Inspection Report
Treatment & Storage Centre

Newcastle Fertility Centre at Life

0017

Date of Inspection: 14 May 2008
Date of Licence Committee: 11 September 2008

CENTRE DETAILS

Centre Name	Newcastle Fertility Centre at Life
Centre Number	0017
Licence Number	L0017-13-a
Centre Address	Bioscience Centre, International Centre for Life, Times Square, Newcastle upon Tyne, NE1 4EP
Telephone Number	0191 213 8213
Type of Inspection	Interim
Person Responsible	Jane Stewart
Nominal Licensee	Mary Herbert
Inspector(s)	Wil Lenton (Chair, HFEA Executive) Andrew Leonard (HFEA Executive) Janet Kirkland (External advisor)
Fee Paid – up-to-date	N/A
Licence expiry date	31 July 2011
NHS/Private/Both	Both

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About the Inspection:
This inspection visit was carried out on 14 May 2008 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between January and December 2007.

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 centre is centrally-located within a science park approximately five minutes walk from Newcastle main train station. It has been licensed since 1992 and is part of the Newcastle upon Tyne Hospitals NHS Foundation Trust.

During 2006 it provided in excess of 600 licensed treatment cycles to NHS and self funded patients in the North East of England.

The laboratories at the centre have undergone extensive refurbishment, but have now been fully functional since July 2007.

The centre has an active research programme and currently holds three research licenses.

The Person Responsible (PR) has been in post since 2004, has the appropriate qualifications and experience for the role and has completed the PR Entry Programme.

Activities of the Centre (Non-verified data from HFEA Registry Jan-Dec 2006)

IVF	263
ICSI	162
FET	42
Donor Insemination	145
Unlicensed treatments	Ovulation Induction
Research	Yes
Storage	Yes

Imposed licence variations by last L.C.

N/A

Requirements by previous Licence Committee minutes	**Date**
1. Implications counselling – Patients to be given opportunity to speak to independent counsellor	In place
2. Risk assessment of practice to be performed concerning the timing of storage consent (presently taken at time of ET)	Undertaken
3. Quarantining of donor sperm samples to be risk assessed	Undertaken

Changes/ improvements since last inspection	**Date**
1. Laboratory refurbishment now complete	July 2007

Additional licence conditions and actions taken by centre since last inspection

Date	**Action taken**
	N/A

Breaches of the Act or Regulations, Standards, Conditions and Directions

Breach	Action required	Time scale
All third party agreements to be formalised. ***S.4.2.10/ S.7.1.1 CoP7***	Outstanding third party agreements to be formalised**.**	6 months
The QMS requires further development with full document control. ***S.5.1.1/S.5.2.5 CoP7***	Further development of the QMS with full document control.	Before next inspection
Timings of witnessing events to be recorded consistently. ***S.7.8.5/S.7.8.15/G.13.2.1 CoP7***	Timings of all witnessing events to be recorded.	Immediately

Non-Compliance

Area for improvement	Action required	Time scale
None.		

Recommendations	Time scale
More regular minuted laboratory meetings	3 months
Formalised contingency plan to be established	3 months

Evaluations from the inspection

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

Summary for Licence Committee

The centre was found to be cohesive and well organised, with an experienced senior management team in charge of service delivery. There were adequate numbers of qualified and trained staff in post to deliver the services provided.

During the course of the visit a number of regulatory issues were identified and are summarised below;

- Outstanding third party agreements need to be formalised.
- The QMS needs to be further developed with full document control in place.
- The timing of all witnessing steps needs to be recorded.

The inspectorate supports the continuation of the centre's licence.

Risk Assessment

The risk assessment was low at 11%

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

   1. General organisation of the centre
   2. Personnel
   3. Contingency arrangements
   4. Equality and Diversity

Full time equivalent staff

GMC registered doctors	4
NMC registered nurses	9
HPC registered scientists	3
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	8
Counsellors	1

Areas of firm compliance
An organisational chart was provided which detailed the centre's lines of communication and reporting structure. A detailed staff list provided evidence that the centre had adequate numbers of qualified/trained staff with which to deliver the range of patient services provided. An induction process is in place for new staff to follow, which covers both NHS Trust and unit specific policies & procedures. Training logs and CPD logs for current staff were reviewed on the day of inspection and found to be up-to-date. Annual appraisals were taking place. A written SOP is in place giving details of managerial cover when the PR is indisposed. Regular minuted meetings occur. The minutes from recent general management and quality management meetings were reviewed on the day of inspection.
Areas for improvement
None

Areas for consideration
Although there have been discussions within the local North East Fertility Forum about such issues, no written contingency plan is currently in place with another local licensed centre. Laboratory meetings are presently occurring on an ad hoc basis and should be more formalised.
Areas not covered on this inspection
None

Evaluation
No improvements 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 (HFEA non-validated data Jan-Dec 2006)
Live birth rate for combined IVF/ICSI = 23% Live birth rate for frozen embryo transfer = 14% Live birth rate for donor insemination = 16%
Areas of firm compliance
An experienced quality manager is in place to oversee the development of the quality management system (QMS) which is based on the Q-Pulse system. A quality manual is in place both as a hard copy and on the Q-Pulse system. The QMS is presently available to senior management but is to be made available to all staff via a password-secure unit wide IT system in the near future. Departmental leads from each discipline (clinical, laboratory and administrative) are in place and attend regular monthly minuted meetings to discuss both ongoing and future development issues. A patient questionnaire has recently been introduced as part of the on-going audit process. A complaints log and incident log were reviewed on the day of inspection and found to be appropriate. The laboratory participates in the NEQAS scheme.
Areas for improvement
All third party agreements to be formalised and put in place. Although documentation supplied was generated via the QMS there was no document/version control identifiers in place.

Areas for consideration
The centre has risk assessed their practice of informing patients about the availability of embryo's for freezing and signing the consents for storage on the day of embryo transfer. The centre provides both written and verbal information/advice about the process well in advance of the procedure and patients have full access to staff if further information is required. The senior management team suggested that a two-part consent form may be more appropriate in such circumstances. Information concerning all aspects of treatment provided by the centre is given to patients both in written form, as an information pack and then verbally at an initial consultation. Patients can discuss any issue with staff during the consultation and are advised to contact centre staff if they have any unresolved issues following the appointment. Further appointments can be arranged to discuss issues as required. Patients have access to an independent counsellor if specific issues cannot be successfully resolved by centre staff. Centre staff would also refer patients to an independent counsellor if they felt that patients had unresolved issues prior to the commencement of any treatment regimen. A checklist of information provided/discussed during consultations is contained within the patient's notes. No photo-ID or passport/driving licence check in place for patient ID (rely upon GP referral system together with name, address and date of birth confirmation) The first annual management review is scheduled for August 2008.
Areas not covered on this inspection
None
Evaluation
Some improvements 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
10. Risk assessments

Areas of firm compliance
The extensive premises and facilities seen during the course of the inspection were considered to be fit for purpose. The newly refurbished 'state-of the-art' laboratories have been in use since July 2007 and were considered fit for purpose. Notes were seen to be kept securely within filing cabinets in the general administration area and the nurses' office. All critical care areas have restricted staff access and are kept secured when not in use. Cryo-dewars containing patient material were seen to be secure and fitted with low liquid nitrogen alarms, connected to an auto-dialler system for out-of-hours incidents. A written protocol was in place to cover such situations. A low Oxygen monitor was in place within the cryostorage area, with an external audio/visual alarm. Air quality within the laboratory is being monitored and was found to be compliant with HFEA requirements. Equipment service/maintenance logs were reviewed during the inspection and found to be up-to-date in all areas.
Areas for improvement
None

Areas for consideration
None
Areas not covered on this inspection
None

Evaluation
No 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
A HFEA treatment & storage licence and two research licences were prominently displayed within the main waiting area, together with details of the centre's complaints procedure and information on local/national support groups. All patient information reviewed prior to and during the inspection was found to be concise and accurate. A home-procurement policy is in place for male partners who need/request to produce their samples at home. During staff interviews it was noted that personnel were aware of welfare of the child, patient confidentiality, dignity and respect issues. HFEA alerts were discussed at regular monthly meetings, where staff were also able to highlight any other issues and report back any concerns .
Areas for improvement
None

Areas for consideration
None
Areas not covered on this inspection
Surrogacy Transport/ packaging of gametes/embryo’s
Evaluation
No improvements 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

Summary of laboratory audit / Audit of records
Laboratory audits of cryopreserved material (sperm and embryos) were supplied with pre-inspection documentation and found to be appropriate.
Outcome of spot check of stored material
One cryopreserved sperm and embryo sample was tracked from database to cryotank and vice versa. No discrepancies were found.
Areas of firm compliance
The new laboratory facilities were commissioned for use in July 2007. Validation and commissioning documentation for the new facilities were viewed by the scientific inspector and found to be appropriate. All critical equipment such as incubators and heated stages, are monitored (temperatures / % $C0_2$ levels) and are connected to an emergency power supply (NHS Trust standby generator which is tested monthly) Laboratory training and CPD logs were seen to be up-to-date. Any new staff member undergoes a general induction course prior to undergoing specific laboratory training which is monitored and signed off by a supervisor Witnessing practice has been risk assessed. The centre intends to introduce an electronic system in the near future. The laboratory has a traceability system in place for recording all media, laboratory consumables and equipment used when processing gametes/embryo's. Evidence was seen of monthly laboratory KPI's and yearly outcome data from 2001 onwards. Laboratory outcomes are discussed regularly at the monthly management meeting. Cryopreserved samples are stored in a quarantine tank prior to blood-test clearance. (Vapour-phase tanks to be commissioned imminently)

Areas for improvement
Timings of witnessing events to be recorded consistently.
Areas for consideration
None
Areas not covered on this inspection
None.

Evaluation
Some improvements required.

Report compiled by:

Name……Wil Lenton…….

Designation……Inspector…….

Date…… 14 May 2008……

Appendix A: Centre Staff interviewed

PR plus six other staff members.

Appendix B: Licence history for previous 3 years

Licence	Type	Active from	Expires
L0017-13-a	T&S	05/07/2007	31/07/2011(EUTD variation)
L0017-12-a	T&S	01/05/2007	31/07/2011(superceded)
L0017/11/a	T&S	01/09/2005	30/04/2007

L0017/11/a

No conditions

Recommendation

- That the Person Responsible should get written confirmation that the witnessing protocols in use at the Hexham transport centre are in line with those protocols in use at Centre 0017.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……0017……

Name of PR……..Dr Jane A Stewart…….

Date of Inspection……14th May 2008……..

Date of Response……report received 2nd July 2008; response dated 11th July 2008

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

Signed……

Name……Dr Jane A Stewart…….

Date……11th 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).

Part 2 Quality of Service; Areas for Consideration

T o clarify - with regard to the discussion regarding two part consent for embryo freezing – we practice this now. Our consent for IVF (in house consent) includes confirmation of discussion regarding embryo freezing and disposal. We use the HFEA form which only has room for single consent for confirmation of firm plan to store once that decision has been made. We do not consider it appropriate to sign this form in advance of that decision since storage may not always take place (including if a couple change their minds) and this has led to confusion by patients about what has been done (hence previous discussions and risk assessment last year). The comment about a two part form pertains then to the HFEA form not our own procedures which already make allowance for this. If it is felt that the HFEA form regarding freezing should be signed in advance of that decision there should be a second place to sign for confirmation of that consent or indeed its retraction in the event of embryos not subsequently being frozen. I would suggest therefore that this is an issue for the HFEA, not us, to consider.

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

The unit has already complied with the requirement to add times to the recording of witnessing events.

Full development of the QMS is an ongoing process. Document control is in place but will be properly formalised as required when Q-Pulse is made fully functional in the near future.

Continued progress is being made to finalise the portfolio of third party agreements as required.

The further recommendations are being acted upon as required.

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

11 September 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 5

Newcastle Fertility Centre at Life (0017)
Interim Inspection

Members of the Committee:

Clare Brown, Lay Member – Chair
Sue Price, Consultant in Clinical Genetics, Oxford Regional Genetics Service
Chris Barratt, Head of the Reproductive and Developmental Biology research group, University of Dundee
Roger Neuberg, Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary

In Attendance:

Debra Bloor, Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice:

Graham Miles, Morgan Cole Solicitors

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 (25 pages)
- no papers were tabled.

1. The papers for this item were presented by Wil Lenton, HFEA Inspector. Mr Lenton informed the Committee that this centre has been licensed since 1992 and provided in excess of 600 treatment cycles during 2006, to a mixture of NHS and self funded patients.

2. Mr Lenton informed the Committee that the interim inspection visit took place on 14 May 2008. The inspection found the centre to be cohesive and well organised, with adequate numbers of qualified and trained staff in post to deliver the services provided. Mr Lenton summarised the main findings of the inspection. He reported that the following areas for improvement were identified in the course of the visit:
   - third partly agreements are not all formalised

- the QMS needs to be further developed with full document control
- the timing of all witnessing steps needs to be recorded

Mr Lenton stated that the inspectorate supports the continuation of the centre's licence with no additional conditions.

3. Mr Lenton directed the Committee to the response to the inspection report by the Person Responsible. This is appended at pages 20 to 21 of the inspection report and indicates that the centre is in the process of addressing all the areas for improvement.

The Committee's Decision

4. The Committee noted the response by the Person Responsible and agreed to continue the centre's licence with no additional conditions. The Committee asked that the centre's success rates be a focus of the next inspection.

Signed……. … Date……..
Clare Brown (Chair)