Inspection Report Interim

The Woking Nuffield Hospital
0144

Date of Inspection: 29 April 2008
Date of Licence Committee: 24 July 2008

CENTRE DETAILS

Centre Name	The Woking Nuffield Hospital
Centre Number	0144
Licence Number	L0144/10/a
Centre Address	Victoria Wing Shores Road Woking Surrey GU21 4BY
Telephone Number	01483 227859
Type of Inspection	Interim
Person Responsible	Andrew Riddle
Nominal Licensee	Caroline Lewis
Inspector(s)	Parvez Qureshi (Lead)
	Vicki Lamb
	Tony Knox (External)
	Peter Hollands (Observer)
Fee Paid – up-to-date	Up-to-date
Licence expiry date	31 October 2011
NHS/Private/Both	Private

Index

Page

About the Inspection:
This inspection visit was carried out on 29 April 2008 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between April 2006 and March 2008.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

NB: Where there are very minor issues to be addressed these are noted in the "minor issues to be addressed" section for each topic, and this will facilitate the evaluation of 'no improvements required'. Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The Woking Nuffield Hospital which is privately owned has been licensed since 1994. It has a good history of compliance with no previous conditions on its licence. Currently around 1000 treatment cycles are carried out per year.

Since the last inspection, expansion of premises and recruitment of additional staff have taken place to address an increase in workload.

An organisational chart is in place indicating key functions and lines of accountability. The centre is open for business Monday to Friday from 0700 to 1800 and if required 0800 to 1200 on Saturday.

The Person Responsible (PR) has completed the HFEA PR Entry Programme.

Activities of the Centre for the time period from 01/01/07 - 31/12/07*

Licensed treatment cycles	IVF ICSI FET(IVF & ICSI)	485 326 188
Donor Insemination		25*
Unlicensed treatments		✓
Storage		Yes

*This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA on our website is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems."

Summary for Licence Committee

The inspection team considered the centre to be well organised and managed. In order to accommodate an increase in workload, both expansion of the facilities and recruitment of additional staff have taken place.

Issues highlighted in the previous inspection have been addressed. However, it was noted that some improvements can be made to certain aspects of service, in particular to the cryostorage facilities and the patient record storage areas.

The inspection team recommends the continuation of the centre's licence.

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation	✓		
2. Quality of the service	✓		
3. Premises and Equipment		✓	
4. Information		✓	
5. Laboratory and clinical processes		✓	

Breaches of the Act, Standard Licence Conditions or Code of Practice: The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
None.	None.	None.

Non-Compliance

Area for improvement	Action required	Time scale
Not all of the required witnessing steps are captured in the laboratory witnessing protocol.	Witnessing procedures should be reviewed in consideration of the Code of Practice guidelines at G.13.	29 July 2008.
Not all staff training records reviewed in the course of the inspection showed evidence that competency had been assessed.	The competency of the personnel must be evaluated at appropriate intervals specified in the quality system. (A.10.9).	To be monitored at the time of the next inspection.

Recommendations	Time scale
Patient records are stored securely but over several locations, including in toilet areas off consulting rooms. This may result in notes being difficult to locate. The PR should assess whether there are any risks associated with the storage of records in different locations and take corrective actions to minimise and risks that are identified.	To be monitored at the time of the next inspection.

Cryopreservation dewars are stored over several locations including the ensuite to a consulting room and in a room next to the reception area. The facilities are fitted with appropriate alarms and are secure. The PR should assess whether there are any risks associated with the location of the cryopreservation facilities and take corrective actions to minimise any risks that are identified.	To be monitored at the time of the next inspection.
The centre has a protocol in place for transportation of samples. However, the protocol is not fully compliant with the recommendations of Alert 21. Procedures for transfer of cryopreserved arterial should be reviewed in consideration of the recommendations of the Alert.	By 29 July 2008.

Proposed licence variations by last L.C.

None.

Changes/ improvements since last inspection

Expansion of centre and recruitment of additional staff to meet increase in workload.
Issues noted on the last inspection have been addressed, as have areas highlighted in the EUTCD application.
In order to reduce multiple births, currently the centre is performing single embryo transfers (SET) in approximately one third of all treatments. The centre has a detailed procedure in place for selecting patients suitable for SET.

Additional licence conditions and actions taken by centre since last inspection

Date	**Action taken**
	None.

Report of Inspection findings

1.**Organisation**
Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence is drawn from:

1. Leadership and management
2. Organisation of the centre
3. Resource management
4. Risk management
5. Incident management
6. Contingency arrangements
7. Business planning
8. Clinical governance
9. Payment of treatment fees

Areas of firm compliance
The inspection considered the centre to be well organised with a comprehensive documentation system in place. A detailed organisational chart showing responsibilities and lines of accountability within the unit was submitted for the inspection. The majority of staff have extensive experience of working in the fertility field and have been at the centre for a considerable time. A risk management policy is in place, evidence of assessment of the risks of handling of liquid nitrogen was made available to the inspectorate. An incident log is in place and this was reviewed by the inspectorate. Entries in the log showed that the HFEA had been informed of all relevant incidents. Staff who were interviewed by the inspection team were aware of the incident reporting process to the HFEA. The PR confirmed that in the event of cessation of service, the centre has contingency arrangements in place with the Nuffield Hospital Brentwood for continuation of service. A list of third party agreements was seen during the inspection and was considered to be appropriate. Arrangements are in place for patients who need to contact the centre outside working hours. If required, policies have been drawn up for admitting patients to both the Nuffield Hospital Woking and two local NHS hospitals. No issues have been raised by the HFEA finance department regarding payment of treatment fees.
Areas for improvement
None.

Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
All areas covered.

Evaluation
No improvement required.

2. Quality of service
Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection:

1. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality objectives and plans
5. Quality Management review/evaluation
6. Monitoring and resolution of complaints
7. Staff suggestions
8. Document control
9. Live Birth Rates

Live Birth Rates
Relative live-birth success rate: (April 1st 03 – March 31st 06) HFEA data. DI, FET and IVF/ICSI success rates similar to national average, except for IVF/ICSI for age group under 35 significantly above national average.
Areas of firm compliance
A Quality Manager is in post to ensure that the centre complies with the current HFEA Standards and the requirements of the EU Tissue and Cells Directive. A comprehensive quality manual is in place which was reviewed by the inspection team. The centre has procedures in place for conducting regular audits of practice including reviews of patient feedback, patient notes and success rates. It was noted by the inspectorate that any areas of concern are subject to corrective action. A review of the complaints log showed that since the last inspection a total of eight complaints had been received by the centre. All complaints, except one, had been resolved. The centre has effective document control procedures. A total of 23 patient questionnaires have been returned to the HFEA and the majority of the responses made by the patients were complimentary regarding their experience at the centre. However, some patients commented on the limited space available in the waiting room.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
In consideration of patient feedback supplied to the HFEA the centre should consider gathering feedback on the waiting room facilities from patients.

Areas not covered on this inspection
All areas covered.

Evaluation
No improvement required.

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection:

1. General Suitable premises
2. Clinical facilities
3. Counselling facilities
4. Laboratory facilities
5. Air quality
6. Storage facilities for gametes and embryos
7. Staff facilities
8. Management of equipment and materials
9. Control of records

Areas of firm compliance
Since the last inspection, a considerable expansion of the premises has taken place. This has resulted in a number of additional rooms being made available to complement the existing premises. A new ICSI laboratory and a new andrology laboratory have been added to the facilities. All areas seen during the visit appeared to be clean and well presented. The unit is accessible to authorised personnel only. The inspection team considered the centre's current cryostore facilities to be adequate for the volume of work being carried out. Access to the storage area is restricted to authorised personnel only. All dewars are alarmed and linked to an auto dialler. The cryostore facilities are also fitted with a low oxygen monitoring system and there are procedures in place for responding to alarms Documentation submitted for the inspection and discussions held with staff indicated that laboratory processes take place in an environment of at least Grade C air quality. With the background air quality in the laboratory area being of at least Grade D. Maintenance contracts are in place for key pieces of equipment and evidence of this was seen during the visit. Logs of checks carried out in the laboratories including monitoring of carbon dioxide levels and fridge temperatures are maintained. Staff changing facilities are provided. All medical records are stored in secure areas with only members of the staff having access to them. The PR confirmed that in the event of a power failure the centre has access to a back up power supply.
Areas for improvement
None.

Areas for consideration
Patient records are stored securely but over several locations, including in locked filling cabinets in two key pad entry decommissioned bathrooms adjacent to consultation rooms. This may result in notes being difficult to locate. The PR should assess whether there are any risks associated with the storage of records in different locations and take corrective actions to minimise the risks that are identified. Cryopreservation dewars are stored in two locations one of which is a decommissioned bathroom adjacent to a consultation room and the second in another room next to the reception area. The facilities are fitted with appropriate alarms and are secure. The PR should assess whether there are any risks associated with the location of the cryopreservation facilities and take corrective actions to minimise any risks that are identified.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
All areas covered.

Evaluation
Some improvements required.

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of findings from inspection:

1. General Information
2. Meetings and communication
3. HFEA Alerts
4. Welfare of child
5. Confidentiality and access to health records
6. Traceability and coding
7. Coding/ identification of samples
8. Information for service users/consents
9. Donor information
10. Donor registration
11. Surrogacy
12. Procurement and distribution of receipt of gametes and embryos
13. Home procurement report documentation
14. Packaging &distribution
15. Labelling of packages containing procured gametes
16. Transportation, labelling of shipping container and recall
17. Receipt of gametes

Areas of firm compliance
Information submitted for the inspection and provided on the day of the visit was reviewed and was found to be of a good standard. The following information was also seen during the course of the visit: • The centre's treatment licence and complaints procedure. • Details of a variety of treatments available. • HFEA leaflets. • Counselling service offered to patients at the centre. Regular multi-disciplinary team meetings are held to discuss practice related issues. Minutes of these meetings are made available to all staff including those who are unable to attend them. In addition various departmental and management meetings also take place. Documented evidence for a number of recently held meetings was seen by the inspection team and was considered to be satisfactory. There are appropriate procedures in place to ensure that proper account is taken of the welfare of the child when considering treatment. This was also evident from discussions held with staff and evidenced in records reviewed during the course of the inspection. Patients' confidentiality is well maintained and evidence of this was seen during the visit. All consultations are held in private rooms. An effective traceability system is in place for materials that come in contact with gametes and embryos.

There are procedures in place for obtaining consent to treatment. Evidence of this was seen in the medical notes reviewed and from discussions held with staff.

Patients are allowed to produce semen samples at home but only in exceptional circumstances. The centre has a policy in place which requires the patients to confirm the provenance of the sample.

Areas for improvement

The centre has a protocol in place for transportation of cryopreserved material. However, the protocol is not fully compliant with the recommendations of Alert 21.

Areas for consideration

None.

Executive recommendations for Licence Committee

Procedures for transfer of cryopreserved material should be reviewed in consideration of the recommendations of Alert 21.

Areas not covered on this inspection

Donor information.
Donor registration.
Surrogacy.
Coding/ identification of samples.

Evaluation

Some improvement required.

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

1. Laboratory processes
2. Selection and Validation of laboratory procedures
3. Laboratory's documented procedures
4. Storage of gametes and embryos
5. Counselling
6. Witnessing

Full time equivalent staff

GMC registered doctors	4
NMC registered nurses	11 (equivalent to 7 full time)
HPC registered scientists	5
Scientists working towards registration	3
Support staff (receptionists, record managers, quality and risk managers etc)	5
Counsellors	1

Summary of laboratory audit / Audit of records
The inspection team was provided with information of a recent laboratory audit of stored samples. Some discrepancies were identified during the audit but these were reported to have been resolved. Eight patient records were reviewed during the inspection. Overall the notes were found to be well organised. However, some of the WT consent forms showed that the female had given consent for their partners to use their embryos in the event of mental incapacitation. This was raised with the staff on the unit. It was explained that all consents are completed with a member of staff who explains the consent forms to them. A number of the patients sign in this way in the event that they are mentally incapacitated for a short period of time (e.g., coma) in which case the husband would have the right to extend storage, in the hope that they would recover afterwards. Discussion was held regarding the possibility that they did not recover however and the fact that the embryos may not be able to be used. The staff at the unit stated that they would consider advising the patients to add a comment beneath this section of the form indicating their exact wishes in the case of mental incapacitation. Should female patients wish to permit the use of their embryos after death (either by their partner or in donation) then the centre is reminded that the female partner would need to be screened as a gamete donor and donor registration forms for submission to the HFEA would need to be completed. The finding of an HFEA operational audit conduct in December 2007 reflected the inspection findings. The following is a summary of the operational audit : • Arrangements are in place to restrict access to confidential information. • Some compatibility issues between the centre's database and the HFEA Electronic Data Interchange (EDI) system were identified and these require rectifying.

- In terms of completeness and timelines of activity the centre performed favourably.
- Overall the quality of activity reporting was considered to be satisfactory.
- Consents and welfare of child are appropriately considered and recorded.

Summary of spot check of stored material

An audit of embryos from dewar to records and vice versa was carried out. No discrepancies were found.

Areas of firm compliance

The centre participates in the National External Quality Assessment Service (NEQAS) scheme and evidence of this was seen during the inspection and was considered to be appropriate.

A personnel folder for a member of staff working on the unit was reviewed and contained evidence of the staff member undergoing a criminal records bureau check and of professional registration details. All new staff joining the centre undergo a comprehensive induction. The program is very detailed and records when competencies have been signed off by the allocated mentors.

Continuing professional development (CPD) for all of the staff is well maintained. Documented evidence of this was seen for a number of staff and it was further confirmed by staff who met the inspection team.

The centre's counselling service is well promoted through the patient information and patients are informed about service at their initial consultation. The counsellor stated that she was well supported by the centre's staff. Her CPD was up to date and she attends the centre's multi-disciplinary team meetings.

Counselling notes are kept in a secure filing cabinet. A counselling audit submitted for the inspection showed that a total of 481 sessions were conduct between March 2007 and February 2008, reflecting a good uptake rate for the number the treatment cycles being carried out at the centre.

Review of the 3 embryo transfer (3ET) log showed that, since the last inspection, all patients who had 3ET were 40 years or above.

Areas for improvement

Overall the centre has a good witnessing procedure but not all of the required witnessing steps are captured. Centres should have in place witnessing protocols, relevant to their local systems and conditions, based on HFEA model protocols. Where appropriate however, clinics may adapt HFEA model protocols to take into account their local systems (G.13.3.3).

Not all staff training records reviewed in the course of the inspection showed evidence that competency had been assessed.

Areas for consideration

None.

Executive recommendations for Licence Committee
Witnessing procedures should be reviewed in consideration of the Code of Practice guidelines at G.13. The competency of the personnel must be evaluated at appropriate intervals specified in the quality system. (A.10.9).
Areas not covered on this inspection
Storage of gametes and embryos. Selection and Validation of laboratory procedures

Evaluation
Some improvement required.

Report compiled by:

Name……..Parvez Qureshi…….

Designation……Inspector…….

Date……20th June 2008……

Appendix A: Centre Staff interviewed

PR and 7 other members of the staff.

Appendix B: Licence history for previous 3 years

2008

Licence Committee 14th April 2008

The Committee noted that the addition of new laboratory facilities were suitable and agreed that they were content for licensed work to take place there.

2007

Licence Committee 26th April 2007

The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

2006

Licence Committee 16th August 2006

The Committee agreed that Mrs Caroline Lewis was a suitable person to be the centre's new Nominal Licensee and decided to vary the licence to record this change.

Licence Committee 10th July 2006: Renewal Inspection

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.

2005

Licence Committee 7th July 2005: Interim Inspection

The Committee agreed to the continuation of the licence with no additional conditions or recommendations and agreed to recognise Mr Iain McKenzie as the Nominal Licensee.

Licence Committee 28th February 2005

The Committee agreed to recognise Mrs Caroline Lewis as Nominal Licensee for the centre.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number…….0144…….

Name of PR……..Andrew Riddle……

Date of Inspection……29th April 2008…….

Date of Response……22nd July 2008…….

I have read the inspection report and agree to meet the requirements of the report.

Signed……Hard signed copy received from PR ……

Name…… Andrew Riddle ……..…

Date……22nd July 2008……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

Factual corrections have been made where necessary.

2. Please state any actions you have taken or are planning to take following the inspection with time scales

(Comments taken from PR response received)**.** I believe that all required actions have been put in place already including evidence of "correct" air quality sampling. Continued regular air sampling will occur and corrective action put in place if sampling fails. I note and accept comments regarding cryopreservation dewars and note storage facilities. Further risk assessment is on going.

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

24 July 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 6

The Woking Nuffield Hospital (0144)
Interim Inspection

Members of the Committee:

Anna Carragher, Lay Member – Chair
Ruth Fasht, Lay Member
Roger Neuberg, Emeritus Consultant in Obstetrics and Gynaecology, Leicester Royal Infirmary

Present via conference telephone:
Chris Barratt, Head of the Reproductive and Developmental Biology research group, University of Dundee

In Attendance:

Debra Bloor, Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice to the Committee:
Mary Timms, Field Fisher Waterhouse

Declarations 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 (23 pages)
- one tabled paper: response to the report by the Person Responsible (2 pages).

1. The papers for this item were presented by Parvez Qureshi, who informed the Committee that this centre has a good history of regulatory compliance and performs in the region of 1,000 treatment cycles per year. Mr Qureshi explained that this number represented an increase in workload and extra space and staff have been taken on by the centre to accommodated this increase. Mr Qureshi reported that the centre was well organised with a good quality of service and a well developed Quality Management System. Furthermore, feedback from patients of the centre had been very complimentary.

2. Mr Qureshi reported that some areas for improvement were identified at the inspection visit as listed at page 6 and 7 of the inspection report. He explained that the report cites the fact that the centre has not fulfilled requirements in respect of air quality; however this fact had been disputed by the Person Responsible who had pointed out that air quality monitoring in the hoods was not required since the background air quality was already higher than that required inside the hoods.

3. Mr Qureshi reported that all the other areas for improvement identified in the report had now been addressed to the satisfaction of the Executive.

The Committee's Decision

4. The Committee welcomed the clarification from the Person Responsible with respect to air quality monitoring and agreed that they were happy that air quality monitoring at the centre was adequate. The Committee asked that the report be modified to reflect this new understanding.

5. The Committee agreed that the centre's licence should continue with no additional conditions.

Signed…… … Date……..
Anna Carragher (Chair)