



Human Fertilisation and Embryology Authority

Report of an interim inspection at

The Woking Nuffield Assisted Conception Unit

July 2005

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Key facts about the centre

Centre name Woking Nuffield Assisted Conception Unit

Centre address Victoria Wing
Shores Road
Woking
Surrey
GU21 4BY

Centre number 0144

Person responsible Andrew Riddle

Nominal licensee (Acting) Iain MaKenzie

Activities of centre

		2004
Licensed treatment cycles	In Vitro Fertilisation (IVF)	280
	Intra-Cytoplasmic Sperm Injection (ICSI)	114
	Egg Donor	5
	Egg recipient	6
	Gamete Intrafallopian Transfer (GIFT)	0
Donor Insemination		Yes
Research		None
Storage		Yes

Additional licence Conditions 0

Licence expires 31/10/06

Summary

1. The infertility centre at the Woking Nuffield Hospital has been licensed since 1994. Treatments are offered to both private patients and patients referred through the NHS.
2. The centre is part of a private hospital and therefore benefits from all facilities on offer at the hospital. The Person Responsible (PR) is Mr Andrew Riddle (Consultant Obstetrician and Gynaecologist). The Nominal Licensee is Caroline Lewis (Unit Manager). An application has been received for the Hospital Manager to become Nominal Licensee (NL) for the centre and this will be submitted to Licence Committee together with this report.
3. The current licence which is displayed in the centre is due to expire on 31 October 2006. There are currently no additional conditions on the centre's licence. The two recommendations made by Licence Committee following the previous site visit have been implemented.
4. This report relates to an announced HFEA inspection. The site visit was undertaken on 14 June 2005. Relevant paperwork was submitted by the PR and NL prior to the inspection visit which assisted in the inspection process.
5. Patient areas were well presented. The location of the centre is divided between the ground and first floor of the hospital. There is a passenger lift to enable all areas to be accessed without negotiation of stairs.
6. Space within the centre is restricted. When commissioned, the centre undertook approximately 250 treatment cycles. Over the years, this has increased to 500 cycles and the aim of the centre is to increase to 800 cycles. However the centre is aware that this relies upon expansion of the existing facilities.
7. Staff, make the best use of the space available. However space within the laboratory is restricted and patient areas are expanding into the main hospital. Currently two bedrooms are being used as consulting rooms.
8. Woking Nuffield Hospital (which includes the assisted conception unit) is also registered with the Healthcare Commission. The most recent inspection by the Commission took place in November 2004. A report following this visit is available directly from the Healthcare Commission.
9. The following issues will be raised with Licence Committee as a result of this site visit.
 - The centre is expanding and requires more space.
 - The laboratory protocols need to be expanded to include the transfer of gametes both into and out of the centre and the action/s to be taken when an alarm sounds in the cryostore.
 - The centre needs to review its practice of having more than one unprocessed sperm sample in the process area at any one time. It was

agreed that a risk assessment will be undertaken in the first instance by the centre.

It is recommended that the Centre's licence be continued.

Background to inspection

10. The report covers the period from June 2004 to June 2005.
11. The site visit took place on 14 June 2005 and lasted 7 hours.
12. During the course of inspection discussions and/or interviews were held with eight members of staff. 24 patient questionnaires were completed on the HFEA website and discussions were held with five patients. Outcomes of the discussions held and the completed questionnaires are included in this report.
13. The HFEA audit visit took place on 13 and 14 June 2005.
14. The report was reviewed by the centre in June 2005.

The centre's context

15. Patients attend the centre for private treatment and can be referred through the NHS. Approximately 500 treatment cycles were undertaken from 1/4/03 to 31/3/04. Of the 500 treatment cycles, approximately 150 were referred through the NHS.
16. Patients can be referred from overseas. However this has not occurred since the previous inspection visit.
17. Opening hours at the clinic are as follows

Monday to Friday	08.00 to 06.00pm
Saturday	Variable to meet the needs of patients. On call arrangements in place when closed.
Sunday	On call arrangements in place.

Type of work carried out

Licensed treatment

18. The centre carries out the following licensed treatments;
 - Donor Insemination (DI)
 - In Vitro Fertilisation (IVF)
 - IVF with donor eggs
 - IVF with donor sperm
 - Intra Cytoplasmic Sperm Injection (ICSI)
 - Storage of sperm
 - Storage of embryos
 - Gamete intra fallopian transfer (GIFT)

- GIFT with donor sperm
- GIFT with donor eggs
- Zygote intra fallopian transfer (ZIFT)
- Assisted hatching (mechanical and chemical)

Satellite/transport arrangements

19. The centre does not have any satellite/transport arrangements in place.

Staff

20. There is a stable staff core which facilitates continuity in care for patients. However since the previous inspection visit, three members of staff have left the team and six members of staff have joined the team. This includes the General Manager of the hospital who has applied to be Nominal Licensee for the centre.
21. All new staff receive corporate induction training and also training which is relevant to the infertility centre. This has assisted in the integration of new staff members in the team.
22. The hospital has a personnel department. Corporate recruitment procedures are in place at the hospital to ensure that staff, are fully vetted prior to their recruitment. Staff files were sampled which demonstrated that proof of identity, references, proof of qualifications and an interview process takes place prior to staff being employed. In addition all staff have had enhanced Criminal Record Bureau (CRB) checks undertaken.
23. Doctors have practicing privileges contracts with the hospital which are reviewed at regular intervals. Doctors records were sampled at random which confirmed appropriate vetting procedures are in place, including CRB checks. Both the PR and the Accredited Consultant are included on the Specialist Register of the GMC.
24. Staff appraisal takes place annually which is linked with training.
25. Medical staff also provide proof of appraisal in line with the General Medical Council (GMC) as part of their practicing privileges agreement.

Staffing profile

Person responsible	Mr Andrew Riddle
Nominal licensee	Mrs Caroline Lewis
Accredited consultant	Mr Edward Paul Curtis
Other medical staff	
Embryologists	4
ICSI practitioners	4
Nursing staff	8
Independent counsellors	1
Complaints manager	Iain Makenzie
Administration staff	

Professional registration and continuing professional development (CPD)

26. Doctors provide proof of continuing professional development (CPD) as part of their practicing privilege agreement.
27. Staff employed in the laboratory provided evidence of CPD including conferences attended at the time of the site visit.
28. Staff files confirmed that nursing staff, undertake induction and ongoing training. Staff on the inpatient unit who care for patients undergoing egg retrieval under general anaesthetic (GA) link in with training undertaken by staff in the infertility centre.
29. The counsellor confirmed that issues raised at the previous site visit regarding her CPD have been addressed by the organisation.
30. Nursing staff are registered with the Nursing and Midwifery Council, doctors with the General Medical Council and Embryologists are registered with the Association of Clinical Embryologists(ACE) .The professional registration of staff is checked centrally by the Personnel Department.
31. The hospital has a Medical Advisory Committee (MAC) which monitors medical practice and reviews any new procedures to be introduced at the hospital. The PR is a member of the MAC which meets every two months. It was confirmed that there have been no new treatments introduced in the infertility centre since the previous inspection visit.
32. Short staff meetings are held as necessary with multidisciplinary meetings held each week. Monthly meetings are held with the Hospital Manager. Meetings are minuted with minutes seen during the course of the site visit.

The premises, equipment and other facilities

Premises

33. All patient areas were clean and well presented.
34. When built in 1994, the centre undertook approximately 250 treatment cycles and the size of the centre was appropriate to the size of the workload. However activity has increased to 500 treatment cycles and as a result, the laboratory is working to full capacity and the centre is expanding into the main hospital. Ultimately the centre would like to increase treatment cycles to a maximum of 800 cycles but are aware that expansion relies upon additional allocated space within the hospital.
35. The centre is arranged over two floors of the hospital. The waiting area, consulting rooms, men's production room, the laboratory, storage area for dewars, treatment room, laboratory and offices are located on the first floor. Through double doors and across a landing is a dedicated counselling room and the inpatient unit. Due to the level of work currently carried out in the centre, two bedrooms are being used as consulting rooms. The theatre suite/ procedure room is located on the ground floor with a laboratory alongside. A hatch is located between the laboratory and the procedure room. Two patients commented on the lack of a suitable waiting area on the HFEA website.
36. WC's are available on each floor. Patients admitted to a room prior to treatments being carried out are allocated a single bedroom with en suite facilities.

Equipment

37. Equipment is in use which is regularly maintained and replaced as necessary. There is a preventative maintenance plan in place. Maintenance contracts are in place with external contractors to ensure that equipment is kept in good order. Maintenance of equipment used in the laboratory was randomly checked at the time of the visit. Checks had taken place on equipment tracked.
38. Where daily checks are needed on equipment, a record of checks was seen to be made. This included the temperature of the refrigerator used to store medicines and the incubators in the laboratory.

Security

39. The centre is located within a private hospital and overall security measures are in place. In addition, access to the centre itself is protected by a key pad.
40. Access to laboratory and to the theatre suite is restricted to authorised personnel.

Confidentiality

41. It was evident through discussions with staff that there is a high level of general awareness regarding confidentiality.
42. Patient records are stored securely in filing cabinets within the centre.

Arrangements for Collecting Sperm Samples

43. The men's production room is located within the centre. The room is well presented and suitably equipped. One patient commented that reading material made available could be improved and this was fed back to the staff team at the end of the visit.
44. The door can be locked from the inside to ensure privacy.

Cryostore facilities, oxygen and dewar alarms

45. There are secure storage facilities for gametes and embryos. Access is restricted by the use of a coded lock.
46. There are seven dewars. Two contain unscreened material, two contain embryos and two contain sperm samples. Oncology samples have been split between dewars to meet with the Chair's letter dated 7 June 2004. A spare dewar has been purchased for the centre.
47. Tissue for storage is being screened for Hepatitis B, Hepatitis C and HIV.
48. All dewars are alarmed.

Emergency facilities

49. Where complications may result from treatment/s carried out, patients can be admitted to either Frimley Park Hospital or the Royal Surrey County Hospital. The Person Responsible and the Accredited Consultant at the centre hold Consultant posts within each hospital which ensures continuity in medical care for patients. For patients who attend the centre but live outside the catchment area, telephone advice would be provided and liaison with the medical team where necessary.
50. Patients can contact the hospital at any time for advice. There is an experienced Fertility Nurse on call at all times. In addition there is always a Consultant on call. Calls made out of hours by patients are logged together with the advice given.
51. The likelihood of a resuscitation event is low as patients attending the centre are generally fit and well. However, the centre has resuscitation trolleys, which are located within easy reach of patient areas. This includes the centre itself, the inpatient areas and the theatre suite. The equipment meets with guidelines set by the Resuscitation Council (UK). There is a system in

place whereby resuscitation equipment is checked daily with a record kept of each check.

52. The hospital has a resuscitation team which attends an emergency in the centre if called upon. The hospital has a Resident Medical Officer on site at all times who has undertaken Advanced Life Support Training. In addition, staff employed to work in the centre have undertaken Basic Life Support Training. Staff employed in the centre take part in scenarios which are arranged by the resuscitation team.
53. Should a patient require ongoing emergency care the hospital can provide critical care up to level 1.

Clinical, nursing and laboratory procedures

Clinical and nursing procedures

54. Clinical and nursing protocols are in place which were reviewed at the renewal visit and found to be satisfactory.
55. There are protocols in place for the management of complications resulting from treatments carried out, including Ovarian Hyper stimulation Syndrome (OHSS).
56. Patients undergoing egg retrieval are offered a choice of sedation or general anaesthetic when the procedure is carried out. Patients spoken with confirmed that they were given a choice but were relieved to be offered a “light” general anaesthetic when this procedure was being carried out. Patients are admitted to the inpatient unit prior to the procedure and remain in hospital for approximately six hours. Where patients may need to stay overnight they can remain in their allocated bedroom at no extra cost.
57. Patients spoken with confirmed that they had met staff on the inpatient unit prior to their admission.
58. Checklists are in place, which ensure that all issues are discussed with patients in relation to their treatments. The checklists are signed by the patient and the member of staff leading the consultation. This facilitates continuity in approach.

Laboratory

59. Laboratory protocols are in place some of which require updating. It was agreed that the protocols will be expanded as follows
- The protocol titled “Laboratory Alarms” will be expanded to cover areas of risk.
 - A protocol will be developed to cover the transfer of gametes both into and out of the centre.

60. The Code of Practice 6th Edition 15.3(i) states that centres are expected; *“not to have more than one unprocessed sperm sample in the processing area at any one time”*. At the time of the site visit more than one sample was being processed and it was reported that this practice operates when treatments are underway. The embryologist confirmed that this is considered safe practice taking into account the high level of witnessing in operation in the laboratory. However it was agreed that this will be reviewed taking into account the guidance given in the code of practice. It was suggested that a risk assessment be undertaken in the first instance.

Procedures for assessing clients and for assessing and screening donors

Welfare of the child

61. The centre has clear written criteria for assessing welfare of the child issues. Separate information has been developed for patients.
62. A comprehensive record regarding welfare of the child was seen in each set of patients notes sampled. The patients GP had been contacted for each patient.
63. The centre has a procedure in place should an unsatisfactory response be received from a GP. However this has not occurred.

Ethics committee

64. Multi disciplinary meetings are held regularly in the clinic where patients are reviewed individually and any issues can be raised. Supporting information can be obtained through referral to the independent counsellor who will prepare a report for the centre for consideration.
65. An example was tracked through at the time of the site visit where a case had been referred to the independent counsellor. The process for considering the issues was clearly recorded together with the outcome.
66. The centre also has access to an ethics committee where cases can be referred if not resolved at the multi disciplinary team meeting/s. There have been no referrals to the ethics committee since the previous inspection visit.

Assessing and screening donors

67. Donors are not actively recruited by the centre.
68. For patients using donor gametes in their treatments, nursing staff match characteristics. Patients sign to agree and are given the donor code. Disclosure of the donor code was an issue raised with the centre following the previous site visit. However in October 2004, a Chair's letter advised centres that non-identifying codes can be shared with recipients.

69. Nursing staff then order gametes from a specialist centre in readiness for treatment. The centre orders material from one of two centres.
70. The donor code is used in labelling and consenting procedures for individual treatments carried out.

Counselling process and facilities

Counselling protocols

71. Counselling protocols were reviewed at the previous site visit and were satisfactory. The counsellor works for two days each week. Hours are flexible. During discussions with patients, one couple were attending at 7.30 am the next morning to fit in with their working day.
72. Patients expressing a wish to see the counsellor are usually given an appointment to attend within one week.
73. Counselling is available to all patients and there is no additional cost for this service.
74. Since the previous site visit, a support group has been introduced which meets approximately every two months.

Supervision and professional registration

75. The Counsellor has a Diploma in Counselling and is a member of the British Infertility Counselling Association (**BICA**).

Counselling audit

76. A counselling audit has been undertaken which shows that 253 patients were seen by the centre's counsellor between May 2004 and April 2005. 166 patients had attended for support counselling with 87 attending for implication counselling.

Location of counselling facilities

77. Patients are seen by the counsellor in a dedicated room within the hospital. Counselling records are kept in a locked filing cabinet in the counselling room which is kept locked when not in use.

Patient experience

Patient feedback

78. Seven patients were spoken with at the time of the site visit. The patients lived within the catchment area of the hospital. Patients were highly complementary regarding the care and attention given by all groups of staff.

There is a “named nurse” system in place. However patients said that they knew all staff. Comments included “care has been planned to suit our individual needs”, “full information was given to enable the right choice to be made”, “we have not been rushed into making a decision about anything and have been encouraged to ask questions” “we were not overwhelmed with information and staff prepared us for each stage as we went along” “we were helped to complete consent forms” and “staff have always been realistic about the success of treatment which has kept our feet on the ground”. One suggestion made which involved billing arrangements was fed back to the management team at the end of the inspection.

79. 24 questionnaires were completed on the HFEA website. Outcomes were generally positive. However 15 patients said that they were unaware of the counselling arrangements, One said that there was a delay in waiting to be seen, six with gametes in storage said that they were not advised of the need to stay in touch and one said that they were not given sufficient time to consider treatment options. These comments were fed back to the management team at the end of the inspection.

Patient information

80. Patients receive an information pack prior to commencing treatment. In addition following the first consultation when treatment options have been discussed individually with patients, information is given the patients, which is specific to their chosen treatment.
81. Patient information includes complications which can arise from treatments carried out. This includes OHSS. Emergency contact details are given to patients.
82. Patients receive a full price list for investigations and treatments carried out.
83. Information is well presented and could be developed in different languages through corporate arrangements in place if necessary.
84. There is clear written information for people considering donation and for recipients which details screening procedures.
85. Donors are given information regarding changes in law in relation to donor anonymity.
86. The information pack includes information regarding the counselling service on offer. In addition, leaflets were seen to be displayed in the waiting area.

Record keeping procedures

87. The HFEA audit took place on the 13 and 14 June 2005 which included an audit of records in relation to consent and welfare of the child (see section 93).

Three embryo transfer arrangements

88. The three embryo log confirmed that three, three embryo transfers had taken place since June 2004. Two transfers were undertaken with patients over the age of 40 with reasons for three embryo transfer recorded.
89. One embryo transfer had taken place with a patient aged 39 years and 10 months old. The clinical team are aware of good practice guidance in relation to 3 embryo transfer. However taking into account the actual age of the patient and the exceptional circumstances in relation to the patient the clinical decision was taken to undertake the transfer. Patient notes confirmed that discussions had been held with staff at the HFEA prior to undertaking the transfer.

Audit

Centre's own audit of stored material

90. An audit of stored gametes takes place annually. The audit took place in March/April 2005. There were no discrepancies found.

Spot check of tracking process for stored material

91. An audit was undertaken on randomly chosen samples including two sperm samples from dewar to patient records. Embryos were not audited as the centres own audit was only undertaken in April 2005. There were no discrepancies found.

HFEA register

92. The HFEA audit was undertaken on 13 and 14 June 2005. There were no significant errors found in the 30 files sampled. The error rate was less than 6% which can be expected in a clerical system. There were no errors found which would give rise to for concern about patient care. Staff communicate clearly in patient records. Checklists are used consistently which are well designed ensuring responsibility and accountability for procedures carried out.
93. All but one file included self assessment and welfare of the child documents. The one file related to embryos being taken out of storage in 2004 and applied to treatment undertaken in 1999. The centre said that procedures had been tightened since then which was confirmed in the records audit undertaken.
94. There were no errors found in 006 or 007 consent forms.

Clinical governance

95. The Nuffield group of hospitals has corporate clinical governance arrangements in place which include the fertility centre. Monthly meetings are held with the hospital manager. Systems of audit have been introduced which are ongoing. Outcome data is regularly reviewed at the centre and discussed at meetings of the MAC.
96. Regular staff meetings take place where issues relating to practice can be discussed. In addition to multidisciplinary meetings, departmental meetings also take place. Formal minutes are kept of meetings which are kept which are shared with staff unable to attend a meeting.

Risk management

97. Risk management systems are in place for the management of the building.
98. Any risk to patients as a result of treatments being carried out are considered individually with patients and recorded in their notes together with the outcome.
99. There is a procedure in place for the management of incidents. One incident has been reported to the HFEA since the last site visit which was managed in accordance with the procedure in place.
100. Staff were aware of the HFEA alert system. Procedures are in place for the management of alerts which are accessible to staff at all times.
101. Outcome/s of any incidents or alerts are discussed during staff meetings. Any internal incidents are also raised at corporate level. There are systems in place whereby any incidents or complaints involving doctors would be investigated with the assistance of the Management Advisory Committee (MAC). However the need for this has never arisen.

Complaints

102. The Complaint Manager is Mr Iain MaKenzie (Hospital Manager). A corporate complaint procedure in place which is used in conjunction with a local procedure developed for patients attending the centre. The local procedure reflects HFEA requirements.
103. The complaint procedure is displayed in the waiting area at the centre
104. There are robust systems in place for the management of complaints. Mechanisms are in place, to ensure that staff learn from complaints made to prevent re occurrence. Any complaints made relating to medical practice would be fully investigated with the involvement of the MAC.
105. There have been no complaints received by the HFEA since the previous site visit. However three complaints have been received by the centre.

Each complaint had been resolved and had been managed in accordance with the procedure.

Breaches of the Code of Practice or Act

106. One three embryo transfer has taken place for a patient under the age of 40 years (the patient was 39.10 months of age).
Code of Practice 6th Edition 8.20(i)
107. The centre should not have more than one unprocessed sperm sample in the process area at any one time.
Code of Practice 6th Edition 15(3)(i)

Compliance with previous conditions and recommendations

Conditions

108. There are currently no additional conditions on the centre's licence.

Recommendations

109. The licence committee made 2 previous recommendations. They are listed below along with the centre's response.

<i>Recommendation</i>	<i>Adopted by centre (Y/N)</i>	<i>Comment</i>
1. That the centre obtains the specific patient information used at UCH and Guys regarding the research projects that embryos at Woking may be donated to and provides it to patients considering donation.	Yes	For patients who express and interest in donating their embryos, they are referred to the research centre/s who provide all necessary information
2. The centre is asked to consider purchasing a new dewar and consider the very small risk of cross contamination which the re use of a dewar which had	Yes	The centre has a spare dewar.

previously contained un-screened samples may imply.		
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Key points for the Licence Committee

110. The inspection team supports the continuation of the centre's licence for treatments set out in paragraph 19 above.

Issues

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

112. The centre had no conditions included on its previous licence. Two recommendations were made which have received attention.

113. The centre has two breaches of the Code of Practice 6th Edition detailed in section 0107/8 of this report.

114. Two further issues were raised which the centre has agreed to implement

- The laboratory protocol "Laboratory Alarms" needs to be expanded to include the action to be taken when an alarm is sounded in the cryostore.
- A protocol regarding the transfer of gametes into and out of the centre needs to be developed.

Appendix A The inspection team and staff interviewed

The inspection team

Christine Williamson	Chair, Senior Regulatory Manager, HFEA
Lynne Nice Christine Woodrow	Scientist HFEA Auditor

Conflicts of interest

None declared.