Human Fertilisation and Embryology Authority

Report of a renewal inspection at

CARE Manchester
(0185)

Inspection date: 29 March 2006
Licence Committee Date: 10 July 2006

Contents

Key facts about the centre

Centre name CARE Manchester

Centre address 108-112 Daisy Bank Road
Manchester, M14 5QH

Centre number 0185

Person responsible Glenn Atkinson

Nominal licensee Charmian Russell

Activities of centre

		2005
Licensed treatment cycles	IVF ICSI FET Egg sharing (donor) (recipient) Egg donation (donor) (recipient)	362 290 191 96 96 26 28
Donor Insemination		33
Unlicensed treatments	IUI Gonadotrophin ovulation induction Surrogacy	
Research	None	
Storage	Yes	

Focus of inspection General

Additional licence conditions None

Licence expires 30 September 2006

Summary

1. The centre is part of the CARE fertility group and provides self funding treatments to patients referred from all areas of the North West and occasionally from other regions of the UK and overseas. The centre also provides some NHS funded treatments. The centre was established in 1999 and carried out 1122 licensed treatments in the time covered by this report.

2. A number of regulatory issues were identified in the course of the inspection and these are summarised as follows:
   - At the time of the inspection a number of cryopreserved samples were in storage for which there were no valid consents;
   - Staffing levels in the embryology team are a cause for concern;
   - The centre does not screen patients who are also blood donors for HIV and hepatitis infection prior to storage of gametes, embryos or tissue;
   - The centre does not screen gamete or embryo donors who are also blood donors for HIV and hepatitis infection prior to donation;
   - The centre does not quarantine sperm used to inseminate eggs that are to be transferred to a surrogate or frozen embryos before transfer to a surrogate;
   - Not all of the dewars used to store cryopreserved material are fitted with low nitrogen level alarms;
   - In feedback from 61 patients who have received treatment at the centre, 32 commented that the counselling services are not readily accessible;
   - Consent forms suggest that storage of sperm by a man for use by a relative can be extended to the 55th birthday of the gamete provider. A family member storing sperm for a relative would not satisfy the criteria for extended storage;
   - Patient information for egg or embryo donors and for patients receiving treatment with donated gametes does not consistently reference the all of the information required by parts 5.6 and 5.7 of the 6th Code of Practice and requires revision in relation to advice given on parental responsibility.

   The PR considers the centres staffing levels and screening practices to be appropriate (see the Person Responsible's comments at appendix C). Patient information and consents were revised as recommended following the inspection.

3. Despite concerns over staffing and workload in the embryology team, the centre has responded to workload pressures by increasing recruitment and some management of workflow. The centre is proactive in monitoring outcomes and in responding to audit information. The counselling service is considered to be of high quality and feedback from 61 patients who received treatment at the centre was positive. Information requested by the inspection team on the day of the inspection was provided promptly reflecting overall good management and organisation.

4. The inspection team would support the renewal of the centre's licence.

Background to inspection

5. This inspection report covers the time from the last inspection in April 2005 to March 2006 and includes outcome data from January to December 2005.

6. One site visit took place on 29 March and lasted 7½ hours. The last operational audit was carried out in April 2005.

7. The report was reviewed by the centre in April 2005. The centre had not been invoiced for the renewal fee at the time the report was presented to a Licence Committee.

The centre's context

8. The centre is part of the CARE fertility group and shares premises with the Manchester Lifestyle Clinic.

9. The centre treats predominantly self funding patients from the North West of England.

10. Working patterns at the centre have not changed since the interim inspection in 2005. The centre operates routinely from Monday to Saturday and provides a flexible service on Sundays as required.

11. The workload for 2005 was largely unchanged compared to 2004; a total of 1122 licensed treatments were provided in 2005. However, the PR reported that while there was a steady increase in workload in 2006, there was an unprecedented increase in increase in workload in March 2006 and that this, as might be expected, had tested the system

Type of work carried out

Licensed treatment

12. The centre carries out the following licensed treatments (delete/add as appropriate)
    - Storage of eggs
    - Storage of sperm
    - Storage of embryos
    - Gamete intra fallopian transfer (GIFT) with donor gametes
    - Donor insemination (DI)
    - Treatment with donor gametes
    - In vitro fertilisation (IVF)
    - Zona drilling
    - Intra cytoplasmic sperm injection(ICSI)
    - Chemical assisted hatching

Treatments that do not need a licence

13. Intra uterine insemination (IUI), gonadotrophin ovulation induction, surrogacy.

Satellite/transport arrangements

14. The centre has a satellite arrangement with the following centres:
    - The Beaumont Hospital, Old Hall Clough, Chorley New Road, Lostock, Bolton;
    - Leigh Infirmary, The Avenue, Leigh, WN7 1HS.

15. At the time of the interim inspection in 2005 the possibility of producing a formal report of visits to satellite centres was discussed. The PR reported that although visits had taken place, no report was compiled however, minutes of the meetings were made available at the time of the inspection. The satellite centres use the same procedures and documentation as centre 0185 and staff from the satellites are included in some CARE group meetings. The PR reported that there are written agreements in place between CARE Manchester and the satellite centres.

Staff

Staffing profile

16.

Person responsible	Glenn Atkinson
Nominal licensee (and unit manager)	Charmian Russell
Accredited consultants	3 (including the PR – 2.8 WTE)
Embryologists	6 (4 qualified, 2 trainee – 4.5 WTE)
ICSI practitioners	8
Nurses	11 (7.5 WTE)
Ultrasonographers	3 (1.5 WTE + 1 bank ultrasonographer)
Health care assistants	4 (3.6 WTE)
Laboratory assistants	2 (1.5 WTE)
Counsellors	2 (both sessional)
Administrative staff	11 (9 WTE including unit manager and accounts administrator)
Complaints manager	Charmian Russell

The centre includes a large number of staff from other CARE facilities on its licence. These individuals work at the centre on a sessional basis and to provide emergency cover and are not included in this staff profile. The PR reported that there have been considerable increases in staff in the last year and further recruitment is planned. A summary of actual and planned staff recruitment is shown at appendix B.

17. The unit manager was able to provide information on the number of whole time equivalent members of staff on the day of the inspection. This information had not been requested previously and it is therefore not possible to make direct comparisons with information on staff numbers gathered at the time of the 2005 interim inspection however staffing levels

appear generally unchanged. This information and other documentation was provided promptly on the day of inspection reflecting overall good management and organisation of the centre.

18. Six embryologists are currently employed by CARE Manchester. One member of the team has been on leave and is expected to return in the summer of 2006 and some members of the team work part time: taking these factors into account this equates to approximately 4.5 whole time equivalent (WTE) embryologists. A workforce planning questionnaire[1] commissioned by the Association of Clinical Embryologists (ACE) in 2002 reported that centres carrying out between 9001 and 1200 treatment cycle equivalents employed on average 4.8 WTE staff with the range being 2.5 - 6.5 WTE. Using the cycle equivalent criteria in the report, CARE Manchester provided 1151 cycle equivalents in 2005 and therefore operated with fewer than the average number of embryologists but within the reported range. Taking into account the number of IVF and ICSI treatments provided, the centre provided 871 treatments in 2005. The workforce planning report recorded that in centres providing 801-1000 IVF or ICSI cycles, an average 5.5 WTE staff were employed with the range being 4 – 6.5. Again, in 2005 CARE Manchester, which provided 872 IVF and ICSI cycles operated with fewer than the average number of staff but within the reported range.

19. At the time of the inspection in March 2005 it was noted that while the embryology team had been understaffed pending the appointment of the new laboratory manager, opportunities for training and mentoring of junior members of the team had been more limited than usual. It was expected that when the laboratory regained a full staff complement junior staff would be allocated one day per two weeks as protected time for training and it was reported that protected time had been allocated in the time covered by this report.

20. However, in the course of the renewal inspection in March 2006 laboratory staff reported that as a result of a sharp increase in workload in February and March 2006 protected training time had been temporarily suspended. Over this time period some members of the embryology team were remunerated for weekend work rather than taking the usual half days leave and when questioned, staff reported that opportunities for regular breaks had occasionally been limited. Inspection of the embryology rotas for February and March 2006 showed that the laboratory was staffed by the reported minimum three embryologists on 17 occasions: the rotas suggest that only two members of staff were available on 14, 15 and 22 March 2006 as a result of sickness. The embryologists were supported by a laboratory assistant on these dates. Information from rotas suggests that additional staff cover was provided by staff from other CARE facilities on two occasions in March.

[1] Jamieson, M (2002) **The Embryologist 32**, *Workforce Planning Questionnaire 2002,* pages 6-8

21. Staffing levels in the embryology team are a cause for concern. When these concerns were raised in the course of the inspection, it was reported that the recruitment of an additional junior member of staff has been approved. Initially the appointment was delayed pending refurbishment and expansion of the laboratory facilities but it has been recognised that this work could be delayed and it was agreed that the recruitment could proceed.

22. The inspector advised that as an immediate measure, a risk assessment of laboratory practice should be carried out to establish the number of treatment cycles that can safely be accommodated taking into account the number of embryologists and the current limitations of space and equipment in the laboratory. The inspector recommended that the results of the assessment be reviewed and if necessary, workload should be limited to ensure continuing safe practice. A risk assessment was carried out following the inspection and a copy of the assessment submitted to the HFEA. However, the assessment did not estimate the number of treatment cycles that can safely be accommodated.

23. Both the PR and nurse manager commented that workload has put pressure on the nursing team. The centre has recently appointed two new nurses (1.35 WTE) in response to increases in workload. There has also been an agreement to fund an additional 10 hours per week for patient services and an operating department assistant has been recruited. It was also reported that steps had been taken to monitor and if necessary, to limit the number of referrals. A counsellor reported that both members of the counselling team can increase the number of counselling session provided to meet the needs of patients.

Professional registration and continuing professional development (CPD)

24. All clinical staff (including clinicians working at satellite centres) are registered with the General Medical Council (GMC) and the PR is on the GMC specialist register. All nursing staff are registered with the Nursing and Midwifery Council. Both counsellors are members of the British Infertility Counselling Association. All members of the embryology team are registered with the Health Professions Council with the exception of the junior embryologists who are studying for the ACE Certificate in Clinical Embryology prior to applying for state registration.

25. The PR reported that he follows the Royal College of Obstetrics and Gynaecology programme for continuing medical education and has been appraised in the last year. He reported that he has not undergone advanced life support training in the last year but this was planned for 24 May.

26. The training records of three members of the embryology team were reviewed in the course of the inspection. All embryologists follow the ACE CPD programme and were able to demonstrate attendance of relevant training sessions and/or meetings in the last year. Members of the embryology team had not had their annual appraisal at the time of the inspection but the PR reported that appraisal of members of the embryology

team was expected to recommence in June 2006 following a review of the appraisal policy.

27. A recently appointed member of the nursing team reported that she received induction training and mandatory health and safety training in manual handling, fire safety, infection control and basic life support. A member of the administration team also reported that new members of staff receive two to three weeks of induction training.

28. A member of the counselling team confirmed that the centre funds her CPD training for one or two days annually.

29. Members of the embryology team were not able to show evidence of mandatory health and safety training in the last year because a training event scheduled for February 2006 was cancelled. Subsequent to the inspection, two members of the embryology team provided evidence of their attendance at a mandatory health and safety training event.

Audits of outcome

30. The centre's audit practices and meeting schedules are unchanged from the time of the interim inspection in 2005 when they were found to be comprehensive.

31. It was noted that there had been a decline in clinical pregnancy rate per treatment cycle for patients undergoing ICSI treatment in 2005 when compared to the live birth rate per treatment cycle for 2004. The centre was aware of the trend and provided evidence of monitoring. Audit information provided by the centre suggests that 43% of the patients undergoing ICSI treatments in the six months from August 2005 to February 2006 were aged more than 37 years. In addition to carrying out demographic analysis a member of the embryology team prepared a report on the loss of biochemical pregnancies following ICSI which compared outcomes for individual practitioners and a range of other patient specific comparators. The report detailed additional factors that were to be considered as part of the ongoing monitoring programme.

32. This demonstrates that the centre is proactive in monitoring outcomes and in responding to audit information.

The premises, equipment and other facilities

Premises

33. The premises are unchanged from the time of the interim inspection in April 2005. The centre anticipates that changes will be made to the reception area and the laboratory will be extended in the next year. Preliminary plans of the proposed laboratory layout were provided in the course of the inspection.

Equipment

34. In response to the issues raised in Alert A20[2], an uninterrupted power supply has been provided for the freezing machine.

Security

35. On the day of the inspection, security appeared appropriate.

Confidentiality

36. Patient records are stored in locked cabinets in various rooms, all of which are locked when unoccupied.

37. The 2005 interim inspection commented on concerns about confidentiality on the reception area. The inspection team were shown plans for the imminent redevelopment of the reception area. The plans are currently being considered by the Health Care Commission. An inspector did see evidence that staff at the reception desk are aware of the issue and take steps to ensure that conversations are not overheard.

Arrangements for collecting sperm samples

38. Arrangements for collecting sperm are unchanged from the interim inspection in 2005 when they were considered appropriate.

Cryostore facilities, oxygen and dewar alarms

39. Gametes and embryos are stored in the main embryology laboratory and in an adjacent laboratory that houses analyser equipment. Access to both rooms is restricted to licensed personnel by key pad. On the day of the inspection, the door to the analyser laboratory was left open when the room was unoccupied. The senior embryologist should monitor security in this area.

40. The cryostore facilities are adequate for the type and volume of activities carried out and evidence of daily vessel checks was seen by an inspector.

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

42. In the last year the centre has acquired three additional dewars and at the time of the inspection these were not fitted with alarms or monitoring systems. This is a breach of Chair's Letter CH(04)03 (see paragraph 83). One is used to store cryopreserved samples for patients who received treatment at a now closed centre (CARE Wirral) and a further two small dewars are used to store material individually for two patients. Subsequent to the inspection the PR reported that the centre is in the process of obtaining quotes for alarms. The PR reported that it is anticipated that dewar alarms will be installed within two months.

[2] HFEA Incident Alert Report A20, Power Supply and Critical Equipment, November 2005.

Emergency facilities

43. The centre is located in close proximity to an NHS hospital with full critical care facilities. If a patient required transfer for emergency treatment, the centre would use an emergency ambulance for the transfer.

44. The centre has resuscitation equipment.

Clinical, nursing and laboratory procedures

45. All of the centre's documents show evidence of revision and are version controlled.

Clinical and Nursing

46. The centre's protocols were reviewed by a clinical advisor and were considered appropriate.

47. The centre's protocols and procedures for the management of ovarian hyper stimulation syndrome (OHSS) were reviewed and considered appropriate.

48. Where patients provide evidence of having made a blood donation within one year of presenting for treatment the centre does not screen for HIV or hepatitis infection prior to the cryopreservation of gametes or embryos. . The inspection team were concerned that this practice may fail to comply with the requirements of the COP and that as there are no identity checks on blood donors, this practice may be at risk of abuse. Part 9.2 of the COP states:
    - All patients placing gametes, embryos and ovarian or testicular tissue in storage which falls under an HFEA licence are expected to be screened for Hepatitis B, Hepatitis C and HIV, as outlined in Association for Clinical Embryologists' Guidelines.

    The centre should assess the risks of not screening blood donors prior to storage and this should be reviewed via the centre's clinical governance process. A copy of the risk assessment should be submitted to the HFEA.

49. HIV and hepatitis screening is also required for gamete donors (including commissioning couples in surrogacy arrangements) and it is the centre's practice not to screen patients who show evidence of blood donation. In addition, while the centre's standard operating procedures for surrogacy clearly outline the need for quarantining of sperm samples and frozen embryos prior to transfer to a surrogate, discussions in the course of the inspection suggested that it is not the centre's practice. Failure to carry out HIV and hepatitis screening and to quarantine sperm or embryos is a breach of appendix C of the COP and British Andrology Society[3] and British Fertility Society[4] guidelines. The centre should review these practices and provide

[3] British Andrology Society (1999) **Human Reproduction 14(7),** *British Andrology Society guidelines for the screening of semen donors for donor insemination,* page 1823-1826

[4] Aird, I., Barratt, C., Murdoch, A. and the BFS Committee (2000) **Human Fertility 3,** *BFS Recommendations for Good Practice on the Screening of Egg and Embryo Donors,* page 162-165

the HFEA with confirmation that screening will comply with relevant guidelines in the future.

Laboratory

50. 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.

51. Witnessing requirements are clearly documented in laboratory standard operating procedures and a review of six sets of patient records showed that witnessing had been carried out and documented in accordance with Directions D2004/4.

52. The 2005 interim inspection report commented that the centre did not have a robust system for the identification of material approaching the end of the consented period of storage and recommended that a revised procedure be implemented. New procedures for the identification of material approaching the end of the consented period of storage were submitted on the day of the inspection. However, the scientific inspector was advised that at the time of the inspection, a number of cryopreserved samples were in storage for which there was no valid consent. This is a breach of the Human Fertilisation and Embryology Act 1990, Schedule 3, paragraphs 8(1) and (2) (see paragraph 85).

53. Following the inspection the laboratory manager submitted a report to the HFEA which showed that at the time of the inspection 14 patients had material in store without consent. The report documented what action has been taken to resolve the issue and predicted the process would be complete by the end of May 2006. The storage of cryopreserved material without consent was also reported as an incident.

Procedures for assessing clients and for assessing and screening donors

Welfare of the child

54. The centre's procedures for carrying out a welfare of the child assessment were reviewed at the time of the interim inspection in 2005 when they were considered appropriate. The centre has made some changes following the issue of revised guidelines in 2005 and has adopted the questionnaire developed by the HFEA.

Ethics committee

55. The centre has access to an ethics committee.

Assessing and screening donors

56. The centre buys supplies from a sperm bank.

57. Counselling is provided for potential egg donors, and couples involved in egg sharing and surrogacy arrangements.

58. The 2005 interim report recommended that the centre revise information for donors to provide a full list of all of the screening tests carried out and to inform patients about the non-identifying information that may be available to the recipients of donor gametes. However, the recommended changes have not been made. Patient information for egg or embryo donors and for patients receiving treatment with donated gametes does not consistently reference the following information:
    - Egg donors should be no older than 35 years;
    - Donors must notify a centre if a deleterious recessive condition is revealed;
    - Restrictions on payment to donors;
    - The maximum number of permissible families that can be created using a single donors gametes;
    - The circumstances under which identifying information can be revealed;
    - The circumstances under which non-identifying information can be revealed;
    - Information that is collected for the HFEA register;
    - The law if defects are not disclosed by a donor;
    - The requirement for screening for Thalassaemia and Tay-Sachs in patients from relevant population groups;
    - That tests may reveal previously unsuspected conditions;
    - The limitations of screening (donors may carry genetic defects or infection despite screening).

    Some of this information may be provided verbally and discussions with the counsellor confirmed that patients are provided with appropriate information relating to the availability and exchange of identifying and non-identifying information. Revised patient information was submitted subsequent to the review of the draft report.

59. The 2005 interim inspection report recommended that the centre update information for recipients of donated sperm to reflect the changes introduced in the Adoption and Children Act 2002: section 111 states that an unmarried father shall acquire parental responsibility for the child if he becomes registered as the child's father. The centre should revise the information (at page 74 of the HFEA inspection papers and at page 4 of the CARE Patient's Guide and Information Document) as a matter of urgency and revised documentation should be submitted to the HFEA.

Counselling process and facilities

60. Counselling was considered to be of high quality by the external advisor.

61. Implications counselling for egg share providers is offered independently of treatment implications counselling.

Counselling protocols

62. Counselling protocols are version controlled and showed evidence of revision.

Counselling referral arrangements

63. The centre offers implications, support and therapeutic counselling. The counselling service is referenced in all relevant patient information.

64. Patients receiving treatment at satellite centres are referred to CARE Manchester for counselling.

65. The centre offers three counselling sessions per treatment cycle at no additional cost to the patient.

66. The centre's counsellors do not carry our assessment counselling. Outside agencies (social services, psychiatric services, probation services etc) are used as required to provide additional information and assessment of clients where issues have been identified. Referrals to specialist genetic counselling are made as required.

Supervision and professional registration

67. Both counsellors are appropriately qualified and experienced and their practice is supervised. Both are members of the British Infertility Counselling Association.

Counselling audit

68. Information on the number of counselling sessions provided in the time covered by this report was provided with the application. However, the information was not analysed to show what proportion of new patients had received counselling and it was recommended that counselling uptake is monitored more effectively to evidence the high standard of the service.

Location of counselling facilities

69. The centre provides a private and comfortable room for counselling.

Patient experience

Patient feedback

70. The HFEA has received feedback from 61 patients who received treatment at the centre. The responses were positive with 54 patients having compliments about the treatment that they received and only 9 patients having any complaints about the treatment that they received.

71. The only significant negative comments were made by 32 patients who commented that the counselling service is not readily accessible. On the basis of similar feedback received prior to the interim inspection of 2005 the inspection report recommended that the centre review the accessibility of the counselling service. On the day of the inspection, there were discussions about how patients contact the counsellors and/or make appointments. As counsellors are not on site full time, patients cannot be given a direct contact number for a member of the counselling team and make appointments through the clinic reception. The centre should consider

whether access to the service could be improved and the issue should be monitored at the time of the next inspection.

Patient information

72. Information is comprehensive and largely compliant with the requirements of the COP. A number of minor omissions were communicated to the PR in the course of the inspection and it is recommended that these are considered at the time of the annual review of information.

73. Paperwork submitted with the renewal application includes information for patients considering reproductive immunology treatments provided at other CARE facilities. This information was reviewed and was considered appropriate.

74. Consent forms (at pages 225 and 227 of the HFEA inspection papers) suggest that storage of sperm by a man for use by a relative can be extended to the 55th birthday of the gamete provider. The criteria for extended storage[5] up to the gamete providers 55th birthday require that the gametes were provided by a person
    - whose fertility since providing them has or is likely to become, in the written opinion of a registered medical practitioner, significantly impaired,
    - who was aged under 45 on the date on which the gametes were provided,
    - who does not consent to the gametes being used for the purpose of providing treatment services to persons other than that person, or that person and another together, and never has so consented while the gametes were ones to which this regulation applied.

    A family member storing sperm for a relative would not satisfy these criteria and the centre should not offer extended storage of gametes under the circumstances referenced in the submitted consents. Subsequent to the inspection the centre submitted appropriately revised consent forms. The centre should take any necessary action to advise patients whose sperm has been cryopreserved for use by a relative of the appropriate statutory storage periods.

Record keeping procedures

75. A review of welfare of the child assessment and consent to treatment and storage forms in 30 patient records was carried out during the operational audit visit that was carried out concurrently with the interim inspection in 2005. This audit identified a small number of errors that all related to the completion of GP welfare of the child reports. Following the implementation of revised guidelines for carrying out these assessments in November 2005, these reports are no longer required and in consideration of this, no general records inspection was carried out in the course of the renewal inspection.

[5] The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991

Three embryo transfer arrangements

76. Inspection of the treatment log showed that no three embryo transfers were carried out in patients of less than 40 years.

Audit

Centre's own audit of stored material

77. An audit of cryopreserved material carried out between October 2005 and March 2006 showed no discrepancies.

Spot check of tracking process for stored material

78. A spot check audit tracking two embryos and two sperm samples from tank to records and from records to tank was carried out: no discrepancies were found.

Clinical governance

79. The CARE group is continuing the development of clinical governance strategies. The NL is the clinical governance lead at the centre and three other individuals from the nursing, laboratory and administration teams have been designated to provide a link with the unit's clinical governance structure.

Risk management

80. The centres procedures for managing risk were reviewed at the time of the interim inspection in 2005 when they were considered appropriate.

81. In the course of the renewal inspection, a file of risk assessments was made available for review. The PR confirmed that the centre maintains an active programme for reviewing clinical governance and risk management issues.

Complaints

82. The centre received 22 complaints in the time covered by this report: only one complaint remains unresolved. The complaints log was reviewed by the inspection team who identified no issues of concern.

Breaches of the Act or Code of Practice

83. Not all of the cryopreservation dewars used to store patient material are fitted with low nitrogen level alarms or an auto dial system (see paragraph 41)

Chair's Letter CH(04)03 states that: 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. Centres were expected to have implemented these guidelines by the end of June 2005.

84. The centre does not screen blood donors for HIV and hepatitis infection prior to gamete or embryo donation or quarantine sperm prior to use in the creation of embryos transferred to a surrogate (see paragraphs 48 to 49).

Appendix C of the COP states:

- **It is expected that semen will be used only for others when immediate and 180 day tests for HIV antibody are negative. In no circumstances is it expected that donated semen be used which has been collected less than 180 days before the most recent negative HIV antibody test;**
- **<u>At the beginning of the treatment and collection cycle</u> of a woman whose eggs are to be taken for the treatment of others, her blood is expected to be tested for the presence of HIV antibodies;**
- **It is expected that the blood of both people whose gametes were used to produce an embryo will be tested for HIV antibodies if and when they decide to make the embryo available for the treatment of others. It is expected that stored embryos will not be used if they have been created less than 180 days before the most recent negative antibody tests on both donors.**

Guidelines from the British Andrology Society[4] and the British Fertility Society[5] recommend that donors should be screened for the presence of: HIVl, HIV2, Syphilis, hepatitis B and C, *Neisseria gonorrhoea, Chlamydia trachomatis* and CMV.

85. At the time of the inspection, a number of cryopreserved samples remained in storage for which there was no valid consent (see paragraph 52).

Human Fertilisation and Embryology Act 1990, Schedule 3, Paragraph 8 (1) A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent (2) An embryo the creation of which was brought about in vitro must not be kept in storage unless there is an effective consent, by each person whose gametes were used to bring about the creation of the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents.

Compliance with previous conditions and recommendations

Conditions and recommendations

86. The previous licence was issued without any additional conditions or recommendations

Key points for the Licence Committee

87. The inspection team supports the renewal of the centre's licence for treatments set out in paragraph 12 above.

Issues

88. The inspection team would like to draw the following points to the attention of the licence committee:
    - Staffing levels in the embryology team were a cause of concern to the inspection team (see paragraphs 18 to 23). A risk assessment has been carried out and was submitted to the HFEA: the assessment does not establish the number of treatment cycles that can safely be accommodated. The PR has reviewed staffing levels which he considers appropriate. The PRs comments are included at appendix C;
    - At the time of the inspection a number of cryopreserved samples were in storage for which there were no valid consents. This is a breach of the Human Fertilisation and Embryology Act 1990, Schedule 3, paragraphs 8(1) and (2). The laboratory manager confirmed that the issue would be addressed as a matter of urgency and that the HFEA would be informed when all the samples had been removed from storage (see paragraph 52);
    - The centre does not screen blood donors for HIV and hepatitis infection prior to storage of gametes, embryos or tissue or prior to gamete or embryo donation. The centre does not quarantine sperm used to inseminate eggs that are to be transferred to a surrogate or frozen embryos before transfer to a surrogate. This is a breach of appendix C of the COP and British Andrology Society and British Fertility Society guidelines (see paragraphs 48 to 49). The PR has reviewed the practice which he considers appropriate. The PRs comments are included at appendix C;
    - Not all of the dewars used to store cryopreserved material are fitted with low nitrogen level alarms. This is a breach of Chair's Letter CH(04)03. The centre should comply with the requirements as a matter of urgency. The HFEA should be advised when the installation is complete (see paragraph 41);
    - In feedback form 61 patients who have received treatment at the centre, 32 commented that the counselling services are not readily accessible. The centre should consider whether access to the service could be improved and counselling uptake should be monitored (see paragraph 71);
    - At the time of the inspection, consent forms suggested that storage of sperm by a man for use by a relative can be extended to the 55th birthday of the gamete provider. A family member storing sperm for a relative would not satisfy the criteria for extended storage. The centre has revised the consent forms but should also take any necessary action to advise patients whose sperm has been cryopreserved for use by a relative of the appropriate statutory storage periods (see paragraph 74);
    - At the time of the inspection patient information for egg or embryo donors and for patients receiving treatment with donated gametes did not consistently reference the all of the information required by parts 5.6 and 5.7 of the COP and advice relating to parental responsibility requires revision. The centre has revised the information (see paragraph 58).

Appendix A The inspection team and staff interviewed

The inspection team

Debra Bloor	Chair, Inspector, HFEA executive
Richard Kennedy	Clinical advisor
Sheila Pike	Social and ethical advisor

Centre staff interviewed

Glenn Atkinson	Person responsible
Charmian Russell	Nominal licensee

Nine other members of the centre's staff met with members of the inspection team.

Conflicts of interest

None declared.

Appendix B Information on recruitment

Additional staff recruited in 2005:

Reception	2 extra receptionists from August 2005 (37.5 and 30 hours)
Secretarial	Increase of 3 hours per week
Nursing	2 posts 25 hours per week from August 2005, 1 healthcare assistant (30 hours) from January 2006
Medical	One extra whole day session
Embryology	One extra embryologist full time (to cover maternity leave of 24 hrs per week appointed April 2005

Planned recruitment:

Reception	1, 25-hour post
Embryology	1 full time, trained embryologist, 1 full time trainee
Nursing	2 RGN appointed and commenced 15th May (22.5 and 30 hours)

Appendix C: Comments of Person Responsible

1. Staffing levels in the laboratory

I do not believe that staffing levels in the laboratory are a cause for concern and wonder where the evidence is that would lead the inspection committee to such a conclusion. The ACE questionnaire is simply a survey of embryology staffing and therefore it is not correct to use the mean of the responses as a yardstick to measure staffing level against, as the average does not correlate with 'best practice'. This average does not take into account experience or mix of work carried out. No mention is made of lab assistants of whom we have 2 (One of whom has recently increased his hours from 19 to 37.5 hours) who undertake work which may be done by embryologists in other clinics. CARE Manchester is a growing unit and is actively seeking to recruit a trained embryologist and an embryology trainee to augment the embryology team.

2. Consents for stored embryos

In the previous report it had been commented that CARE Manchester did not have a robust system for identifying embryos for which storage consent has expired. We have been endeavouring to update the computer records of all embryos to provide an accurate source of such information. In the course of this update it became apparent that we had some embryos for which the consent period had expired. I have had a series of meetings with the laboratory manager and deputy and unit manager to try to manage this problem. Although some embryos had reached their consented expiry date an executive decision was made to make every effort to contact the patients by mail, telephone or e-mail to make absolutely sure they did not want to extend storage before destroying the embryos. This has necessarily resulted in a delay in some cases. Systems in place now allow us to prospectively contact patients when expiry is due.

3. Screening

Statements relating to screening in the report are not accurate

a. We do accept evidence of recent blood donation as proof of negative HIV, HepatitisB and C status. In order to do this we require to see the blood donor card and proof of when the donation took place. I do not believe that this is a breach of the Code of Practice. The issue of identity check is not covered in either the ACE guidelines or the COP.
b. With regard to egg donation, whilst we may accept blood donation as an initial screen for HIV, the practicalities of requiring a second sample within the treatment cycle mean that this is invariably done at CARE as there is not enough time to ascertain that the blood donation has been accepted.

4. Surrogacy

The policy of the unit is to advise surrogates that a period of quarantine is advised for either sperm or embryos to be transferred in a surrogacy arrangement and we have undertaken a number of cycles in the last year in which such a period of quarantine has taken place. **When requested by the surrogate to waive this period of quarantine, after appropriate counselling about possible risks, we have undertaken fresh embryo transfers.**

Justification

The guidelines which exist for screening of the commissioning couple in a surrogacy arrangement are flawed. The original guidelines related to sperm as published by the British Andrology Society 1999 relate to the use of donor sperm for insemination in an anonymous donation. In a partial surrogacy arrangement (which is the only type of surrogacy we carry out), IVF is required and therefore the sperm itself is not inseminated into the patient. The COP fails to distinguish between different types of surrogacy and therefore any guidelines contained within it have doubtful relevance. The surrogacy arrangement is not anonymous. i.e. the surrogate has been in contact with the commissioning couple for at least 6 months prior to treatment.

The guidelines at the moment indicate that sperm should be quarantined for 180 days for the male partner of a commissioning couple but that eggs from the female within the same relationship can be used fresh. Whilst difficulties with egg freezing mean that egg donation uses fresh gametes, it is clearly illogical to insist on a period of quarantine for sperm and to use eggs fresh when both partners are in a relationship where sexual transmission of HIV is possible. I do not believe that the 'recommendations for Good Practice on screening of Egg and Embryo donors' BFS have explored all possible scenarios. As far as I am aware they were put forward as recommendations and thus it is difficult to see how a 'breach' of recommendations can occur.

The quarantining of embryos for 6 months is more logical, however frozen embryos have less chance of achieving a pregnancy than fresh and therefore an insistence on using frozen embryos significantly reduces a commissioning couple's chance of achieving a pregnancy, putting them at a disadvantage to other patients requiring IVF and prejudicing their treatment. Often stimulation of the ovaries and the procedure of egg collection is difficult in surrogates due anatomical abnormalities i.e.Rokitansky Syndrome or previous surgery i.e. hysterectomy. Reducing the number of such procedures necessary by increasing the chance of success must be considered.

In practice couples wishing to commission a surrogacy arrangement have often had years of HIV testing prior to their treatment cycle. We insist that copies of previous results are available and repeat these tests at consultation and in the treatment cycle. At CARE, Manchester, we have just completed an audit of repeat HIV, Hepatitis B and C tests (as the policy at the moment is to repeat yearly) in our IVF patients. We now have over a thousand repeat tests and have not seen a new positive result in all these patients. We therefore have evidence that the likelihood of HIV infection in patients who have previously had a negative result is nil. In this era of evidence-based medicine I wonder

whether the HFEA have evidence to support the need to quarantine embryos. Does the HFEA or anybody know the incidence of new HIV infection in couples within a stable relationship i.e. those undergoing IVF or surrogacy? CARE's experience is that this is nil.

As surrogates are given this information, this would seem to be an issue of 'informed consent'. If surrogates request fresh embryo transfer after being counselled as to a possibility of infection it would seem not unreasonable to facilitate this.

Perhaps, with revision of the HF&E Act, the specifics of surrogacy could be looked at as an entity on its own rather than trying to fit it in to the anonymous donation scenario.

5. Dewar alarms
Alarms are being sourced and the HFEA will be informed of their implementation.

6. Counselling
It is difficult to conceive of a way to make counselling more accessible as we have an open access system. The provision of a direct line would not answer this need as our counsellors are part-time and therefore patients would have to leave a message on an answer phone a great deal of the time. The clinic will continue to explore this service.

7. Consent forms for storage of sperm and information for egg or embryo donors has been reviewed and is enclosed.

Licence Committee Meeting

10 July 2006
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 3

CARE Manchester (0185)
Licence Renewal

Members:
Walter Merricks, Lay Member – Chair
Jennifer Hunt, Lay Member
Hossam Abdalla, Director of Lister Fertility Centre

In Attendance:
Frances Clift, Legal Adviser
Marion Witton, Head of Inspection
Debra Bloor, HFEA Inspector
Claudia Lally, Committee Secretary

Observing:
David Archard, Lay Member
Ruth Fasht, Lay Member

Observers from Korea:
Ock-Joo Kim, MD., Ph.D., Member of Bioethics Education and Assessment Subcommittee, National Bioethics Committee Professor, College of Medicine, Seoul National University.
Jung Ok Ha, Ph.D., Member of Assisted Reproduction Subcommittee, National Bioethics Committee Senior Researcher, Institute for Gender Research, Seoul National University
Hae Wol Cho, Ph.D., Director General of National Institute of Health, Korea
Inho Jo, Ph.D., Director General of Center for Biomedical Sciences, NIH, Korea
Sung Soo Kim, Ph.D., Senior Scientist, Division of Life Science Research Management, NIH, Korea

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

The following papers were considered by the Committee:

- papers for Licence Committee (67 pages)
- no papers were tabled.

1. The papers for this item were presented by Marion Witton, Head of Inspection and Dr Bloor, HFEA Inspector. Dr Witton informed the Committee that this centre currently carries out approximately eleven hundred treatment cycles per year. The centre provides treatments primarily to self funded patients referred

from the North West of England. A number concerns were recorded in the inspection report.

2. The Committee noted that the inspection team had been concerned about staffing levels in the laboratory in relation to the number of treatments taking place. The Committee also noted the Person Responsible's response to this problem, included in the report at appendix C. Dr Bloor stated that although the centre has submitted a risk assessment addressing this issue, this assessment does not look in detail at the level of activity which current staffing levels can safely support. The Committee supported the recommendation made in the report that the centre should submit to the HFEA a detailed risk assessment which addresses in detail the question of how many treatment cycles can be safely accommodated given current staffing and equipment levels.

3. The Committee noted that at the time of the inspection there were a number of cryopreserved samples for which there were no valid consents to storage. The Committee noted that the centre is taking action to resolve this issue and asked Dr Bloor to monitor the progress being made. The breaches of the Human Fertilisation and Embryology Act 1990, Schedule 3, paragraph 8 (1) and (2) were noted.

4. The Committee noted that the centre accepts evidence of recent blood donation as proof of negative HIV and Hepatitis status. The Committee noted that it might be difficult for the centre to securely establish the origin of a blood donation certificate. The Committee expressed concern that the centre were placing so much faith in a certificate the provenance of which they could not be certain. The Committee noted that in doing so, the centre left themselves open to the challenge that they were compromising the safety of its stored samples.

5. Dr Bloor informed the Committee that the centre does not always quarantine sperm prior to the insemination of eggs where the resulting embryos are to be transferred in a surrogacy arrangement. This is a breach of Appendix C of the Code of Practice and of British Andrology Society and British Fertility Society Guidelines. Dr Bloor informed the Committee that the Person Responsible has reviewed this practice and considers it appropriate. The Committee noted the Person Responsible's comments, at Appendix C of the report, and in particular the statement that the quarantine is only waived when this is requested by the surrogate. However, the Committee expressed the view that it was possible to imagine pressure being brought to bear on the surrogate in such a situation. The Committee agreed to refer this issue for consideration by the Authority's Regulation Committee. Meanwhile, the Committee noted the breach of the Code of Practice. The Committee agreed that whilst the guidance set forth in the Code of Practice is not mandatory, and leaves room for the exercise of clinical judgement, it is regrettable that the centre appears to have decided not to follow this advice as a matter of policy.

6. The Committee noted that the centre has not fitted low nitrogen alarms to all of its dewars. The Committee noted that this was a breach of Chair's letter CH(04)03 and agreed that the centre should install alarms, and notify the Authority accordingly, within three months of receipt of these minutes. The Committee asked Dr Bloor to bring this issue back to the Committee in three months time if it has not been resolved by then.

7. The Committee noted that feedback forms from patients had expressed the view that the counselling service was difficult to access. Dr Bloor informed the Committee that this comment was frequently made on patient questionnaires regardless of the take up of counselling by patients. The Committee asked that this question be referred to Regulation Committee for further discussion and to assess the wording of the questionnaires. The Committee noted the comments of the Person Responsible, however the Committee also agreed that the provision of a direct line to the counselling service, with an answer machine which counsellors could access remotely, might be a useful measure.

8. The Committee noted the centre's low risk score. However, on the basis of the number of regulatory issues raised in the inspection report the Committee agreed to renew the centre's licence for a period of three years. The Committee requested that the centre be subject to an interim inspection at which resolution of the issues raised in the report can be monitored.

Signed……. … Date……..
Walter Merricks (Chair)