Human Fertilisation and Embryology Authority

Report of a renewal inspection at

Hewitt Centre for Reproductive Medicine, Liverpool (0007)

May 2005

Contents

Key facts about the centre

Centre name Hewitt Centre for Reproductive Medicine

Centre address Liverpool Women's Hospital
Crown Street
Liverpool, L8 7SS

Centre number 0007

Person responsible Charles Kingsland

Nominal licensee D Iwan Lewis-Jones

Activities of centre

		2004
Licensed treatment cycles	IVF ICSI FET Egg donation Egg recipient	547 585 275 16 23
Donor Insemination		166
Unlicensed Treatments	GIFT IUI Ovulation induction Surgical sperm retrieval	
Research	Yes	
Storage	Yes	

Focus of inspection General renewal

Additional licence conditions Two

Licence expires 31 October 2005

Summary

1. The centre is part of the Liverpool Women's NHS Foundation Trust and was first licensed to provide infertility treatments in 1995. The unit provides NHS and self funding treatments to patients from the North West of England and North Wales. The centre is the largest provider of NHS assisted conception treatments in the UK and carried out approximately 1500 licensed treatment cycles in the period covered by this report.

2. The centre is negotiating to provide NHS funded treatments for patients from North Wales. This will increase the workload significantly in a centre already considered to be working at full capacity. The centre has experienced pressure on staffing in the nursing and administration teams in the last year and has reduced workload as a result. The PR considers that the management of the expansion of the service poses a considerable challenge. The centre should submit an action plan to the HFEA detailing how the planned expansion will be carried out.

3. The centre's documentation is generally of a high standard but requires updating. The centre is in the process of revising all documents in preparation for an application for ISO 9001 certification. The centre should use the review as an opportunity to address the issues raised in this report and submit a complete set of the centre's documentation on its completion.

4. A number of minor issues were identified during inspection and these are as follows
   - The security of the records stores and the cryostore was considered an issue of concern and the centre should review security in these areas.
   - Patients referred to the centre for storage of gametes prior to treatment that may impair their fertility are provided with information by a member of the seminology team. The centre should consider how counselling by an appropriately qualified member of the team can be made available to these patients.
   - The centre does not have specific information for children or young people seeking the storage of gametes prior to treatment that may impair their fertility. The centre should consider developing suitable procedures and information.
   - The complaints officer named in the centre's complaints policy is not included on the centre's licence. The centre should consider including the trust complaints officer on the HFEA licence**.**
   - Staff joining the unit do not always have an opportunity to take part in the centre's induction programme at or near the commencement of their employment. The centre should ensure that staff participate in the induction programme and keep a record of training and CPD.

5. The centre has a robust system of meetings and staff reported good communication across departments. The unit has an active programme of audit and quality assurance. Ongoing staff training and development is well supported and turnover is relatively low. The inspection team supports the renewal of the centre's licence for 3 years.

Background to inspection

6. This inspection report covers the time from the last inspection in May 2004 to May 2005 and includes outcome data from January to December 2004.

7. One hundred patient questionnaires were distributed during the four months preceding the inspection.

8. One site visit took place on 10 May 2005 and lasted 9 hours. An operational audit was carried out in January 2005.

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

The centre's context

10. The centre is part of the Liverpool Women's NHS Foundation Trust. Patients are referred to the centre from the North West of England and occasionally from Staffordshire, North Wales and Cumbria. Annually, the centre treats less than six patients from overseas. The centre has been commissioned to provide 750 NHS funded treatment cycles by 15 Primary Care Trusts (PCTs) in the region. Approximately one quarter of the treatments provided by the centre are self funded.

11. The centre is open from 0800 to 1800 Monday to Friday and between 0815 and 1315 on Saturdays. Medical, embryology and nursing staff operate a rota system to provide weekend staffing. The unit is staffed by a clinician or a nurse trained in embryo transfer, two embryologists and three nurses on Saturdays.

12. The PR finds the administrative burden imposed by the HFEA is a significant strain on resources. The centre is the largest provider of NHS funded IVF treatments in the UK. Historically, increases in HFEA levies caused significant difficulty for the centre which is having to renegotiate with commissioning PCTs for additional funding.

13. Due to an expanding workload, the centre experiences ongoing staffing difficulties in the nursing team. The number of treatment cycles carried out has been reduced for periods in the previous year due to inadequate staffing levels. An evaluation of the staffing needs of the centre has been carried out by the trust and this concluded that the centre's nursing team should be increased to include two additional whole time equivalent members of staff. Unfortunately the trust has been unable to provide funding for the additional staff members. In recognition of the staffing deficiencies the centre has reduced the number of cycles carried out by approximately 25% and recruitment is in progress.

14. The position of nominal licensee is currently held by the senior andrologist who provides the centre with specialist expertise. However the centre should consider transferring this role to a member of the trust's senior management team as recommended in chair's letter CH(01)01. This change in the

centre's licence could improve links with the wider trust and more direct involvement could increase awareness of the impact of resource issues within the centre.

15. As a result of the implementation of guidelines issued by the National Institute for Clinical Excellence (NICE) on the provision of IVF treatment the centre is in negotiations to provide NHS funded treatment for North Wales. This will increase the workload at the centre significantly. The PR does not consider that the current premises are adequate to accommodate the expansion and the centre is involved in negotiations with the trust to obtain additional space within the Liverpool Women's Hospital. Alternatively, the PR has proposed that self funded treatment could be carried out on a new site**.**

16. The previous licence committee commented that the centre was operating at full capacity. In the time covered by this report the number of treatment cycles increased by approximately 100 cycles although as a result of staffing pressures, workload was reduced at the centre during the early part of 2005. The centre is in the process of planning how the additional NHS commissioning workload can be accommodated and should submit an action plan to the HFEA providing details of how workload is to be managed.

Type of work carried out

Licensed treatment

17. The centre carries out the following licensed treatments
    - Storage of sperm (patient)
    - Storage of sperm (donor)
    - Storage of embryos
    - Donor insemination
    - Gamete intra fallopian transfer (GIFT) with donor eggs
    - GIFT with donor sperm
    - In vitro fertilisation (IVF)
    - IVF with donor eggs
    - IVF with donor sperm
    - Intra cytoplasmic sperm injection (ICSI)
    - ICSI with donor sperm
    - ICSI with donor eggs
    - Chemical assisted hatching
    - Zygote intra fallopian transfer (ZIFT)

Treatments that do not need a licence

18. The centre carries out the following treatments that do not need a licence
    - Intra uterine insemination (IUI)
    - GIFT
    - Ovulation induction
    - Surgical sperm retrieval

Transport arrangements

19. The centre has transport arrangements with the following centres:
    - Karen Woodcock
      Countess of Chester Hospital
      Fertility Unit
      Liverpool Road
      Chester CH2 1UL
    - Wendy Mellor
      Leighton Hospital
      Middlewich Road
      Crewe, CW1 4QJ
    - Geneve Buchanan
      Whiston Hospital
      Bleeding/Early Pregnancy and Fertility Clinic
      Warrington Road
      Prescot, L35 5DR

20. The nurse coordinator and the scientific director carry out an annual inspection of the transport centres and produce a record of their findings. Transport centres also submit outcome data to the PR for discussion and review at biannual audit meetings.

Staff

21. The centre has a large staff but has a relatively low turnover. As a result of increasing workload, the centre has experienced understaffing in the administration and nursing teams during the past year (see paragraph 13). However, the centre has been proactive in managing staff shortages and has implemented a 25% reduction in workload.

Staffing profile

Person responsible	Charles Kingsland
Nominal licensee	D Iwan Lewis-Jones
Accredited consultant	3.4 WTE*
Other medical staff	3 (2 research fellows, 1 sub specialty trainee)
Embryologists	9 (1 director, 1 senior, 5 qualified, 2 trainee)
Laboratory assistants	1
ICSI practitioner	6
Consultant andrologists	1.2 WTE* (1 senior consultant, 0.2 consultant)
Seminologist	3 (2 full time, 1 part time)
Nursing staff	13 (1 co-ordinator, 8 full time qualified, 3 part time qualified, 1 full time qualified on maternity leave))
Health care assistant	3
Independent counsellor	2 (1 senior part time, 1 part time)
Administration staff	11 (4 part time)
Complaints manager	Liz Campbell

* Whole time equivalents

22. In the time covered by this report the centre have increased the clinical input at the centre by 0.4 WTE, nursing staff by 2 WTE, embryology staff by 1.5 WTE and administration staff by 1.8 WTE. The centre are actively recruiting a further 2.5 WTE nursing staff and a 0.5 WTE member of the nursing team is expected to return from maternity leave imminently.

Professional registration and continuing professional development (CPD)

23. Staff are recruited to the centre in line with the written recruitment policy of the trust. All staff recruited after the implementation of the policy have been screened by the criminal records bureau (CRB) although this has not carried out retrospectively. The CRB informs employers of any criminal activity undertaken by screened individuals.

24. Clinical staff are registered with the General Medical Council.

25. Nursing staff are registered with the Nursing and Midwifery Council.

26. Embryology staff are registered with the Health Professions Council (HPC) with the exception of the trainee embryologists who are working towards the Certificate in Clinical Embryology and subsequent state registration.

27. The HPC does not currently recognise the position of andrologist and as a result, laboratory seminologists are not registered.

28. The trust recruitment policy specifies a requirement for induction of new staff. However the induction programme runs sporadically and staff joining the unit do not always have an opportunity to take part in the induction programme at or near the commencement of their employment. The centre should ensure that all new staff have an opportunity to take part in the induction programme.

29. All staff undergo mandatory annual training in infection control, fire safety and manual handling.

30. All clinical staff undergo appraisal and continuing medical education in line with the requirements of the trust including training in basic resuscitation.

31. Nursing staff have good opportunities for training although staffing levels have impacted on training in the last year. A significant amount of in house training is provided in the centre. Members of the nursing team wishing to extend their role have either received accredited ultrasound scanning training, or are working towards accreditation. Specialist fertility nurses have received or are planning to undertake in house training in embryo replacement.

32. Embryologists and seminologists receive appropriate in house training and have opportunities and funding for attending external meetings. Embryologists are enrolled in the Association of Clinical Embryologists (ACE) scheme for continued professional development.

33. The centre is preparing for certification with the International Standardization Organization (ISO 9001) later in the year. In preparation for this, the centre has developed new job profiles that specify the required proficiencies for each post. It is expected that these profiles will be used during the annual personal development review to identify training requirements. It is recommended that the centre should use the accreditation process as an opportunity to formalise the identification of training requirements and to ensure that all staff maintain written records of training activities.

34. The centre carries out a monthly review of outcomes. Evidence from the minutes of team meetings shows that the centre is proactive in monitoring trends in outcomes.

35. The centre holds a weekly senior management team meeting. Minutes are taken at these meetings and copies were made available on the day of inspection. This forum is used for the discussion of patient issues, protocol review, adverse incidents, regulatory issues (HFEA Alerts), health and safety, and quality assurance. Information from the meeting is disseminated to all staff through departmental meetings.

36. The centre also holds a weekly “open agenda” meeting which is open to the entire team. This meeting is the forum for a monthly review of outcomes.

37. The centre employs part time staff in all departments and some staff do not have an opportunity to attend the Friday team meeting. The PR should consider how excluded staff members might be given the occasional opportunity to participate.

The premises, equipment and other facilities

Premises

38. The premises appeared spacious and well presented.

39. There have been no changes in the premises since the last inspection.

Equipment

40. There have been no changes in equipment since the last inspection.

Security

41. Laboratories and the cryostore have controlled access. Clinical and treatment rooms can be locked when occupied.

Confidentiality

42. Patients enter the unit into a spacious waiting area which has a screened reception area. Off this reception area is a records store. The door to the record store is not locked during normal working hours. Staff consider that the store is secure because the reception area is manned continuously but the inspection team were concerned that if the reception staff were distracted or engaged with a patient this room could be entered unseen. When leaving the centre, at a time when the exterior unit doors were still open, members of the inspection team were able to access the records store without challenge.

43. The unit stores current patient records in filing cabinets behind the nurse’s station. The cabinets are not locked during normal working hours. Unauthorised access to the cabinets in this area would be immediately obvious to a member of the unit’s staff but again, the inspection team were concerned that if the station was unmanned, then access would be possible. The centre should review the security of its records stores and consider installing locks as appropriate.

Arrangements for collecting sperm samples

44. The majority of sperm samples are produced off site. The centre has adequate procedures for receiving samples and obtains written confirmation of the samples provenance.

Cryostore facilities, oxygen and dewar alarms

45. As recommended in the previous report, ventilation in the cryostore has been improved and keys to dewars are now inaccessible. Staff consider the area secure because the store is adjacent to the nurse's station, but the centre should include this area in its review of security.

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

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

48. Dewars are alarmed and are connected to an auto dial up system.

49. The cryostore is fitted with a low oxygen level alarm and the centre has developed an appropriate procedure for responding to the alarm. Staff have received training in how to respond to a low oxygen level alarm.

Emergency facilities

50. Patients requiring critical care can be admitted to the on site high dependency unit or can be transferred to intensive care facilities within the trust.

Clinical, nursing and laboratory procedures

Clinical and Nursing

51. The clinical and nursing protocols that were submitted with the renewal application do not provide detailed instructions for staff on how a procedure should be carried out. Many protocols serve as checklists and referral criteria. Protocols show varying degrees of revision and version control. The centre is in the process of reviewing all its documentation in preparation for making an application for ISO certification. On the day of the inspection, newly revised nursing protocols were seen. These protocols satisfied the inspection team that a thorough and rigorous review of standard operating procedures is in progress. A complete set of revised clinical and nursing standard operating procedures should be submitted to the HFEA on completion of the review.

52. As part of its ongoing review of documentation the centre should consider including information in clinical and nursing protocols that clarifies the responsibilities of staff to confirm identity, ongoing consent and in repeating WOC assessments in line with the requirements of sections 3.5, 3.6 and 6.4 of the COP before carrying out treatments.

53. Adequate protocols are in place for the management of ovarian hyperstimulation syndrome (OHSS).

54. Members of the nursing team who have elected to develop their role have been trained to carry out IUI, ultrasound scanning and embryo transfer.

Laboratory

55. Laboratory protocols are version controlled and show evidence of revision and reflect current laboratory practice.

56. There are written standard operating procedures for cleaning vessels, filling vessels, freezing and thawing procedures, location and duration of storage.

57. The centre does not have a standard operating procedure for securing vessels and handling of contaminated samples. Suitable protocols should be developed and submitted to the HFEA on completion of the review of documentation.

58. Witnessing stages are documented in protocols and the centre has comprehensive procedure witnessing forms for completion at key stages.

59. The centre stores samples for patients undergoing treatment that may impair their fertility. Storage of these samples is split between two locations.

Procedures for assessing clients and for assessing and screening donors

Welfare of the child

60. The centre has written patient information that explains the welfare of the child assessment procedures used by the centre. The centre asks patients for their consent to disclose of their treatment to their GP and once consent is granted, a GP report for both partners is sought. Refusal to consent to disclosure to a GP is taken into account when considering whether to offer treatment. The GP report addresses issues related to social and medical history that may be relevant to the provision of treatment.

61. Patients are asked to complete a self assessment questionnaire that addresses
    a. the commitment to raise children
    b. ability to provide a stable and supportive environment for a child/children
    c. immediate and family histories
    d. age, health and ability to provide for the needs of a child/children
    e. the risk of harm to children including inherited disorders (or transmissible diseases), multiple births, neglect or abuse, the effect of a new baby or babies upon any existing child of the family

62. A detailed medical history taken at the time of referral addresses issues related to the risk of inherited disorders and immediate and family histories.

63. The centre has a written protocol that details the procedure when a patient refuses to consent to the disclosure of their treatment to their GP. This includes obtaining consent to contact and subsequent contact with appropriate external agencies, verifying identity and referral to the ethics committee. The centre also has a written protocol for refusing treatment based on WOC considerations.

64. The centre has an appropriate policy for addressing WOC issues where patients are foreign nationals not normally resident in the UK.

65. The centre provides relevant, up to date written information to patients on issues of parental responsibility. The centre's consent forms request and advise that the male partner of an unmarried couple acknowledge and consent to the treatment although it is noted that this consent is not required.

Ethics committee

66. The centre has access to an ethics committee. The remit of the committee is to provide advice and guidance concerning ethical issues arising from the provision of assisted conception treatments. The centre has a written policy on providing patients with information about a referral to the ethics committee and providing them with a written report of the considerations.

67. Information for patients describes the ethics committee as an independent body however the scientific director and the ward manager of the centre are both members of the seven person committee. The centre should consider advising patients that the committee comprises some representatives of the unit's senior management.

68. Approximately 12 cases are referred to the ethics committee annually with approximately one third of those referred being refused treatment. Minutes of management meetings and patient records showed evidence of consideration of issues by the ethics committee

Assessing and screening donors

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

70. The centre does not have an egg share programme but recruits a small number of egg donors (14 in the time covered by this report).

71. Egg and embryo donors are screened for HIV, hepatitis, syphilis, CMV, chlamydia, and cystic fibrosis. Donors are also karyotyped.

72. Prior to egg collection, patients making an ovum donation are asked to sign a declaration that they have no reason to suspect that they or their partner could be infected with HIV or hepatitis or that they have been involved in behaviour that would make them at high risk of infection.

73. All donors are made aware of the availability of counselling through patient information. Three to four sessions of counselling are mandatory for all known donors.

74. Patients are provided with written information that explains the reason for HIV and hepatitis screening. This information currently states that the HFEA requires all patients undergoing treatment to be screened for HIV and hepatitis. The information should be revised to reflect that the 6th Code of Practice (COP) requires all gamete donors and all patients placing gametes, embryos or ovarian or testicular tissue in storage to be screened for hepatitis and HIV. Screening is not required by the HFEA for all patients undergoing treatment.

75. The centre's current written information for gamete or embryo donors does not include information on why screening tests are carried out (with the exception of HIV and hepatitis), that the tests may reveal previously unsuspected conditions, that a donor can withdraw from the process of

donation at any time until embryos or gametes have been used in treatment (as required by section 4.1 of the COP) or the limitations of the testing procedures (as required by section 4.18 of the COP). The written information does not explain that screening tests for Tay-Sachs, thalassaemia and sickle cell anaemia may also be carried out in individuals from relevant population groups (section 4.14 of the COP). This information should be included in the revised patient information currently being prepared by the centre.

76. The centre supplying sperm advises the centre when a donor is approaching the ten live birth event limit. After this information has been received, sperm samples are not used without authorisation from the supplying centre. The centre does not have a system for ensuring that egg or embryo donors do not exceed the ten live birth event limit. Although it is recognised that this is unlikely to occur, the centre should ask egg and embryo donors to confirm whether they have made previous donations.

Counselling process and facilities

Counselling protocols

77. Counselling protocols are appropriate and version controlled and show evidence of revision. The protocols reflect current and good practice in line with professional body guidelines.

78. The senior counsellor is a trained social worker and is confident to carry out assessment counselling. The centre also has access to independent social workers if required.

79. The centre has two counsellors who spend 32 and 22 hours per week respectively at the centre. This means that patients can receive counselling at short notice if required. The counsellors are fully integrated into the team.

Counselling referral arrangements

80. The centre provides implications, therapeutic and support counselling.

81. Patients are advised of the availability of counselling in general and specific patient information and members of staff encourage patients to use the service.

82. Information on referral to the counselling service is provided in written information for patients. Patients are advised of a telephone number that gives access to a message line when patients wish to self refer. Alternatively, patients can be referred by any member of the unit's staff.

83. Patients can be referred for specialist genetic or infectious diseases counselling.

84. All counselling is provided free to NHS funded patients or without additional charge to self funding patients. The service is available after delivery if required.

85. Patients having treatment that may impair their fertility can be referred to the centre at very short notice; occasionally on the day that life threatening illness has been diagnosed. These patients are provided with information by a member of the seminology team. The centre should consider how these patients can best be provided with adequate counselling by an appropriately qualified member of the team. The centre should also develop suitable patient information for these patients and protocols for staff outlining the circumstances in which children and young people can consent to the storage of sperm in line with the requirements of section 6.10 to 6.12 of the COP.

Supervision and professional registration

86. Both counsellors have appropriate experience and qualifications and receive professional supervision. Counsellors are supported in training and CPD.

Counselling audit

87. A comprehensive audit of counselling covering the period from March 2004 to February 2005 was submitted with the renewal application. A total of 255 patients received 442 counselling sessions. This represents a counselling uptake of approximately 19% (data for the total number of patients treated relates to January to December 2004). 19% of the patients who received counselling referred themselves to the service.

Location of counselling facilities

88. The centre provides a private and comfortable room for counselling which ensures confidentiality. However, this room is in frequent use and an alternative room is used on occasion. The centre should consider the provision of additional counselling facilities when developing plans for expansion of the unit's accommodation.

Patient experience

Patient feedback

89. The centre carries out a rolling programme to gather patient feedback on aspects of the centres practice. The centre is in the process of analysing information gathered from patients attending a patient information evening.

90. One hundred HFEA patient feedback questionnaires were distributed in the months preceding the inspection; 23 responses were received by the HFEA. The feedback was very positive with 14 respondents having compliments about the care they received and 4 patients having complaints. When asked about the counselling service, 19 patients had been aware of the service but 8 stated that the service was not made accessible. However, evidence from the counselling audit shows that 19% of the patients who received counselling referred themselves to the service (see paragraph 87).

Patient information

91. Patient information and consent forms are given to patients at the patient information evenings; these are attended by the PR and the nursing specialists. The information is discussed with patients who also have the opportunity to ask questions. The information and consents are discussed again during the patient's first appointment so that any questions or concerns can be addressed.

92. Patient information on OHSS includes clear instructions on what the patient should do if they have symptoms of the condition. The information states that in rare cases OHSS can result in death.

93. The patient information submitted with the centre's application contained a number of minor errors. These were discussed with the HFEA Register Form Co-ordinator who noted the errors and agreed to ensure that documents are revised appropriately. Errors included spelling mistakes, lack of version control and the updating of the HFEA address and telephone number in the patient information leaflet on the welfare of the child.

94. Patient information for specific treatments is clear and comprehensive with the following exceptions
    - Patient Information relating to the removal of donor anonymity is provided as a stand alone page and this information should be incorporated into the literature provided for donors and recipients of donor gametes or embryos.
    - Patient information provided to egg donors refers to "10 children"; this should be replaced with "10 live birth events".
    - Patient information for freezing and storage of sperm needs to be updated in line with the Deceased Father's Act 2005.
    - Patient information provided on HIV and hepatitis screening, should be changed to clarify that the HFEA does not require all patients having IVF treatment to undergo screening for HIV and hepatitis

- Consent forms for oocyte donation and embryo donation include a three embryos transfer option that is not in accordance with the COP section 8.21.
- Patient information for donors does not adequately reflect that donors are able to withdraw consent up to the point when gametes or embryos created using gametes are used.
- Patient information does not include guidance on making a complaint.

95. These issues should be addressed as part of the review of all literature which is taking place in preparation for the application for ISO 9001 certification.

Record keeping procedures

96. An operational audit was carried out at the centre in January 2005. During the audit, 148 patient files were reviewed for consent to treatment, use and storage of gametes and to assess whether issues relating to the welfare of the child were properly considered and recorded by the clinic. In 144 cases the necessary written consent to treatment and use and storage of gametes had been obtained from both partners.

97. A review of a further eight patient records was carried out during the inspection. In six of these records all documentation was present and correctly completed.

98. The table below provides a summary of the errors in patient records recorded during the operational audit and on the day of inspection. These errors represent an error rate of approximately 5%, suggesting that the centre has a robust system for the completion of consent forms and welfare of the child assessments.

Error	Breach of Code reference	Number of errors
(00)6 or (00)7consent forms missing from file	**1990 HFEA Act Schedule 3 paragraph 6(3)** An embryo the creation of which was brought about in vitro must not be used for any purpose unless there is an effective consent by each person whose gametes were used to bring about the creation of the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents.	3
No WOC assessment in record	**1990 HFEA Act Section 13 (5)** A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father) and of any other child who may be affected by the birth.	3
No repeat of WOC following a break in treatment	**COP section 3.5** Treatment centres are expected to repeat the welfare of the child assessment where there has been: (i) A gap of two years or more in contact between the clinic and the patient(s)	1
Patients not provided with a copy of their (00)6 or (00)7consent forms	CE007 Guidance notes for the completion of HFEA (00)6 and (00)7 (20 July 2000)	2

Three embryo transfer arrangements

99. The centre provides written information to patients that outlines the current HFEA policy on the number of eggs/embryos that can be transferred during treatment.

100. Patient records contained documentation of the reasons for three embryo transfers in line with the requirements of the COP.

101. The patient consent forms for recipients of donor eggs include a three embryo transfer option (see paragraph 94). Section 8.21 of the COP states that where donated fresh or frozen eggs or embryos are used, centres are expected to ensure that no more than two eggs or embryos are placed in a woman regardless of her age at the time of transfer and regardless of the procedure used. The consent forms should be revised to reflect this requirement.

102. Clinical protocols for embryo transfer and GIFT do not reference the HFEA guidelines relating to the number of eggs or embryos that can be transferred. The centre should revise the protocols to reflect the requirements of sections 8.20 and 8.21 of the COP.

Audit

Centre's own audit of stored material

103. The centre completed an audit of stored material in March 2005. The centre should submit a report of the findings of the audit to the HFEA.

104. The centre currently stores approximately 4500 embryos for 1100 patients and 3500 semen samples for 1300 patients. The annual audit of samples is estimated to take more than 800 working hours. The centre acknowledges the value of a periodic review of stored material but questions the value of an annual review especially since all material moved in and out of storage dewars is now witnessed by two individuals. The centre is also concerned that the repeated handling of samples may compromise viability. The licence committee are asked to consider what, if any, alternative practices would allow the centre to fulfil the requirements of the code of practice.

Spot check of tracking process for stored material

105. A spot check tracking two sperm samples and two embryos from patient file to dewar and from dewar to patient file was completed successfully with no discrepancies observed.

HFEA register

106. An operational audit was carried out at the centre between in January 2005. During the audit, 148 patient files were reviewed for consent to treatment, use and storage of gametes, and to assess whether issues relating to the welfare of the child were properly considered and recorded by the clinic. The results of this audit are outlined in paragraphs 96 to 98.

107. The audit also included a review of 376 treatments to evaluate whether reporting of treatment cycles by the centre is complete and accurate. The systems for handling information relating to patients, treatments and HFEA forms were also reviewed. The audit team concluded that the systems for collating and recording data were robust; the reporting of treatment cycles is complete; the reporting of HFEA register information is accurate.

Clinical governance

108. The centre is part of the Liverpool Women's NHS Foundation Trust and adheres to the clinical governance policy of the trust.

Risk management

109. The centre carries out monthly reviews of outcome and the laboratory carries out a programme of regular quality assurance checks. All equipment is serviced appropriately and the centre has installed a monitoring system that alerts staff to malfunction in all key laboratory equipment.

110. The centre has a written incident policy that was seen on the day of inspection. The centre reported three incidents to the HFEA in the time covered by this report: all of the incidents were dealt with appropriately.

111. Information from Alerts is disseminated through the weekly senior management team meeting and departmental meetings as appropriate.

Complaints

112. The centre adheres to the trust's written complaints policy. The policy provides clear instructions on the appropriate management of complaints but does not include specific information on the management of complaints from the reproductive medicine unit. The centre should revise the trust's complaints policy to include advice on how constraints on patient confidentiality affect reporting of complaints to non-licensed individuals. The complaints manager identified in the policy is not included on the HFEA licence and the centre should consider including this individual.

113. The centre received one complaint in the time covered by this report. The centre took appropriate action in response to the complaint which resulted in changes in the pharmacy department waiting area and in the advice given to patients collecting prescriptions.

Breaches of the Code of Practice or Act

114. Information for gamete and embryo donors does not comply with the requirements of sections 4.1, 4.18 or 4.14 of the COP (see paragraph 75).

115. A small number of errors were observed during the operational audit of records and during the review of records carried out on the day of inspection and these are detailed in paragraph 98.

Compliance with previous conditions and recommendations

Conditions

116. The centre's previous licence included two additional conditions and these are listed below.

117.

Conditions	***Adopted by centre (Y/N)***	***Comment***
1. That the centre submit to the Authority within 28 days an action plan demonstrating how the centre will contact all relevant patients to advise them of the Deceased Father's Act 2003. The date for completion of this contact should be no later than 31 March 2005. This plan should also include procedures for ensuring regular annual contact with patients with regard to their stored material (as required by the Code of Practice 9.1).	Y	
2. That the centre ensure that when they permit a man to provide sperm produced at home, there is full compliance with section 8.14 of the Code of Practice.	Y	

Recommendations

118. The licence committee considering the centre's previous interim report made six recommendations. They are listed below along with the centre's response.

119.

Recommendation	***Adopted by centre (Y/N)***	***Comment***
1. The centre should ensure that the keys for the dewar padlocks are not left on display if the cryostore door is left open	Y	
2. The ventilation in the cryostore should be improved to remove the perceived requirement that any work in the store be conducted with the door open	Y	
3. The centre should update and implement a witnessing protocol to better reflect compliance with current HFEA Directions, and submit this updated protocol to the Authority	Y	
4. The centre should produce a written protocol for how it traces what happens to individual embryos, eggs and sperm samples from the date of collection	N	Working towards compliance
5. The centre's patient information should be updated in the light of the sixth Code of Practice and the removal of donor anonymity	Y	Agreed to make further revision
6. The Person Responsible should read the independent report conducted on behalf of the Department of Health by Professor Toft.	Y	

Key points for the Licence Committee

120. The inspection team supports the renewal of the centre's licence for treatments set out in paragraph 17 above.

Issues

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

- At the time of the last report the centre was considered to be operating at full capacity. In the time covered by this report the number of treatments increased by approximately 100 cycles and the centre has experienced staff shortages in the nursing and administration teams. The centre is in negotiations to provide NHS treatments for North Wales and expects workload to increase further (see paragraphs 13 to 16). The centre is in the process of planning how additional workload can be accommodated and should submit an action plan to the HFEA providing details of how the expected increase in workload is to be managed in the next year.
- The centre's documentation requires updating in a number of areas (see paragraphs 51, 74, 75, 75, 93, 94, 101 and 102). The centre is in the process of reviewing all its documentation in preparation for making an application for ISO certification. On the day of the inspection newly revised nursing protocols were seen. These protocols satisfied the inspection team that a thorough and rigorous review of documentation is in progress. A complete set of revised documents should be submitted to the HFEA on completion of the review.
- Patient records are stored in a room off the reception area and in filing cabinets behind the nurse's station in the main clinical area. The inspection team were concerned that if the reception staff are distracted or the nurses station was unmanned the security of patient records could be compromised (see paragraphs 42, 43 and 45). There were similar concerns about the security of the cryostore. The centre should review the security of its records stores and the cryostore.
- Patients referred to the centre for storage of gametes prior to treatment that may impair their fertility are provided with information by a member of the seminology team (see paragraph 85). The centre should consider how counselling by an appropriately qualified member of the team can be made available to these patients.
- The centre does not have specific information for children or young people seeking the storage of gametes prior to treatment that may impair their fertility (see paragraph 85). The centre has not encountered this situation but should consider developing suitable procedures and information to ensure that if such a situation does arise, the centre are able to provide appropriate treatment quickly and sensitively.
- The complaints officer named in the centre's complaints policy is not included on the centre's licence (see paragraph 112). This may make the centre at risk of inadvertently breaching patient confidentiality when handling complaints. The centre should consider including the trust complaints officer on the HFEA licence.

- The centre's staff reported good opportunities for training and CPD but no records of training were seen on the day of inspection and not all staff have an opportunity to take part in an induction programme at or near the commencement of their employment (see paragraphs 28 and 33). The centre should use the ISO certification process as an opportunity to ensure that all staff maintain written records of training activities and to ensure that new staff have an opportunity to take part in the induction programme.

Appendix A The inspection team and staff interviewed

The inspection team

Bernard Bentick	Clinical advisor
Caroline Lewis	Social and ethical advisor
Debra Bloor	Chair, inspector, HFEA
Delia Kelleher	Inspector, HFEA
Mary Seller	Scientific advisor

Centre staff interviewed

Charles Kingsland	Person responsible
D Ivan Lewis-Jones	Nominal licensee

Nine other members of the centre's staff were also interviewed by the inspection team.

Conflicts of interest

None declared.