Human Fertilisation and Embryology Authority

Name of Centre: Lanarkshire Acute Hospital NHS Trust

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Report of an interim inspection at

Lanarkshire Acute Hospital
NHS Trust,
Airdrie
(0098)

Inspection Date: 19 October 2005
Date of Licence Committee: 27 April 2006

Contents

Key facts about the centre

Centre name Lanarkshire Acute Hospital NHS Trust

Centre address Infertility Department
Monkscourt Avenue
Airdrie
Lanarkshire, ML6 0JS

Centre number 0098

Person responsible Ian Smith

Nominal licensee John Browning

Activities of centre

		June 2004 – July 2005
Donor Insemination		47
Unlicensed treatments	Ovulation induction IUI with husband sperm Tubal surgery	
Research	None	
Storage	Yes	

Focus of inspection General

Additional licence conditions None

Licence expires 30 June 2007

Summary

1. The Lanarkshire NHS Trust Infertility Department is a small centre that provides NHS funded donor insemination treatments to patients from the local area. The centre has been licensed since 1992. The centre has a low volume of activity and provided 78 licensed treatments in the time covered by this report.

2. At the time of the interim inspection, not all dewars used to store patient samples were fitted with low nitrogen level alarms or auto dial facilities. In addition, approximately **10%** of the samples stored for patients who have had treatment that may impair their fertility have not been split between two storage locations. The centre has submitted a application to the Trust to secure funding for additional dewars and should inform the HFEA when the new dewars are installed and splitting of samples is complete.

3. A number of minor issues were identified and discussed on the day of the inspection and these are as follows:
   - Not all members of the team received training and CPD opportunities in the time covered in this report;
   - In feedback received by the HFEA from five patients who received treatment at the centre, three patients commented that the centre had not made counselling services accessible;
   - A number of laboratory protocols specified as required in section 2.16 of the COP have not been submitted to the HFEA;
   - Patient information does not explain what non-identifying information is available to patients receiving treatment with donated gametes or that patients and donors can consent to the exchange of non-identifying outcome information.

   These issues should be addressed as recommended in the report and revised documentation submitted to the HFEA with the next application

4. The centre's live birth rate per cycle started is above the national average figures reported in the 2005/6 HFEA guide to infertility. The centre is CPA accredited and takes part in NEQAS to assure quality of the andrology services. The inspection team would recommend the continuation of the centre's licence.
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Focus of the Inspection

5. The focus of the interim inspection was derived by consideration of information from the previous report, the centre's application, Licence Committee minutes, information from the registry, finance, audit and clinical governance departments of the HFEA and the risk management tool. The inspection team also monitored how guidelines that came into effect in the time covered by the report were implemented by the centre.

6. The inspection focused on the following aspects of the centre's practice
   - Training, induction and continued professional development (CPD);
   - Patient information, particularly in relation to revisions introduced as a result of changes in donor anonymity;
   - Implementation of guidelines in relation to splitting of samples stored for patients who have had treatment that may impair their fertility;
   - Counselling practice.

7. The inspection included a general laboratory inspection and discussion with the PR about general management of the facilities and service.

8. Aspects of the centre's procedures and practices which have not changed in the time covered by the report were not reviewed in the course of the inspection.

Background to inspection

9. This report covers the period from October 2004 to September 2005 and includes consideration of outcome data from the period June 2004 to May 2005.

10. One site visit took place on 19 October 2005 and lasted seven hours.

11. The last operational audit inspection was carried out in December 2002.

12. The centre reviewed the report in January 2006.

The centre's context

10. The centre is part of the Lanarkshire Acute Hospitals NHS Trust and is based in the Monklands Hospital in Airdrie. The centre provides NHS funded donor insemination (DI) treatments to patients from the local area.

13. The centre reported a decline in the number of patients seeking DI treatment in the time covered by this report. This was attributed to patients choosing to have IVF treatment with ICSI rather than DI treatment. The centre also expects the reduction in availability of the sperm donors to impact on the provision of the service.

14. The centre operates from Monday to Friday.

Type of work carried out

Licensed treatment

15. The centre carries out the following licensed treatments
    - Donor insemination (DI)
    - Storage of sperm

Treatments that do not need a licence

16. The centre also offers intrauterine insemination (IUI) with husband's sperm, ovulation induction and tubal surgery treatments.

Staff

Staffing profile

17.

Person responsible	Ian Smith
Nominal licensee	John Browning
Medical staff	1
Andrologists	**5** (**2 Chief** 1 senior, **2** qualified biomedical scientists)
Nursing staff	2 (1 nurse co-ordinator, 1 staff nurse)
Independent counsellor	1
Complaints manager	Christine McNeil

18. A member of the clinical team retired in July 2005 and a biomedical scientist also left the team. Professional registration and continuing professional development (CPD)

19. The PR and other scientists are registered with the Health Professions Council (HPC). The NL (and accredited consultant) is registered with the General Medical Council (GMC). The two members of the nursing team are registered with the Nursing and Midwifery Council (NMC). Registrations were confirmed by accessing the relevant websites. The infertility uniit is recognised by the BFS and RCOG for the Special Skills Training Module In the Management Of The Infertile Couple and that Dr Conway is the recognised preceptor for such training.

20. The personal development plans (PDPs) for a sample of the centre's staff were reviewed in the course of the inspection. These plans showed that two biomedical scientists had received training and CPD in the time covered by this report but two other members of the team had nothing documented in their PDP since 2003. The PDPs of both members of the nursing team and the counsellor showed evidence of training and CPD in the last year. The PR should ensure that all members of the team receive appropriate opportunities for training and CPD, (including mandatory health and safety training) and that training opportunities are recorded.

21. All information on outcomes of treatment is recorded on the centre's database and a member of the nursing team monitors outcomes on a monthly basis. The PR reported that trends are difficult to monitor because of the small number of treatment cycles carried out and the large number of variables in the clinical background of patients seeking treatment.

22. Members of the team are in daily contact and issues relating to the provision of DI treatments are addressed as required. The centre operates a memo system which ensures that all staff are well informed of developments and/or issues and ad hoc meetings are arranged as required. The centre finds this arrangement more suited to the relatively **size and nature** of the infertility unit.

The premises, equipment and other facilities

Premises

23. There have been no changes to the premises since the last inspection.

Equipment

24. The centre purchased a new hot block in the time covered by this report and an additional cryopreservation dewar.

Security and confidentiality

25. The andrology laboratory and dewar storage room are locked when not in use. Patient records are stored in the nurses' room which is also kept locked when unoccupied.

Arrangements for collecting sperm samples

26. Most sperm samples are produced off site. The centre has a written protocol for accepting samples which documents the required checks on patient identity. Patients are required to sign a form to confirm the provenance of the sample.

27. The centre's policy is not to store semen for patients less than 16 years of age. However in the rare event of a young patient being referred for this service, their ability to provide informed consent is assessed by the PR. The centre should consider making appropriate literature available for these patients and formalising the assessment of "Gillick" competence to ensure that appropriate procedures could be followed in the absence of the PR.

Cryostore facilities, oxygen and dewar alarm

28. The centre has a dedicated storage room inside the andrology laboratory which stores five dewars. The laboratory and the cryostore have key pad locks. At the time of the interim inspection, two dewars did not have a low nitrogen level alarm and were not connected to autodial facilities. Three dewars were fitted with low nitrogen level alarms but only two of these dewars was fitted with autodial facilities.

29. One tank is used solely for the storage of donor sperm samples and **does not** require a low nitrogen level alarm.

30. At the time of the inspection, approximately **10**% of the samples stored for patients who have had treatment that may impair their fertility had been split between two storage locations.

31. 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 storing gametes and / or embryos for patients whose fertility may be impaired by medical treatment are now expected to divide individual patients' samples into separate storage vessels.

    Centres were expected to have implemented these guidelines by the end of June 2005. The centre has not been able to comply with this requirement and was in breach of these guidelines at the time of the inspection. However, the Trust has approved the capital expenditure required for the purchase of additional dewars to and the purchase of alarms and auto dial systems. However, if there is continuing delay in completing the installation of new equipment and splitting of samples the PR should carry out an assessment of the risk of failing to comply with this requirement and submit the assessment to the Trust's risk manager and the HFEA.

32. A large liquid nitrogen reservoir tank is connected to two of the dewars; this tank fills the dewars automatically, as required. The centre also monitors nitrogen use by all of the dewars and evidence of this monitoring was seen by an inspector. The centre has an annual service contract for the cryopreservation dewars and evidence of servicing was seen in the course of the inspection.

33. The cryostore has a low oxygen level sensor. The system contacts the PR on activation. The centre carried out a risk assessment for a large scale liquid nitrogen spill in liaison with the local fire brigade and has suitable protocols for responding to the low oxygen level alarm.

34. The centre should develop written protocols for responding to dewar alarms or a low oxygen level alarm and these should be submitted to the HFEA with the next licence application.

35. The centre has completed the process of contacting patients with sperm in storage to advise then of changes in the law as a result of the Human Fertilisation and Embryology (Deceased Fathers) Act 2003.

36. During the 2005 annual audit of donor sperm samples, expiry dates were changed in line with requirements on use of sperm following the removal of donor anonymity.

Emergency facilities

37. The centre is housed within the Monklands Hospital which has full facilities for treating patients in an emergency.

Clinical, nursing and laboratory procedures

38. Revised protocols submitted with the interim application are version controlled and some documents show proposed revision dates. The centre should ensure that all documentation shows revision dates.

Clinical and Nursing

39. Revised clinical protocols were submitted with the interim inspection. These were reviewed by the clinical inspector and were considered appropriate.

40. Both members of the nursing team carry out ultrasound scanning (USS). Both Nurses have attended the same accredited course. Section 1.8(iii) of the 6th Code of Practice states that all nursing and midwifery staff are expected to be appropriately qualified and to be working towards an accredited ultrasound course/qualification, if involved in that procedure. An assessment should be completed that considers any risks that may be associated with this members of staff carrying out USS. This risk assessment should be communicated to the Trust risk manager.

41. Nursing staff carry out inseminations and have received locally approved training in the procedure.

Laboratory

42. The laboratory has Clinical Pathology Accreditation and is accredited to provide training. The laboratory also participates in the National External Quality Assessment Service (NEQAS) which evaluates the centre's performance in semen analysis and sperm motility assessments. The inspection team was shown copies of NEQAS reports in the course of the inspection.

43. The centre has detailed laboratory protocols that are version controlled. The documents do not show a proposed revision date and it is recommend that at the time of the next review, this information is included.

44. There are written standard operating procedures for filling vessels and protocols describe how the cryostore is secured.

45. The infertility manual submitted with the interim application does not include protocols for the following:
    - freezing and thawing of samples;
    - how location of storage is determined;
    - how records are updated particularly in relation to recording duration of storage;

    These protocols are required by section 2.16 of the 6th Code pf Practice (COP). The centre should develop and/or submit these protocols to the HFEA at the time of the next application.

Welfare of the Child

46. Procedures for assessing the welfare of the child were reviewed at the time of the interim inspection in 2004 when they were considered to be appropriate.

Counselling

47. In feedback received by the HFEA from five patients who received treatment at the centre, three patients commented that the centre had not made counselling services accessible. This was discussed by the counsellor who commented that sessions can be arranged at weekends and in the evenings to accommodate patients. Patients are provided with contact details for the counsellor and can contact her directly if they choose. The counsellor does not consider the service to be inaccessible. The centre should consider gathering their own feedback from patients on the accessibility of counselling.

Counselling referral arrangements

48. Patients requiring counselling can be referred to external specialists.

Supervision and professional registration

49. The Counsellor is supervised for one and a half hours a month. The sessions are funded by the Trust. She reported good opportunities for training and CPD and this was confirmed by inspection of her PDP.

Counselling audit

50. The centre submitted an audit of the counselling sessions provided to patients for the period April 2005 to June 2005. The counsellor saw 10 of the 18 patients who received treatment in this time for a total of 28 hours of counselling time.

Patient experience

Patient feedback

51. The HFEA received feedback from five patients who received treatment at the centre in the last two years. Respondents were extremely positive in their comments. Three patients had compliments about the care they received and none of the patients had any complaints. The only negative comments related to the accessibility of the counselling service (see paragraph 47)

52. A patient was interviewed on the day of the inspection. The patient commented that they had found the patient information to be clear and understandable. They had been provided with emergency contact details, advised of the side effects of treatment and received information on how to make a complaint. The patient had felt able to ask questions and found the unit quiet, relaxed and private.

Patient information

53. Patient information was examined at the last renewal and interim inspections when it was considered appropriate.

54. An information sheet has been developed that advises patients of the changes in the law relating to donor anonymity.

55. Consent forms for patients having treatment with donor gametes do not reflect that recipients can consent to the exchange of non-identifying information on the outcome of treatment. The centre should revise consent forms to reflect that recipients can consent to the exchange of outcome information.

56. At present, patients undergoing treatment with donated gametes are provided with the information that is used in the donor selection process. Donor registration forms introduced in June 2004 may contain more detailed information than was previously available to the recipients of donor gametes. Patient information should also be revised to inform patients that non-identifying information that may be available to the recipients of donor gametes or children born as a result of treatment with donor gametes (chair's letter CH(04)07). It is expected that patients will approach centres for this non-identifying information in the first instance (see HFEA Update Issue 5, November 2004) and the centre should ensure that they have been provided with the necessary information by suppliers of donor sperm.

Record keeping procedures

57. The records of eight patients were reviewed in the course of the inspection and were found to be correctly completed and compatible with the treatments carried out.

Audit

Centre's own audit of stored material

58. The centre completed an audit of donor samples in the time covered by this report and submitted a report of the findings with the interim application. During this audit a single discrepancy in paper records was found and this was rectified.

59. All unscreened patient samples were audited at the time of splitting when all documentation was renewed to reflect changes in location of storage.

60. Screened patient samples were not split at the time of the interim inspection pending the purchase of an additional dewar and alarm systems. The audit of this material was delayed until the samples could be divided to minimise handling. No progress has been made with splitting of material so far.

Spot check of tracking process for stored material

61. A spot check of four sperm samples (two from tank to records, two from records to tank) was carried out. All samples were tracked successfully.

Clinical governance

62. The centre's clinical governance procedures were considered appropriate at the time of the previous renewal and interim inspections and were not considered in the course of the inspection.

Complaints

63. The centre received no complaints in the time covered by this report. The centre's complaints manager is not included on the centre's licence. The

centre should consider including the complaints manager on the licence to ensure that there is no inadvertent breach of patient confidentiality when complaints are reported.

Breaches of the Code of Practice or Act

64. Not all dewars used to store patient samples are fitted with low nitrogen level alarms or auto dial facilities and at the time of the inspection, approximately 50% of the samples stored for patients who have had treatment that may impair their fertility had been split between two storage locations (see paragraphs 28 to 31).

    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 storing gametes and / or embryos for patients whose fertility may be impaired by medical treatment are now expected to divide individual patients' samples into separate storage vessels.

    Centres were expected to have implemented these guidelines by the end of June 2005

Compliance with previous conditions and recommendations

Conditions

65. The centre's licence was renewed in July 2004 with no additional conditions.

Recommendations

66. The licence committee considering the previous renewal application made five recommendations. The centre had complied with four of those recommendations at the time of the last interim inspection. The fifth recommendation required the PR to organise a specified time each week when the counsellor is available and to promote the benefits of counselling more prominently in the clinic and literature. At the time of the previous interim inspection the centre commented that they did not consider this would be the best use of the counsellor's time and that the counselling arrangements meet the needs of patients. There have been no changes in the provision of the counselling service in the time covered by this report.

Key points for the Licence Committee

67. The inspection team supports the continuation of the centre's licence for treatments set out in paragraph 15 above.

Issues

68. The inspection team would like to draw the following points to the attention of the licence committee:
    - At the time of the interim inspection, not all dewars used to store patient samples were fitted with low nitrogen level alarms or auto dial facilities. In addition, approximately 50% of the samples stored for patients who have had treatment that may impair their fertility have not been split between two storage locations. This is a breach of the guidelines outlined in Chair's Letter CH(04)03. At the time of the inspection the centre had applied to the Trust to secure funding for the purchase of additional dewars to allow samples to be divided and the purchase of alarms and autodial systems. However, if there is continuing delay the centre should carry out an assessment of the risk of failing to comply with this requirement and submit the assessment to the Trust's risk manage and the HFEA (see paragraph 27-30)
    - Not all members of the team received training and CPD opportunities in the time covered in this report. The PR should ensure that all members of the team receive appropriate opportunities for training and CPD, (including mandatory health and safety training) and/or that training opportunities are recorded (see paragraph 20).
    - In feedback received by the HFEA from five patients who received treatment at the centre, three patients commented that the centre had not made counselling services accessible. The PR and the counsellor do not consider the service to be inaccessible. The centre should consider

gathering their own feedback from patients on the accessibility of counselling services (see paragraph 47).

- A number of laboratory protocols specified as required in section 2.16 of the COP have not been submitted to the HFEA. The centre should develop and/or submit these with the next HFEA application (see paragraph 45).
- The centre has developed patient information that explains changes in donor anonymity. However this information does not explain what non-identifying information is available to patients or that patients and donors can consent to the exchange of non-identifying outcome information. The centre should ensure that patients are provided with this information (see paragraph 53 to 54).
- The complaints manager is not included on the centre's licence. The centre should consider including the complaints manager on the licence to ensure that there is no inadvertent breach of patient confidentiality if a complaint is reported (see paragraph 63).

Appendix A The inspection team and staff interviewed

The inspection team.

Debra Bloor	Inspector, HFEA
Neelam Sood	Chair, Inspector, HFEA

Centre staff attending meetings with the inspection team

Ian Smith	Person responsible

Three other members of the centre's staff also met with inspectors.

Conflicts of interest

None declared.