Human Fertilisation and Embryology Authority

Report of Renewal inspection at

The Rosie Hospital, Cambridge (0051)

Date of Inspection 02.05. 2006
Date of Licence Committee 10 July 2006

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Key facts about the centre

Centre name The Rosie Hospital

Centre address Centre for Reproductive Medicine and Surgery
Cambridge University Hospital trust
The Rosie Hospital
Robinson Way
Cambridge, CB2 2SW

Centre number 0051

Person responsible Andrew Prentice

Nominal licensee K. Haynes

Activities of centre

		2005
Donor Insemination		43
Unlicensed treatments	Ovulation induction Ovulation induction with IUI Tubal surgery	
Research	None	
Storage	Yes	

Focus of inspection General

Additional licence conditions None

Licence expires 30 September 2006

Summary

1. The centre has been licensed since 1992 and is also a satellite centre of the Bourn Hall Clinic (centre 0100) for the provision of IVF. The centre offers licensed treatment of donor insemination to both private and NHS funded patients.

2. The current licence is due to expire on 30 September 2006. The centre has a good history of compliance with no previous conditions on its licence. The recommendations made by Licence Committee following the previous site visit have been implemented.

3. This renewal inspection was undertaken on 2nd May 2006. Currently the centre is carrying out around 43 treatments per year for donor insemination.

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

    - No breaches were found during the inspection.

5. The inspection team supports the renewal of the centre's licence.

Background to inspection

6. This inspection report covers the time from the previous inspection April 2005 to April 2006 and outcome data from January to December 2005.

7. One site visit took place on 2nd May 2005 and lasted 6 hours.

8. The report was reviewed by the centre in June 2006.

The centre's context

9. The centre offers licensed treatment to both private and NHS funded patients. All patients receiving licensed treatments are referred by the consultants of Addenbrooke's NHS Trust or by individual consultants in the private sector.

10. The centre is a satellite of Bourn Hall Clinic, Cambridge (centre 0100).

11. The centre is open from 0800 to 1800 Monday to Friday. After working hours and at weekends three doctors are on the rota and patients can contact the on-call gynaecology team at Addenbrooke's NHS Trust who then liaise with the centre's consultant staff.

12. The counsellor undertakes counselling sessions as required on an ad hoc basis. She also provides infertility counselling at Bourn Hall Clinic (centre 0100).

Type of work carried out

Licensed treatment

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

Treatments that do not need a licence

14. Super ovulation with intra-uterine insemination (IUI), ovulation induction and tubal surgery. The PR reported that the centre also undertakes artificial insemination of husband's sperm for sexual dysfunction although this is not included in the application.

Activity (treatment cycles)

15. The centre carried out 43 licensed treatment cycles in the period 1 January 2005 to 31 December 2005. The centre carried out approximately 250 satellite IVF cycles. The centre gets patients from four local PCTs and are in the process acquiring work from more PCTs.

Staff

16. The inspection team was informed by the Person Responsible (PR) that there have been no staff changes since the previous inspection except the Nominal Licensee.

Staffing profile

Person Responsible	Andrew Prentice
Nominal Licensee	K. Haynes
Other medical staff	One (sub specialist registrar)
Nursing staff	Seven
Independent Counsellor	One
Complaints Manager	Jane MacDougall

17. There have been some changes in the workload at the centre over the last year. The main reason for this is the change in law of donor anonymity. Donor patients are going in for ICSI and PESA since there is scarcity of donors.

Professional registration and continuing professional development (CPD)

18. A Review of pre-inspection documentation sent to the HFEA and the information obtained during the site visit confirmed that the staff at the centre is registered with the appropriate professional bodies.

19. The Nominal Licensee informed the inspection team that all staff attend mandatory training on Health & Safety and resuscitation. This training is provided by the hospital. Staff attend on a rota basis and their records were seen on inspection.

20. All new staff is appointed through the Cambridge University Hospitals Foundation Trust in accordance with the Trust's recruitment policy. All staff are subject to Criminal Records Bureau (CRB) checks.

21. Regular multi-disciplinary team meetings are held by the centre to discuss clinical issues. The minutes of the meetings are available to all the staff and an example of these was seen by the inspection team.

The premises, equipment and other facilities

Premises

22. There have been no changes in the premises since the last inspection in April 2005.

23. The centre's current licence and complaints procedure were clearly displayed in the waiting area.

24. The unit comprises of large office (which is shared by the nurses and it also holds the patients records in secure cabinets), a treatment room, a combined scanning and treatment room and offices for clinical staff. The unit has access to adjacent ward space. The cryopreservation dewars are stored in an adjacent laboratory.

Equipment

25. There have been no changes to equipment since the last inspection. The equipment maintenance log book was seen.

Security

26. All rooms within the unit are locked when unoccupied or when they are in use. All clinical and laboratory areas are restricted to authorised staff only.

Confidentiality

27. Patient records are kept in secure cabinets in the unit's office. The office is locked when unoccupied. Only staff included on the centre's licence have access to the records. The security arrangements were found to be adequate.

Cryostore facilities, oxygen and dewar alarms

28. The laboratory is shared with the University of Cambridge Department of Obstetrics and Gynaecology. Access to the room is controlled by a key pad and no one has access to gametes and embryos except the authorised staff. A research registrar is using the laboratory who has no access to the dewars.

29. It was noted that all cryopreservation dewars are locked and stored in the laboratory under the table. All were found fitted with low nitrogen level alarms and these are linked to an autodialler system.

30. Cryostore facilities were assessed as being adequate for the type and volume of activities carried out.

Emergency facilities

31. The unit has access to resuscitation equipment on the gynaecology ward which is situated adjacent to the unit.

Clinical, nursing and laboratory procedures

32. Standard operating procedures are version controlled and show evidence of review.

Clinical and Nursing

33. Clinical and nursing protocols were reviewed and considered appropriate. The protocols are dated and version controlled.

34. The centre has adequate procedures in place for the management of ovarian hyperstimulation syndrome (OHSS).

35. The four nursing staff have undertaken a four day transvaginal scan course and two of them have attended a three day British Andrology Society (BAS) andrology course. The induction training programme of the staff was seen. All the nurses have weekly meetings and a monthly nursing bulletin is provided to everyone. There is an operational meeting every two weeks which is minuted and log books were seen on inspection.

36. Nursing staff carry out ultrasound scanning and insemination procedures. They have a weekend rota system for follicular tracking and for donor inseminations.

Laboratory

37. Laboratory protocols were considered appropriate.

38. There are written standard operating procedures for thawing samples and location and duration of storage.

39. Appropriate protocols are carried out for witnessing procedures. The centre does not store samples for patients who have had treatment that may impair their fertility.

Procedures for assessing clients and for assessing and screening donors

Welfare of the child

40. During the inspection evidence was noted in the patient records of 'welfare of the child' assessments being carried out.

41. Patients are asked to complete a self assessment questionnaire that addresses:-
    a. the commitment to raise children
    b. the risk of harm to children including neglect or abuse and the effect of a new baby or babies upon any existing child of the family

42. Patient information gives clear and up to date information on parental responsibility issues.

43. Regular team meetings are conducted in treatment of single women and same sex couples and these issues are highlighted. Evidence was seen in the records for the treatment of a single woman.

Ethics committee

44. The centre has access to both a clinical ethics forum and a research ethics committee. The PR sits on the ethics forum. No issues about patients requiring treatment at the centre have been needed to refer in these meetings.

Assessing and screening donors

45. The centre sources sperm from three sperm banks.

46. All patients who are having treatment involving donor gametes have to see the counsellor prior to commencement of treatment.

47. Screening tests are carried out by the patient's GP prior to commencement of treatment and results are given by the GP who can make appropriate arrangements for counselling if required. The PR confirmed that some screening is also carried out by the centre.

48. The centre had not used imported sperm in the time covered by this report.

Counselling process and facilities

Counselling protocols

49. The counsellor has revised the counselling protocols. Some of the counselling protocols need to be version controlled.

Counselling referral arrangements

50. All couples considering treatment with donor sperm are encouraged to attend a counselling session. Patient information references the counselling service and recommends that patients use the service. Patients are referred by a member of the nursing staff or self referred by contacting the counsellor directly.

51. One counselling session is included in the cost of treatment but additional counselling sessions can be provided without further charge on an informal basis.

Supervision and professional registration

52. Documentation submitted for the inspection showed that the counsellor is member of BICA.

Counselling Audit

53. The inspection team was provided with a detailed statistical summary of counselling services offered to the patients. There were thirty two patients seen by a counsellor during the period from January 2005 to April 2006.

Location of counselling facilities

54. Counselling takes place in the treatment room or in counselling facilities at Bourn Hall clinic. The Person Responsible reported that the majority of the counselling takes place in the evenings or at weekends when the treatment room is not in use. These rooms were found to be have adequate security.

Patient experience

Patient feedback

55. The centre has not conducted its own patient survey. The Person Responsible reported that they are planning to develop patient's questionnaire but they will develop their own questionnaire.

56. The centre has distributed HFEA patient feedback questionnaires but the HFEA had received no replies to the questionnaires.

Patient information

57. Patient information leaflets submitted to the HFEA were satisfactory. Information is provided at the initial consultation by nurses and is made available in patient's waiting area.

Record keeping procedures

58. Five sets of the patient records were examined from donor insemination and single women's treatment carried out in the centre. All the records were found be satisfactory.

Audit

Centre's own audit of stored material

59. An audit of cryopreserved material was carried out prior to inspection. During inspection it was found that the Dewar A holds samples for sibling use and dewar B holds samples for current treatment use.

Spot check of tracking process for stored material

60. Two samples were tracked from record to dewar and two from dewar to records. No discrepancies were found.

HFEA register

61. During the inspection, no issues regarding the HFEA register were raised

Clinical governance

62. The inspection team was informed by PR that as a consultant he is responsible to the Clinical Director and to the Chief Executive of the Hospital. The Clinical Governance meetings are normally held quarterly and never less than three times a year. Minutes of the meetings were seen on inspection.

Risk management

63. The PR informed the inspection team that copies of any HFEA Alert are distributed to staff and then discussed in the meetings and staff signs a form when they have read it. The minutes of their meetings were seen on inspection.

64. The Trust's incident policy is used, which is available for the staff on the intranet. Incidents are graded and are shared with the other staff in the hospital and if required further changes are made in the policies or procedures. The inspection team was shown a log of the incidents relevant to the centre by the person responsible.

65. Information from the ALERT system is disseminated by the PR.

Complaints

66. The centre received no complaints in the last year.

Breaches of the Code of Practice or Act

67. No breaches of the HFE Act were found during the inspection.

Compliance with previous conditions and recommendations

Conditions

68. The centre has no additional conditions imposed on its licence.

Key points for the Licence Committee

69. The inspection team supports the renewal of the centre's licence for treatments set out in paragraph 13 above.

Issues

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

- Patient questionnaires need to be developed and implemented.
- Although various staff members are included on the rota in an event of alarm sounding in the laboratory area, a detailed written procedure should be in place in an emergency.
- Counselling and some laboratory protocols (most of them were found with revised dates and only few did not have the latest dates) need to be version controlled.

Appendix A The inspection team and staff interviewed

The inspection team

Neelam Sood	Chair, Inspector
Vicky Lamb	Inspector

Centre staff attending meetings with the inspection team

Andrew Prentice	Person responsible

Three other members of the centre's staff also attended meetings with the inspector.

Conflicts of interest

None declared.