



Human Fertilisation and Embryology Authority

Report of renewal inspection at

The Woking Nuffield Hospital
(0144)

Date of Inspection 18th April 2006

Date of Licence Committee 10th July 2006

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Key facts about the centre

Centre name The Woking Nuffield Hospital

Centre address Victoria Wing
Shores Road
Woking
Surrey
GU21 4BY

Centre number 0144

Person responsible Andrew Riddle

Nominal licensee (Acting) Iain McKenzie

Activities of centre

		2005
Licensed treatment cycles	IVF	402
	ICSI	288
	<i>(Egg Donation)</i>	
	Egg Donor	3
	Egg recipient only	5
	<i>(Egg Sharing)</i>	
	Egg provider	11
	Egg recipient	14
Donor Insemination		73
Research		None
Storage		Yes

Additional licence Conditions 0

Licence expires 31 October 2006
All payments to the HFEA are up to date.

Summary

1. The Woking Nuffield Hospital has been licensed since 1994. The centre offers licensed treatment to both private and NHS funded patients from Woking and the surrounding areas.
2. The current licence for treatment with storage is due to expire on 31 October 2006. The centre has a good history of compliance with no previous conditions on its licence. The previous Licence Committee made no recommendations.
3. The centre is currently licensed for:
 - Donor Insemination (DI)
 - In Vitro Fertilisation (IVF)
 - Intra Cytoplasmic Sperm Injection (ICSI)
 - Storage of sperm
 - Storage of embryos
 - GIFT with donor gametes
 - Treatment with Donor Gametes
 - Zygote intra fallopian transfer (ZIFT)
 - Mechanical Assisted hatching
 - Chemical Assisted hatching
4. This renewal inspection was undertaken on 18 April 2006. Currently around 800 treatments per year are carried out at the centre.
5. The inspection team would like to draw the following points to the attention of the licence committee:
 - Issues which were identified during the inspection have been addressed by the centre.
 - No breaches of the HFE Act were observed during the inspection.
6. The inspection team supports the renewal of the centre's licence for treatment with storage.

Background to inspection

7. This renewal inspection report covers the period from June 2005 to April 2006. The inspection considered the centre's treatment outcomes in the period from January 2005 to December 2005.
8. The site visit took place on 18 April 2006 and the report was reviewed by the centre in May 2006.

The centre's context

9. The centre offers licensed treatment to both private patients and those referred through the NHS. The majority of the patients attending the centre are from Woking and the surrounding areas.
10. Since the last inspection, additional space has been acquired by the centre. The inspection team was informed by the centre's staff that this has resulted in improved service being provided to the patients. Currently the Person Responsible (PR) is in the process of negotiating with the Nuffield Hospital's management for additional space being made available to the centre. However, until further expansion of the centre, the PR stated that there is some possibility of reorganising the current premises to create extra working space.
11. It was noted during the inspection that due to the popularity of the centre patients wishing for a new appointment have to wait around eight months before they are seen.
12. Opening hours at the centre are from 7.00am to 6.00pm Monday to Friday and, if required, variable hours on Saturday and Sunday.

Type of work carried out

Licensed treatment

13. The centre carries out the following licensed treatments:
 - Donor Insemination (DI)
 - In Vitro Fertilisation (IVF)
 - Intra Cytoplasmic Sperm Injection (ICSI)
 - Storage of sperm
 - Storage of embryos
 - GIFT with donor gametes
 - Treatment with Donor Gametes
 - Zygote intra fallopian transfer (ZIFT)
 - Mechanical Assisted hatching
 - Chemical Assisted hatching.

Satellite/transport arrangements

14. The centre does not have any transport or satellite arrangements.

Staff

15. The inspection team was informed by the PR that since the previous inspection there has been an increase in the staffing level with a further recruitment in progress. This is in response to the increase in the workload. New staff joining the centre receive relevant training for their background; documented evidence of this was made available for the inspection and was found to be satisfactory.

Staffing profile

Person responsible	Mr Andrew Riddle
Nominal licensee	Iain Mckenzie
Accredited consultant	Mr Edward Paul Curtis
Embryologists	5
ICSI practitioners	4
Nursing staff	8
Independent counsellors	1
Complaints manager	Iain Mckenzie

Professional registration and continuing professional development (CPD)

16. Review of the pre inspection documentation sent to the HFEA and the information obtained during the inspection confirmed that the staff at the centre are registered with the appropriate professional bodies.

17. The inspection team noted that the CPD for the staff at the centre is addressed both in-house and through external conferences and courses. Documented evidence in the form of training records for laboratory, nursing and clinical staff were seen during the inspection and were found to be satisfactory.

18. Regular multi-disciplinary team meetings are held at the centre to discuss clinical issues. Copies of the minutes from recent team meetings were made available for the inspection team.

The premises, equipment and other facilities

Premises

19. All areas seen during the inspection were found to be clean and well presented.
20. The centre's current licence and complaints procedure were seen displayed in the patients waiting area. However, the complaints procedure requires revising to include contact details for the HFEA. Subsequent information from the PR confirmed that this issue has been addressed.
21. The outcome data submitted for the inspection shows that the centre undertook approximately 800 treatment cycles compared to 500 in the previous year. This has resulted in the centre working to full capacity. The PR stated that the current workload is manageable and has been addressed by the recruitment of extra staff and the expansion of the premises with further improvements planned for future.

Equipment

22. Since the last inspection, the centre has acquired a new flow hood, an incubator, an ICSI rig and a freezing machine. The emergency supply of electricity to all key equipment has been reviewed and upgraded and is now connected to an uninterrupted power supply. Maintenance contracts are in place and these were seen during the inspection.

Security

23. As the centre is located within the Woking Nuffield Hospital, adequate security measures are in place. All clinical and laboratory areas are restricted to authorised staff only.

Confidentiality

24. During the inspection it was noted that the current records are kept in the main nurses' office in a lockable cupboard. The old and discontinued records are housed in lockable cupboards in the consulting and meeting rooms. It was noted that these records are collected together and scanned to CD by an external company and then are shredded in the presence of a member of the centre.

Arrangements for collecting sperm samples

25. A dedicated and suitably equipped sperm production room was seen during the inspection.

Cryostore facilities, oxygen and dewar alarms

26. The cryostore is accessed via keypad entry and was found to be adequate for the type and volume of activities carried out at the centre.
27. The dewars are fitted with low level nitrogen alarms and are connected to an auto dial system that alerts the nurse on call when an alarm is sounding. The inspection team were advised that the nurse would contact a member of the embryology team to respond to an alarm.
28. The cryostore is equipped with an oxygen depletion monitor; this was seen during the inspection.
29. Both screened and unscreened samples are stored separately. Oncology samples stored at the centre have been split.

Emergency facilities

30. The Inspection team were informed by the centre's staff that any patient who suffers from Ovarian Hyper Stimulation Syndrome (OHSS) can be admitted to either Frimley Park Hospital or the Royal Surrey County Hospital under the consultants' care.
31. Senior nurses respond to any emergency telephone calls to the centre and, if required, are able to contact one of the consultants. All staff at the centre have undertaken basic life support training. Resuscitation trolleys were seen during the inspection and were considered to be well maintained.

Clinical, nursing and laboratory procedures

Clinical

32. The clinical protocols submitted for the inspection were reviewed and considered to be satisfactory. They reflected the service being offered at the centre and are dated and version controlled.
33. The centre has a protocol in place for the management of complications resulting from Ovarian Hyper Stimulation Syndrome (OHSS).

Nursing

34. Nursing protocols were reviewed by the inspection team and were found to be satisfactory, they are dated and version controlled.
35. Professional development of the nursing staff is encouraged by the PR. Nurses are involved IVF planning, information giving, scanning and IUI procedures.

Laboratory

36. Laboratory protocols are clear and comprehensive, they are version controlled and showed evidence of revision.
37. Witnessing requirements are documented in the relevant laboratory protocols. The witnessing process was reviewed in four sets of patient records and was found to be satisfactory. The laboratory witnessing procedures were discussed in the course of the inspection and it was confirmed that the transfer of material between dishes and procedures at the time of sperm preparation (including transfer of sperm to columns) are witnessed individually and contemporaneously.
38. The last interim inspection report commented that more than one sperm sample was being prepared at the same time. The report recommended that a risk assessment of the procedure be carried out. A copy of the risk assessment was provided in the course of the renewal inspection. The assessment concluded that the procedure has a low risk rating as samples are placed with corresponding tubes and slides on individual trays and every movement is double witnessed. The senior embryologist reported that sperm samples are subject to extended preparation including a one hour swim up step. For this reason it is necessary to stagger the preparation of sperm samples resulting in several samples being in the flow hood at the same time. The senior embryologist and the PR are confident that this system is robust.

Three embryo transfer arrangements

39. The 'three embryo log' checked by the inspection team showed that all the three embryo transfers undertaken by the centre were for patients over 40 years of age.

Procedures for assessing clients and for assessing and screening donors

'Welfare of the Child'

40. The inspection team noted that the centre has protocols for assessing 'Welfare of the Child'. The protocols were found to be satisfactory.
41. Inspection of patient records showed that the centre takes appropriate action when issues of concern are raised by a patient's GP.
42. Inspection of consent forms in patient records confirmed that the centre takes reasonable steps to determine who will have parental responsibility for children born as a result of treatment.

Ethics committee

43. The inspection team were informed by the PR that the centre has access to an ethics committee. However, no referrals have been made to it.
44. The Woking Nuffield Hospital has Medical Advisory Committee (MAC) which meets every two months. The PR attends the MAC and is able to raise any clinical issues concerning the centre.

Assessing and screening donors

45. The centre does not recruit donors. Sperm is purchased from other licensed centres.

Counselling process and facilities

Counselling protocols

46. Counselling protocols were reviewed by the inspection team and were found to be satisfactory. They reflect the services being offered at the centre.

Counselling referral arrangements

47. The counsellor informed the inspection team that the cost of the counselling sessions is included in the treatment. The centre's staff make patients aware of the counselling service during their initial consultation.

Supervision and professional registration

48. Documentation submitted for the inspection showed that the counsellor is both member of British Infertility Counselling Association (BICA) and British Association for Counselling and Psychotherapy (BACP). The counsellor receives regular supervision from a professional mentor. She is up to date with her CPD, which is both self and centre funded.

Counselling audit

49. The counselling data submitted for the inspection confirmed that a total of 310 appointments were booked for the counsellor between May 2005 and February 2006. Counselling sessions occurred for most of the treatments offered by the centre, support counselling being the most frequent.

Location of counselling facilities

50. The inspection team noted that the counselling sessions take place in a dedicated room within the centre and the notes are kept in a locked filing cabinet.

Patient experience

Patient feedback

51. A patient questionnaire has been developed by the centre which is given out approximately 3 times per year. The last audited questionnaire results were evidenced showing that 70 questionnaires had been given out between the embryo transfer and pregnancy testing periods of treatment. Areas of typical concern in the replies from the patients appear to revolve around the size of the waiting room and the waiting time for treatment.

52. A total of 7 completed patient questionnaires were returned to the HFEA. Overall comments received from the patients were positive. The main issue raised by the patients was the waiting area being small. As the counsellor only works at the centre for two days, booking of counselling appointments was also highlighted by the patients. The findings of the patient questionnaires were discussed with the centre's staff.

53. Two couples receiving treatment at the centre were interviewed on the day of the inspection. Their responses were very positive about the quality of service they had received at the centre.

Patient information

54. Patient information submitted to the HFEA was reviewed by the inspection team and was found to be satisfactory. The PR stated that the centre is planning to revise the patient information.

Record keeping procedures

55. A total of fifteen patient records were reviewed during the inspection for different treatments. The notes were found to be well organised. However, some errors were identified and these were discussed with the centre's staff.

Audit

Centre's own audit of stored material

56. The senior embryologist at the centre confirmed that an audit of the stored samples had taken place since the last inspection, with no discrepancies. A copy of the audit report was seen by the inspection team and was found to be satisfactory.

Spot check of tracking process for stored material

57. A spot check of two embryos from records to dewars and two embryos from dewars to the records was carried out. The procedure was repeated for stored sperm samples. No discrepancies were found.

HFEA register

58. The HFEA register was not discussed during the inspection.

Clinical governance

59. The PR is responsible for the clinical governance at the centre. Monthly meetings are held with the Woking Nuffield Hospital management to discuss any practice related issues.

Risk management

60. The inspection team noted that a procedure is in place for the management of incidents at the centre. All staff are consulted regarding any incidents and they are discussed at the regular monthly team meetings.

61. The inspection team was informed by the centre's staff that any HFEA incident alerts are discussed at the centre's team meetings.

Complaints

62. The PR stated that centre's policy is to resolve any complaints as soon as they are reported. Four complaints have been recorded since the last inspection. All have been resolved. A log of complaints was seen during the inspection.

Breaches of the Code of Practice or Act

63. No breaches of the HFE Act were observed during the inspection.

Compliance with previous conditions and recommendations

Conditions

64. The centre has no additional conditions on the current licence.

Recommendations

65. The previous licence committee made no recommendations.

Key points for the Licence Committee

66. The inspection team supports the renewal of the centre's licence for treatment with storage as set out in paragraph 13 above.

Issues

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

- Currently there are no conditions on centre's licence. The previous licence committee made no recommendations.
- Issues raised during the inspection have been addressed by the centre.
- No breaches of the HFE Act were observed during the inspection.

Appendix A The inspection team and staff interviewed

The inspection team

Parvez Qureshi	Chair, HFEA inspector
Debra Bloor	HFEA inspector
Tony Knox	HFEA inspector
Sarah Hopper	HFEA observer
Claudia Lally	HFEA observer

Centre staff attending meetings with the inspection team

Meetings were held with PR and six other members of the staff.

Conflicts of interest

None declared.

Appendix B Sources of evidence

Expand or delete this section as required.

1. Previous licence committee minutes
2. Previous inspection reports
3. Relevant correspondence between the centre and HFEA
4. Staff CVs
5. Outcome data from licensed treatments
6. Patient information
7. Consent forms
8. Treatment forms
9. Standard operating procedures and protocols
10. Audits of stored material, counselling and clinical practice
11. Interviews with centre staff

Licence Committee Meeting

10 July 2006

21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

The Woking Nuffield Hospital (0144) 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
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 (51 pages)
- no papers were tabled.

1. The papers for this item were presented by Parvez Qureshi, HFEA Inspector. Mr Qureshi informed the Committee that this centre has been licensed since 1994 and currently carries out approximately 800 treatments per year. The centre treats both private and NHS funded patients, it has a good history of regulatory compliance and has no conditions on its licence. Mr Qureshi informed the Committee that the centre is hoping to increase its workload but to do so will

need more space and more staff. Negotiations are currently underway to secure these additional resources.

2. Mr Qureshi informed the Committee that all the issues raised by the inspection team on the day of the inspection visit have already been addressed by the centre.

3. The Committee noted the centre's very low risk score and agreed to renew the centre's licence for a period of five years with no additional conditions.

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