered because it is no more clinically effective than unstimulated intra-uterine insemination, it is less cost effective, and it carries a risk of multiple pregnancy;
    - Where IUI is used to manage unexplained fertility problems, both stimulated and unstimulated intra-uterine insemination are more effective than no treatment; however, ovarian stimulation should not be offered, even though it is associated with higher pregnancy rates than unstimulated intra-uterine insemination, because it is less cost-effective and it carries a risk of multiple pregnancy;
    - Where IUI is used to manage minimal or mild endometriosis, couples should be informed that ovarian stimulation increases pregnancy rates compared to no treatment, but that the effectiveness of unstimulated IUI is uncertain;
    - Women with unexplained fertility problems should be offered fallopian sperm perfusion because this is associated with higher pregnancy rates than IUI.

    The PR should review the procedures used for IUI in consideration of these guidelines.

50. The records of four patients who were provided with pre implantation genetic screening treatments in 2002 were reviewed in the course of the inspection. Treatments were observed to have been provided in accordance with the centre's licence.

Nursing

51. Nursing protocols were made available on the day of the inspection; the protocols showed evidence of revision and the nurse coordinator agreed to consider using a system of version control. The revised protocols have not been submitted to the HFEA.

52. The 2005 report of the interim inspection commented that a procedure for obtaining consent was omitted from the nursing protocols. A standard operating procedure for obtaining consent has been developed and was made available for review on the day of the inspection.

[4] Fertility: assessment and treatment for people with fertility problems, National Collaborating Centre for Women's and Children's Health**,** Commissioned by the National Institute for Clinical Excellence, February 2004

53. Members of the nursing team communicate adjustments to drug therapy to patients by telephone. In the course of the inspection an instance was noted where drug therapy information was not communicated according to protocol. The nurse coordinator was advised to carry out spot check monitoring to ensure that communications relating to drug therapy are carried out in accordance with the centre's own protocols.

Laboratory

54. Laboratory protocols previously submitted to the HFEA show evidence of revision and are version controlled. The protocols were reviewed at the time of the renewal inspection in 2004 when they were considered to be of a good standard.

55. There are written protocols for filling vessels, cleaning incubators and freezing and thawing procedures and location and duration of storage. The senior embryologist confirmed that the laboratory does not handle contaminated material. There is no standard operating procedure for securing vessels. A protocol for securing vessels should be developed to ensure compliance with section 2.16 of the 6th Code of Practice (COP).

56. Witnessing stages are referenced appropriately in laboratory protocols. Witnessing sheets were reviewed in three sets of patient records. In one set of records witnessing sheets were complete and compatible with treatment. One set of records contained no witnessing sheet and in another set of records witnessing sheets were not complete. The senior embryologist should review the documentation of witnessing procedures and carry out spot check monitoring to ensure that witnessing is carried out in accordance with the requirements of the directions on records of witnessing clinical and laboratory procedures Ref. D 2004/4.

57. Statistics for ICSI practitioners were provided at the time of the inspection and showed that all practitioners have a damage rate of less than 25%.

Procedures for assessing and screening donors

Assessing and screening donors

58. The centre does not recruit sperm donors but buys supplies from a sperm bank.

59. No outcome data for patients having treatment with donated gametes or embryos was submitted with the interim application but information from the operational audit suggested that a single cycle of treatment with donated embryos and six DI treatments were provided in the time covered by this report. The centre should submit outcome data for these cycles to the HFEA as a matter of urgency. The records of the patient's who donated the embryos were reviewed in the course of the inspection but these records contained no information about the screening tests that the donors had undergone. The PR and the nurse coordinator confirmed verbally that

donors are subject to appropriate screening and that records of screening are kept separately.

60. The 2005 interim inspection report recommended that the centre develop standard operating procedures (SOPs) for the assessment and screening of donors but no protocols have been submitted to the HFEA. Suitable SOPs should be developed and submitted to the HFEA.

61. The centre uses imported sperm and provides the HFEA with appropriate notification of compliance with special directions.

Counselling process and facilities

Counselling referral arrangements

62. Patients are provided with written information on how to contact the centre's counsellor. The information provides the name of the counsellor in compliance with section 7.5 of the COP. Copies of counselling leaflets were prominently displayed in the waiting room.

63. The HFEA received feedback from six people who received licensed treatment at the centre and all of the respondents commented that they had been made aware of the counselling service and that the service was accessible.

64. The counsellor confirmed that counselling is offered to all people seeking treatment with donated gametes or considering donation of gametes. She also reported that although counselling in these circumstances is not mandatory, it is very strongly encouraged by the PR.

65. An additional charge is made for counselling services.

Supervision and professional registration

66. The counsellor provided the inspection team with a copy of her CV which confirms that she has an M.A. in Psychotherapy and Counselling. She also supplied evidence of her registration with the UK Council for Psychotherapy, the British Infertility Counselling Association and the British Association for Counselling and Psychotherapy.

67. The counsellor confirmed that her practice is supervised.

Counselling audit

68. A counselling audit was provided on the day of the inspection. The counsellor saw 72 patients receiving treatment at centre 0157 in 2005 including 7 patients (1 individual and 6 couples) undergoing DI treatment, 9 patients undergoing treatment with donated eggs or donating eggs, 3 surrogates and 3 surrogacy commissioning couples.

69. Information from the operational audit and HFEA register suggests that six DI treatments were provided in 2005. The information from the counselling

audit suggests that all of these patients received counselling. IVF and ICSI outcome information submitted with the interim application states that 624 patients were provided with licensed treatment in 2005: 72 individuals were seen by the counsellor representing a general counselling uptake of approximately 12%.

Location of counselling facilities

70. The centre provides a private and comfortable room for counselling which ensures confidentiality. Patients can also receive counselling at the counsellor's home.

Patient experience

Patient feedback

71. The HFEA received feedback from six patients who received treatment at the centre in the time covered by this report. The responses were all positive with one exception: three respondents commented that consent forms were not fully explained. All six respondents had compliments about the care they had received and one respondent had complaints about the care they had received.

72. Written comments received by the HFEA from patients were generally very positive and praised the helpfulness and friendliness of staff and the individual attention provided. Single comments were made about a lack of privacy in the reception area, lack of space in the waiting room and lack of information on the predicted overall cost of treatments.

Patient information

73. No revised patient information was submitted with the interim application. Subsequent to the inspection, a review of previously submitted documentation was carried out (see paragraphs 45 and 46).

74. Patient information previously submitted to the HFEA does not fully comply with the requirements of the COP as follows:
    - Not all patient information references the availability of counselling although a separate counselling leaflet is provided (COP 5.4(i));
    - The possibility that patients may withdraw their consent to treatment or storage is not addressed consistently although this is referenced in information for egg donors and in an HFEA leaflet that is provided (COP 5.4 (ii));
    - Selection criteria and waiting times are not referenced in all relevant information (COP 5.5(i));
    - There is no reference to the possible disruption of personal and professional life (COP 5.5 (ii));
    - Not all of the risks of multiple pregnancy are referenced in the centres own information but these risks are addressed in an HFEA leaflet that is made available to patients (COP 5.5 (vi));

- The risks of OHSS are not referenced in information for patients undergoing GIFT or frozen embryo replacement and no patient information references the putative risks of cancer (Cop 5.5 (v));
- Variation in outcomes and limitations of treatment are not referenced (COP 5.5 (iv));
- Risks of cross contamination and dewar failure are not referenced in information for patients considering gamete or embryo freezing (COP 5.5 (ix)b).

There is evidence (in the form of a medical consultation check list) that some of the information omitted from written documents is provided to patients verbally. The PR should review patient information and any documentation revised as a result of the review should be submitted to the HFEA with any future application. The PR should ensure that written information is provided to patients in a combination that ensures that patients are provided with all of the information recommended in the COP and that a written record of all information provided to patients in maintained (as required by section 5.3 of the COP).

75. Information for donors or recipients of donor gametes has not been revised to reflect the changes in donor anonymity introduced in April 2005 and provides inaccurate information relating to donor anonymity. The PR reported that an HFEA leaflet is now made available to patients that provides information on the current law relating to donor anonymity and which references the circumstances under which the exchange of identifying and non identifying information can occur. Information for donors and recipients of donor gametes (at pages 38, 41) should be revised as a matter of urgency to remove inaccurate information. The use of the HFEA leaflet for egg donors (at page 76) should also cease as this leaflet was superseded following changes in the law.

76. Information for recipients of donor gametes (at pages 34 and 38 of the bundle) does not reflect the current legal position of unmarried fathers in relation to parental responsibility. This information should be revised as a matter of urgency to reflect changes introduced in the Adoption and Children Act 2002. Section 111, of the act states that an unmarried father shall acquire parental responsibility for the child if he becomes registered as the child's father.

77. Two sets of information for patients undergoing PGD and PGS treatments have previously been submitted to the HFEA (at pages 157 and 260 of the bundle). The PR should clarify which information is currently provided to patients. The information includes a comprehensive list of conditions for which treatment can be offered. The information should be revised to clarify that before PGD treatment could be offered for these conditions, the centre would need to apply to the HFEA for a licence to carry out the treatment.

78. The information for patients undergoing PGD and PGS treatments at page 260 does not reference the following (as required by parts 14.16 and 14.26 of the COP):
    - the risks involved in undertaking IVF and biopsy procedures;

- the procedure to be followed in the case of a diagnostic failure;
- that there is no guarantee against a miscarriage occurring despite preimplantation aneuploidy screening being performed;
- that patients are recommended to undergo prenatal screening.

This information may be provided verbally but no evidence of this was seen in the clinical protocols that were reviewed.

79. Neither sets of information for patients undergoing PGD and PGS treatments reference the following (as required by parts 14.26 and 14.27 of the COP):
    - that embryos that have been biopsied may not be suitable for cryopreservation and use in subsequent treatment cycles;
    - that the more tests that are used to examine the chromosomes, the greater the likelihood of finding chromosome abnormalities (whether they are biologically significant or not), and thus the lower the chance of finding suitable embryos for transfer;
    - of the financial costs of treatment;
    - of the possible emotional burden should a successful pregnancy not result following PGS for aneuploidy;
    - that genetic counselling is available.

    This information may be provided verbally but no evidence of this was seen in the clinical protocols that were reviewed. The PR should review the information that is provided to patients undergoing PGD or PGS and submit any documentation that is revised following the review to the HFEA.

Record keeping procedures

80. The records of nine patients were reviewed in the course of the inspection. In five sets of records consents and welfare of the child assessments were correctly completed and compatible with treatment. Anomalies were observed in four sets of records and these are summarised in the table below.

Treatment type	Error	Breach of Act or Code reference	Number of errors
Embryo donation	No consent to donation	Human Fertilisation and Embryology Act 1990, schedule 3 paragraph 2(1)(b)	1
IVF/ICSI	No consent to disclosure to GP Wishes after death incompatible/unclear	Human Fertilisation and Embryology Act 1990, section 33(5) Human fertilisation and Embryology Act 1990, schedule 3 paragraph 2(2)(b)	1
ICSI	No consent to disclosure to GP No evidence of WOC assessment	As above Human Fertilisation and Embryology Act 1990,	1

		section 13(5)	
DI	No consent to disclosure	As above	1

81. This represents an error rate of approximately 44% in the small number of records reviewed. A similar error rate (43%) was reported in the 2005 interim inspection report with 13 errors found during a review of 30 sets of patient records. The centre should review procedures for obtaining and checking statutory consents and carry out spot check monitoring of their completion to ensure that they are compatible with treatment. In feedback to the HFEA, three patients commented that consent forms were not explained to them before signing (see paragraph 71) and staff should review whether this could be impacting on the accurate completion of the forms.

82. As the HFEA revised the guidelines on carrying out a welfare of the child assessment in November 2005, no further action is required by the centre in relation to the failure to obtain a GP report.

Three embryo transfer arrangements

83. Information obtained from the HFEA register suggested that eight three embryo transfers were carried out in women less than 40 years old in the time covered by this report. The records of five of these patients were reviewed. Four of the patients were aged 39 years and one patient was aged 38 years at the time of the three embryo transfer. Evidence of previous failed cycles was seen in all of the records. This was discussed with the PR who reported that he considered the transfer of three embryos clinically appropriate in these patients.

84. Information from the HFEA register suggests that three embryo transfers may have been carried out in three patients whose ages were 29 years, 30 years and 23 years. One of these patients is thought to be a surrogate who was receiving treatment with embryos produced from the eggs of a patient aged more than 40 years. The records for these patients were requested but were not made available on the day of the inspection. The nurse co-ordinator commented that these records may have been previously requested by the audit team who were on site immediately prior to the inspection. In the absence of the records it was not possible to validate the information obtained from the register.

85. Carrying out three embryo transfers in patients of less than 40 years is a breach of part 8.20 of the COP.

Audit

Centre's own audit of stored material

86. No report of the findings of the annual audit of cryopreserved material was included at section 12 of the interim application although it was indicated that an audit has been completed in the last 12 months. At the time of the inspection, the senior embryologist reported that an audit was in progress

and that approximately half of the cryopreserved material had been audited. A summary report of the findings of the audit should be submitted to the HFEA on completion.

Spot check of tracking process for stored material

87. No discrepancies were observed while carrying out spot check tracking of two sperm samples and two embryos from laboratory file to dewar and from dewar to file.

HFEA register

88. An operational audit was carried out at the centre between the 16th and 18th January 2006. A statistically random sample of 45 IVF treatments provided between September 2004 and August 2005 was reviewed by the audit team.

89. The audit team found that 37 treatments (82% of the sample) had not been reported to the HFEA within 15 weeks. Eight treatment forms (18% of the sample) were outstanding and overdue at the audit date. The PR reported that the outstanding forms have been sent to the Authority. The Authority's Registry Department separately reports that they have not received the forms. The audit team found completed copies of all outstanding forms on file at the centre and a completed copy of the associated batch header during the audit.

90. The operational audit found that of the 1322 IVF treatments reported to the HFEA during the period 01/01/04 to 31/12/05, 919 (70%) were not reported to the HFEA within 15 weeks of treatment.

91. There was a high degree of accuracy in the forms that were submitted to the HFEA.

92. The audit concluded that the centre does not give sufficient importance to ensuring that treatments are reported within the requirements of Directions 1999/1.

Clinical governance

Risk management

93. The clinic is led by the PR, who makes all the key decisions about patient treatments. The PR reported that arrangements are in place for the provision of alternative clinical expertise in the event that he is incapacitated but he acknowledged that patient treatments would suffer in the event of his long term absence. This could be considered to leave patients exposed and represents a risk to the continuity of patient care. The PR is advised to review contingency plans.

94. The laboratory implements a number of quality assurance checks that ensure the ongoing safety of equipment and reagents. There is sufficient capacity to accommodate additional workload as necessary should a key piece of laboratory equipment fail (see paragraph 36).

95. The PR and senior embryologist reported that outcomes are monitored and reviewed on a regular basis (see paragraphs 34 and 36).

96. The centre has a clinical governance folder which was reviewed on the day of the inspection and was seen to contain copies of Alerts and safety bulletins.

97. The centre's incidents policy was reviewed on the day of the inspection and was considered appropriate.

98. The report of the 2004 Healthcare Commission inspection of the centre comments as follows: "A comprehensive risk management policy incorporating the listed issues remained available and in accordance with the standard. An annual report had been written and was available for the inspector. Risk assessments had been done for all areas of the clinic and identified preventative actions taken. MHRA alert letters and hazard notices are received and actioned by the Manager. A written procedure for informing the Healthcare Commission and professional bodies about staff suspended on clinical grounds was in accordance with the standard."

99. The PR reported that information from HFEA Alerts is disseminated by email and is discussed at appropriate team meetings.

Complaints

100. The centre's complaints policy was reviewed on the day of the inspection and was considered appropriate.

101. Section 10 of the interim application which asks for information on the number of complaints received by the centre was not included with the form submitted to the HFEA. One complaint directed to the centre since the previous inspection was recorded in the centre's complaints log. The complaint was in the process of being managed and there was an exchange of letters on file.

Breaches of the Act or Code of Practice

102. The centre has failed to notify the Authority of individuals that have access to confidential information (see paragraph 24). This is a breach of Chair's letter CH(01)08.

Unless specific consent is given by the patients/donors themselves, only the members and staff of the HFEA or those persons to whom an HFEA licence applies can have access to such information.

This latter group is defined in Section 17(2) of the Human Fertilisation and Embryology Act 1990 (HF&E Act) as:
(a) the person responsible,
(b) any person designated in the licence, or in a notice given to the Authority by the person who holds the licence or the person

responsible, as a suitable person to whom the licence applies, and (c) any person acting under the direction of the person responsible or of any person so designated.

103. Cryopreservation dewars were not fitted with low nitrogen level alarms or auto dial systems at the time of the interim inspection (see paragraph 41). Centres were expected to have installed this equipment by the end of June 2005.

Chair's Letter CH(04)03.
The HFEA will expect all centres storing patients' gametes and embryos (including donor gametes stored for 'sibling use') to have effective alarms and monitoring systems in place to ensure the safety of cryopreserved gametes and embryos.

104. A number of breaches of the COP were observed in the centre's previously submitted patient information (see paragraphs 73 to 79).

105. A number of breaches were observed in patient records (see paragraph 80).

106. The PR has failed to provide the Authority with documentation as required by Directions 1999/1 (see paragraphs 89 and 90).

HF&E Act 1990, section 12(g):
The following shall be conditions of every licence granted under this Act-
(g) that the Authority shall be provided, in such form and at such intervals as it may specify in Directions, with such copies of or extracts from the records, or such other information as the directions may specify.

Compliance with previous conditions and recommendations

Conditions

122. One condition was imposed by the Licence Committee considering the renewal of the centre's licence in 2004 and this is listed below.

Conditions	***Adopted by centre (Y/N)***	***Comment***
The centre must submit dated and signed clinical protocols for assisted hatching (mechanical) and ZIFT if you wish to continue to be licensed for treatment. Patient information for ZIFT must also be submitted.	No	ZIFT and mechanical assisted hatching were removed from the centre's licence in August 2005

Recommendations

123. Six recommendations were made by the Licence Committee considering the renewal of the centre's licence in 2004 and these are listed below.

Recommendation	***Adopted by centre (Y/N)***	***Comment***
1. Your centre should formalise and submit to HFEA written protocols regarding the audit of samples and required consents.	No	Not met
2. Your centre should routinely contact all GP's regarding welfare of the child in accordance with Section 3.20 of the HFEA Code of Practice 6th Edition.	Not applicable	No longer required following revision of HFEA guidelines
3. Your centre should seriously consider separating the roles of Person Responsible Nominal Licensee for the protection of patient's interests should the person responsible not be able to fulfil his duties under Section 17 of the HFE Act. (Chair letter CH (01)01.	No	No action taken.
4. Your centre should place a lock directly on the doors of the rooms holding patient records and ensure records are kept secure, with access to them restricted to those who need to see them.	Yes	Confirmed during the inspection of February 2006
5. The independent counsellor for your centre should carry out an audit of the counselling provision for the Centre's patients over the past 12 months and provide a copy to the HFEA.	Yes	Audit submitted during the inspection of February 2006
6. Your centre should review and revise their Patient information in the light of the inspection teams observations; • Information on the storage of sperm does not detail how long the sperm may be stored for nor how long the period can be extended in eligible cases. Patients are not reminded to remain in contact with the centre in order to update their wishes concerning the future of stored samples. • Information on the storage of embryos gives information on how long the embryos may be stored for and that the storage period can be extended in eligible cases. Patients are given a copy	Partial	PR confirmed that HFEA information provided to patients

of the HFEA leaflet on embryo storage but are not reminded in the centres literature to remain in contact in order to update their wishes concerning the future of their stored embryos. It could be made clearer to patients that their embryos will be discarded when the consent period has expired. • The complaint information invites patients to contact the Nurse Co coordinator but does not include a contact name. The complaints process does not appear to be explained to patients. However the centre did provide a copy of the patient questionnaire to be returned to the named Nurse Co coordinator.		

Key points for the Licence Committee

107. The inspection team supports the continuation of the centre's licence for treatments set out in paragraph 19 above.

Issues

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

- Following the HFEA operational audit it was concluded that the centre does not give sufficient importance to ensuring that treatments are reported within the requirements of Directions 1999/1 (see paragraphs 89 to 92).
- Some of the staff listed in documents submitted to the HFEA do not appear on the HFEA centre's database suggesting that there may have been changes in staff which have not been reported to the HFEA (see paragraph 24).
- Cryopreservation dewars are not fitted with low nitrogen level alarms or auto dial systems (see paragraph 41).
- In two of three sets of patient records reviewed, witnessing sheets were absent or not complete (see paragraph 56).
- Eight three embryo transfers were carried out in women less than 40 years old in the time covered by this report see paragraph 83).
- Consents to treatment and evidence of welfare of the child assessment were reviewed in a small number of patient records. An error rate of approximately 44% was observed. A similar error rate (43%) was reported in the 2005 interim inspection report (see paragraph 81).
- The 2005 interim inspection report recommended that the centre develop standard operating procedures (SOPs) for the assessment and screening of donors but no protocols have been submitted to the HFEA (see paragraph 60).
- No report of the findings of the annual audit of cryopreserved material was included at section 12 of the interim application (see paragraph 86).
- There are a number of omissions in patient information previously submitted to the HFEA (see paragraphs 74 to 79).

Appendix A The inspection team and staff interviewed

The inspection team

Angela Sanford	Inspector, HFEA Executive
Debra Bloor	Chair, Inspector, HFEA Executive
Robert Sawers	Clinical advisor

Centre staff interviewed

Mohamed Taranissi Person responsible
Three other members of the centres staff were interviewed in the course of the inspection.

Conflicts of interest

None declared.

Human Fertilisation and Embryology Authority

Centre Name : Assisted Reproduction and Gynaecology Centre

Document Type: Licence Committee Minutes

Date : May 2006

Licence Committee Meeting

24 May 2006
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 5

Centre: Assisted Reproduction and Gynaecology Centre (0157)
Interim Inspection

Members:	In Attendance:
Sharmila Nebhrajani, Lay Member – Chair	Trish Davies, Director of Regulation
Emily Jackson, Lay Member	Frances Clift, Legal Adviser
Richard Harries, Lay Member	Marion Witton, Head of Inspection
Helene Hayman, Lay Member	Claudia Lally, Secretary to the Committee
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary	Observing: Rozlynn Lawrence, PA to Frances Clift

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 (51 pages)
- no papers were tabled.

1. The papers for this item were presented by Debra Bloor, HFEA Inspector. Dr Bloor informed the Committee that this centre takes self-funded patients, and carried out 624 licensed treatments in 2005, with approximately 6 of these using donated gametes. The live birth rate at this centre is significantly higher than the national average as stated in the HFEA Guide to Infertility. Dr Bloor also mentioned that the counselling service at the centre complies with HFEA guidance and that the HFEA feedback from six patients who had received treatment at the centre within the time covered by the report was very positive.

2. Dr Bloor informed the Committee that the inspection team identified a number of regulatory issues at the inspection:

a) The centre has not been submitting treatment forms to the HFEA in a regular and timely fashion, in accordance with the requirements of Directions 1999/1.

b) It appears that there may have been staff changes at the centre which have not been reported to the HFEA. If so, this may be a breach of the confidentiality provisions contained in section 33 of the Human Fertilisation and Embryology Act 1990 which require all persons who have access to patient information to be persons to whom a licence applies as defined in section 17(2) of the Act.

c) Cryopreservation dewars at the centre are not fitted with low nitrogen level alarms or auto dial systems in accordance with Chair's letter CH(04)03.

d) Although witnessing requirements are documented in laboratory procedures, in two of three sets of patient records reviewed by the inspection team, witnessing sheets were absent or not completed.

e) Three embryo transfers were carried out on eight occasions to women less than 40 years old. Five of the patients were aged between 38 and 39 years and had had previous failed cycles. The Person Responsible reported that he considered the transfer of three embryos clinically appropriate in these patients. However, information from the HFEA register had suggested the remaining three transfers were to patients aged 23, 29 and 30 years. The records for these patients were requested but were not made available on the day of the inspection.

f) Consents to treatment and evidence of welfare of the child assessments were reviewed in a number of patient records. An error rate of approximately 44% was observed.

g) The 2005 interim inspection report recommended that the centre develop standard operating procedures for the assessment and screening of donors but no protocols have been submitted to the HFEA. Although the records of patients who had donated embryos were reviewed, there was no evidence that the donors had been screened as required.

h) There were a number of omissions in patient information previously submitted to the HFEA, although most of the omissions are in information for patients receiving treatment with donated gametes, and the centre carries out very few such treatments.

i) The centre has not yet submitted the findings of its annual audit of cryopreserved material, a report of embryo biopsy practice or data on the number and severity of cases of OHSS.

3. Dr Bloor informed the committee of the results of the HFEA's risk analysis of the centre which had given a risk score of 32%, placing it in the top quartile of centres.

4. Dr Bloor informed the Committee that she had sent the inspection report to the Person Responsible at the centre on 5 April in order to give him an opportunity to correct any factual inaccuracies, however, the Person Responsible had not yet taken this opportunity.

5. The Committee asked Dr Bloor why she thought the centre might be taking so long to report treatments in accordance with Directions 1999/1. Dr Bloor replied

that the centre is a very busy centre which prioritises clinical work, above administrative tasks. The Committee noted that the time limit specified in the Directions 1999/1 is that all treatments carried out by the centre must be reported to the HFEA within two months of the outcome of the treatment being known. In practical terms, the register expects all treatments to be reported to the HFEA within five months of being carried out.

6. The Committee agreed that the centre should be reminded of the Directions and the time in which treatments should be reported. The Committee noted that late reporting of treatment undermines the ability of the HFEA to assess and regulate centres, and to compile the statistics used in the Patients' Guide. Dr Bloor informed the Committee that data submitted with the centre's interim application suggested that 640 IVF and ICSI treatments were carried out in 2005 but the HFEA register only contains information about 319 of these treatments. The Committee noted that this failure constitutes a breach of the centre's licence conditions, and a breach of the duties of the Person Responsible. These breaches are serious enough to give the Committee sufficient grounds to revoke the centre's licence.

6. The Committee was concerned about the number of separate occasions on which this centre has breached advice and guidance from the HFEA, and noted the need to remind the Person Responsible of the importance of the regulatory framework for ensuring safe and effective operations.

7. The Committee noted that there were three issues raised in the inspection report which Dr Bloor had clearly not been able to thoroughly explore during the course of the inspection. These issues related to the centre's witnessing procedures, screening of gamete and embryo donors and three embryo transfers in women under 40 years. The Committee asked Dr Bloor to return to the centre and gather more information on these issues and then report back to the same Licence Committee team.

8. In addition, the Committee requested that the centre submits the following information:

- An up-to-date list of centre staff
- Results of the centre's annual audit
- Embryo biopsy success rates

9. The Committee agreed to advise the centre to install low nitrogen level alarms on storage dewars within one month of receipt of these minutes.

Signed…….. … Date……..
Sharmila Nebhrajani (Chair)