Inspection Report Interim

Sunderland Fertility Centre
0096

Date of Inspection: 23 January 2008
Date of Licence Committee: 24 April 2008

CENTRE DETAILS

Centre Name	Sunderland Fertility Centre
Centre Number	0096
Licence Number	L0096/19/a
Centre Address	Sunderland Royal Hospital Kayll Road Sunderland Tyne & Wear SR4 7TP
Telephone Number	0191 569 9779
Type of Inspection	Interim Treatment and Storage
Person Responsible	Menem Yossry
Nominal Licensee	Ken Bremner
Inspector(s)	Parvez Qureshi (Lead)
	Steve Lynch (External)
Fee Paid – up-to-date	Not due
Licence expiry date	31 May 2009
NHS/Private/Both	NHS

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About the Inspection:
This inspection visit was carried out on 23 January 2008 and lasted 5 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 Sunderland Fertility Centre is relatively small unit which has been licensed since 1992. Currently there are no conditions on its licence. Treatments are provided to both National Health Service (NHS) and self funded patients.

The majority of the treatment cycles carried out over the past year have been intrauterine inseminations (IUI) with only four donor inseminations (DI).

Since the last inspection no major changes have been made to the premises. An organisational chart is in place indicating key functions and lines of accountability.

The centre is open for business Monday to Friday from 7.45am to 7.00pm and 8.00am to 2.00pm over the weekends.

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

Activities of the Centre

01/01/2006 to 31/12/2006

Donor Insemination	5
Unlicensed treatments	Intrauterine Insemination Ovulation Induction Tubal Surgery
Storage	Yes

Summary for Licence Committee

Since the previous inspection, a number of improvements have been made at the centre. Some additional improvements are required.

A number of issues were identified which the inspection team considers to be Breaches of the Act or Code of Practice

The inspection team recommends the continuation of the centre's licence for treatment with storage.

Risk Assessment

The current risk matrix score for centre is 11%.

The centre scored a low risk rating of 7% with regard to compliance with the requirements of the EUTD.

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**	

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
Quality Management System (QMS) incomplete. **(S.5.1.1, S.5.2.1, S.5.2.6) Directive 2004/23/EC, Art.16**	Development of a comprehensive QMS.	Within three months from report being presented to a Licence Committee (LC).
Changing area and secure storage for personal effects. **(S 6.3.10)**	Provision of adequate staff facilities.	Within three months from report being presented to a (LC).
Counselling facilities are not provided in suitable surroundings. **(S 6.3.5) (G 1.4.1)**	Comfortable room for counselling.	Within three months from report being presented to a (LC).
Records are not kept of the materials used in the laboratory. **(S 6.4.3)**	Recording of materials used in the laboratory.	Immediately.

Non-Compliance

Area for improvement	Action required	Time scale
None.		

Recommendations	Time scale
Review of arrangements for the laboratory procedures carried out by staff from the Histology department.	Immediately.

Proposed licence variations by last L.C.

None.

Changes/ improvements since last inspection

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.

Recommendations **Action Taken**

None.

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
Documentation including an organisational chart showing main functions and lines of accountability within the unit were submitted for the inspection. Key members of staff have extensive experience of working in the fertility field and have been at the centre for a considerable time. Currently bimonthly multi-disciplinary team meetings are held to discuss practice related issues. However, the PR stated that in the near future these will be taking place on a monthly basis. Minutes of the meetings are made available to all staff. Documented evidence for a number of recently held meetings was reviewed by the inspection team and considered to be satisfactory. Since the last inspection, a number of risk assessments including security at the centre and health and safety have been carried out. Evidence of this was seen during the visit. The centre has an incident log in place and this was reviewed by the inspectorate and considered to be satisfactory. Entries in the log showed that over the last year the centre had no HFEA reportable incidents. The PR stated that the centre has access to an ethics committee but over the past year no case has been referred to it. In the event of an emergency, contingency arrangements are in place for continuation of service. It was noticed by the inspectorate that currently the centre has all the necessary third party agreements in place. 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
Following is a summary of the donor insemination (DI) information from the HFEA Success Rate Assessment (31st March 2002 – 1st April 2005): No data available for the age group 40-42. The success rate for the age group 35-39 is higher than the national average. For the age band below 35 the success rate is lower than the national average.
Areas of firm compliance
A Quality Manager has been appointed to ensure that the centre complies with the new HFEA Standards and the requirements of the EU Tissue and Cells Directive. Many of the issues highlighted in the recent application to vary the centre's licence to include intra-uterine insemination (IUI) treatment have been addressed or are in the process of being actioned. The centre has a comprehensive quality manual in place and it was considered by the inspection team to be satisfactory. There are procedures in place for conducting regular audits of practice including patient comments, notes and centre's IUI success rates, any areas of concern are addressed accordingly. Review of the complaints log showed that all complaints received by the centre since the last inspection had been resolved. Two patients were interviewed during the inspection and they made complimentary comments about the quality of service they received at the centre. A total of 31 patient questionnaires were returned to the HFEA and majority of the responses made by the patients were positive regarding their experience at the centre.

Areas for improvement
A Quality Management System (QMS) is in place. The centre has many documented procedures, but there are some which are incomplete. Further development is required to ensure full compliance with the Code of Practice 7th Edition.
Areas for consideration
None.
Executive recommendations for Licence Committee
Development of a comprehensive QMS.
Areas not covered on this inspection
All areas covered.

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
Since the last inspection no major changes have been made to the premises other than some reorganisation of the existing facilities. All areas seen during the visit were found to be clean and well presented. There is a controlled access to the unit. The scientific inspector 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. Oncology samples have been split into separate dewars. The cryostore facilities are fitted with a low oxygen monitoring system and there are adequate procedures in place for responding to alarms. Laboratory processes take place in an environment of at least Grade C air quality. The background air quality in the laboratory area is of at least Grade D. Since the last inspection, no major changes have been made to the equipment other than the installation of a Laminar air flow cabinet. Maintenance contracts are in place for key pieces of equipment and evidence of this was seen by the inspectorate. Medical records are stored in a secure area with only members of the staff having access to them. Patients' confidentiality is well maintained and evidence of this was seen during the visit. All consultations are held in private rooms. In the event of a power failure the centre has access to a back up power supply.
Areas for improvement
The inspection team considered the current staff changing facilities to be inadequate. In addition, there was inadequate secure storage for personal effects. The PR needs to put in place measures to address this issue. Currently the counselling service is offered in a variety of available rooms. These are not considered by the inspectorate to be comfortable. This was attributed to shortage of space in the unit. The PR needs to review this to ensure that counselling is offered in a comfortable room.

Areas for consideration
None.

Executive recommendations for Licence Committee
Provision of adequate staff facilities. Counselling to be conducted in comfortable surroundings.

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
The patient information submitted for the inspection 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 • The centre's complaints procedure. • Details of various treatments offered at the centre. • HFEA leaflets. • Counselling service offered to patients at the centre. Regular documented team meetings are held to discuss practice related issues. The PR informed the inspection team that staff are made aware of the HFEA alerts and any action required is taken by the appropriate personnel. This was further confirmed by the discussions held with members of staff. There are procedures in place to ensure that proper account is taken of the Welfare of Child when considering treatment, this was further evident from staff who were interviewed. Patient confidentiality is well maintained, all medical notes are kept in a secure area with only authorised access to them. The counsellor confirmed that all counselling notes are kept in a secure place at her home.

Procedures are in place regarding consent to treatment, evidence of this was seen in the documents reviewed during the inspection and from discussions held with staff.

Sperm donors have been recruited in the past but this is currently on hold due to the lack of availability of suitable donors.

If required, patients can produce sperm samples at home. However, they have to sign a declaration form to confirm that samples belong to them.

An adequate packaging and distribution system is in place that minimises the risk of contamination and ensures safety and quality of gametes. There is also a procedure in place to ensure that labelling and packaging of any procured material is tamper proof.

The centre has a protocol in place for compliance with HFEA alert 21 regarding transportation of samples. Evidence of this was made available to the inspectorate.

Areas for improvement
The centre's procedure for traceability of any materials that come in contact with gametes requires reviewing to capture and document all relevant information.
Areas for consideration
None.
Executive recommendations for Licence Committee
Review of traceability procedure for recording of materials used in the laboratory.
Areas not covered on this inspection
Procurement and distribution of receipt of gametes.

Evaluation
Some 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

Full time equivalent staff

GMC registered doctors	1
NMC registered nurses	2
Biomedical scientists	6
Support staff (receptionists, record managers, quality and risk managers etc)	4
Counsellors	1

Summary of laboratory audit / Audit of records
The inspection team was provided with information of a recent laboratory audit of stored samples. No discrepancies were identified. Five patient records were reviewed during the inspection for different treatments. Overall the notes were found to be well organised.
Summary of spot check of stored material
An audit of 2 sperm samples from dewar to records and vice versa was carried out. No discrepancy was found.
Areas of firm compliance
As noticed during the last inspection, four members from the Histology department are trained to prepare the semen samples whilst two members from the Haematology department are responsible for sperm freezing. The centre participates in the National External Quality Assessment Service (NEQAS) scheme. The continuous professional development (CPD) for staff is well maintained through internal and external training and courses and evidence of this was made available for the inspection team. The centre has a good witnessing procedure in place and this was evident from the documents reviewed during the visit.

The counsellor is member of British Infertility Counselling Association (BICA). Patients are made aware of the counselling service through the patient information and at their initial consultation. The counsellor stated that her (CPD) was up to date. She receives regular supervision from a mentor and attends the centre's multi-disciplinary meetings. Patients can contact the counsellor directly or through the staff.

The counselling audit submitted for the inspection confirmed that there were a total of 77 referrals from October 2006 to September 2007. Referral data show that therapeutic counselling was the most frequently attended followed by support counselling.

Areas for improvement

Discussions held with staff indicated that current arrangements for the laboratory procedures carried out by staff from the Histology department require reviewing. The availability of staff particularly for semen analysis is not guaranteed due to conflicting work pressures. This can result in delay in providing treatment on time. As consequence of this there is an impact on the hours worked by other members of the staff. The PR should review the arrangements in place.

Areas for consideration

None.

Executive recommendations for Licence Committee

None.

Areas not covered on this inspection

None.

Evaluation

Some improvements required.

Report compiled by:

Name……..…Parvez Qureshi…….

Designation……Inspector……

Date……27th February 2007……

Appendix A: Centre Staff interviewed

PR and 5 other members of the staff

Appendix B: Licence history for previous 3 years

2007

Licence Committee 26h 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.

Licence Committee 16h April 2007
The Committee agreed that the centre's licence should continue with no additional conditions

2006

Licence Committee 30th October 2006
The Committee agreed to recognise Mr Menem Yossry as the new Person Responsible for the centre.

Licence Committee of 10th April 2006
The Committee agreed to issue the centre with a treatment and storage licence. This licence had no additional conditions attached and is to last for three years.

2005

Licence Committee of 28th April 2005
The Licence Committee agreed to the renewal of the centre's storage licence for a period of 12 months.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……..0096……

Name of PR……Mr Menem Yossry……..……..

Date of Inspection……..28.01.2008……..……..

Date of Response……..17.03.2008……

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

Signed……Hard signed copy received from PR…….……

Name……Mr Menem Yossry…….…….

Date……..17.03.2008…….……

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).

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). Efforts are continuing to complete and update the quality manual to achieve the required standards. Proposals have been put forward to City Hospital Sunderland Trust management for modification of the premises to incorporate adequate facilities for staff and dedicated counselling area. Recording of materials used in the laboratory processes is now in place.

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 April 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 5

Sunderland Fertility Centre (0096)
Interim Inspection

Members of the Committee:
Clare Brown, Lay Member – Chair
Ruth Fasht, Lay Member
Sue Price, Consultant in Clinical Genetics, Oxford Regional Genetics Service
Roger Neuberg, Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary
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:
Graham Miles, Morgan Cole Solicitors

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 (27 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 is a relatively small unit which has been licensed since 1992. The majority of the treatment cycles over the past year have been intrauterine inseminations with only four cycles involving donor insemination.

2. Mr Qureshi stated that this interim inspection identified continued improvements at the centre, which is becoming increasingly compliant. A number of areas for improvement were identified at the inspection and these are listed at pages 6 and 7 of the inspection report. The Person Responsible has set out the measures being put in place to address these areas for improvement. His comments are included at page 19 of the report.

The Committee's Decision

3. The Committee noted the response from the Person Responsible and decided that the centre's licence should continue with no additional conditions.

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