Interim Inspection Report

Centre for Reproductive Medicine and Fertility, Sheffield
0196

Date of Inspection: 12 November 2008
Date of Licence Committee: 23 February 2009

Centre Details

Person Responsible	Professor W Ledger
Nominal Licensee	Sheffield Teaching Hospitals NHS Foundation Trust
Centre name	Centre for Reproductive Medicine and Fertility
Centre number	0196
Centre address	The Jessop Wing Tree Root Walk Sheffield Teaching Hospitals NHS Foundation Trust Sheffield S10 2SF
Type of inspection	Interim
Inspector(s)	Dr Vicki Lamb
	Miss Allison Cummings
Fee paid	N/A
Licence expiry date	30 September 2012
NHS/ Private/ Both	Both

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About the Inspection:

This inspection visit was carried out on 12 November 2008 and lasted for 7 hours.

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.

Where recommendations are made the HFEA will provide details of <u>what</u> needs to be addressed but not <u>how</u> 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 <u>www.hfea.gov.uk</u> .

Brief Description of the Centre and Person Responsible

The Centre for Reproductive Medicine and Fertility has been licensed since 2001 and provides a variety of licensed treatments to self-funded and NHS patients.

The unit is self-contained, with its own dedicated entrance, and is located within the Jessop Wing of Sheffield Teaching Hospital NHS Trust.

The centre is open from 08:00-17:00 Monday – Friday and from 08:00-15:00 on Saturday. Clinical staff are available in an emergency 24 hours a day on a rota basis.

The centre has a system in place for Quality Management and achieved ISO 9001:2000 certification in 2006.

The PR has been in post since 2001 and has appropriate qualifications and experience as defined in the HF&E Act. He has satisfactorily completed the Person Responsible Entry Programme.

Activities of the Centre[1] for the time period from 1 September 2007 – 31 August 2008

In vitro fertilisation (IVF)	329
Intracytoplasmic sperm injection (ICSI)	150
Frozen embryo transfer (FET)	206
Intra uterine insemination (IUI)	132[2]
Research	No
Storage gametes/embryos	Yes

[1] 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 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.

[2] Based on treatments between 5 July 2007 and 31 December 2007.

Summary for Licence Committee

The centre appears well organised and the staff showed evidence of good working relationships.

Three regulatory issues were identified in the course of the inspection and these are summarised below:

- Average payment times are outside the 28 day limit.
- Sperm donor reimbursement is not in line with directions D.2006/1.
- Screening of egg donors is not in line with professional guidelines.

Two recommendations have also been made by the inspection team relating to:

- Submission of HFEA forms.
- Checking the emergency trolley.

The executive recommends the continuation of the centres licence

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
The centre takes an average of 36 days to pay treatment fees. The HFEA payment terms are 28 days. Payment outside these terms is a breach of standard licence condition A.13.3.	The PR should review whether there are any barriers to the prompt payment of HFEA invoices and take steps to ensure the fees are paid within 28 days in compliance with A.13.3.	To be reviewed at the next inspection
Although the donor information complies with	Donors should be reimbursed in line with directions	Immediately

directions, the actual reimbursement made to donors does not. Donors are given £15 for each sample. This is a breach of standard licence condition A.2.6 and directions D.2006/1 which limits reimbursement to reasonable expenses and loss of earnings only.	D.2006/1.	

Non-Compliance

Area for improvement	Action required	Time scale
Screening of egg donors is not in line with professional guidelines. The BFS guidelines state that egg donors should be screened for gonorrhoea and chlamydia. This is non-compliance with code of practice guidelines G.4.9.1.	The centre should follow professional guidelines for screening egg donors or, the rationale for non compliance with the guidelines should be documented. If screening procedures are changed, the provision of patient information should be reviewed.	Screening to be implemented immediately or rationale for non compliance with the guidelines to be documented.

Recommendations

Area for improvement	Action required	Time scale
The HFEA register department have reported problems with the submission of forms. If this situation continues the centre could be in breach of directions D.2008/6.	The centre should monitor the situation regarding submission of HFEA forms to ensure that they do not breach directions D.2008/6.	Immediately
The daily checks on the emergency trolley were seen to be performed at the specified frequency. Some items should be checked weekly according to the centre's policy but these checks had not always been performed weekly.	The centre should follow their own protocol as well as Trust and national guidelines for checking the emergency trolley.	Immediately

Changes/ improvements since last inspection

Recommendations	Action Taken
Witnessing the disposal of embryos is not documented in the patient records in accordance with D2004/4.	This is now documented and evidence of this was seen in patient records.
During the patient records audit gaps in the welfare of the child assessment were noted. In some records there was not evidence that the forms had been checked and approved by centre staff.	This is now being done and was seen in patient records.
All centre staff should be aware of the emergency contact number.	In discussions staff were seen to be aware of this.
According to the centre's policy the emergency trolley should be checked daily. At inspection it was noted that the equipment on the trolley has not been monitored this frequently. The PR should ensure that the emergency trolley is inspected and maintained daily. This check should be documented.	The daily checks on the emergency trolley were seen to be performed at the specified frequency. Some items should be checked weekly according to the centre's policy but these checks had not always been performed weekly.
Update patient information.	This was completed shortly after the previous report was sent to the centre. Evidence of this was seen on the day of the inspection.
Add criminal convictions to staff induction information.	This has been added.

Additional licence conditions and actions taken by centre since last inspection

The previous licence was issued without additional conditions.

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 the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
There are clearly defined reporting systems and relationships within the centre. These are clearly illustrated in the centre's organisational chart. Centre staff reported that new scan machines are being obtained to meet the requirements of the centre. Since the last inspection the centre have moved to electronic witnessing. A full risk assessment of this has been undertaken, showing that this new method would not increase the risks of an error, and this was provided to the inspection team. The pre-inspection questionnaire stated that risk assessments are reviewed annually. The centre have a good incident reporting history. The incident log was reviewed by the inspection team and appropriate incident reporting was seen to be in place. When an HFEA alert is received by the centre this is emailed to all staff. Heads of departments must write a report on the alert which is then sent to all staff and the clinical lead will then discuss the issues raised at the next staff meeting. HFEA alerts were seen displayed on the staff notice board. A summary of the complaints received by the centre was provided and appropriate actions were seen to have been taken in resolving these issues. The centre have an agreement with centre 0021 to ensure that in the event of termination of activities the stored material will be transferred to another licensed centre in compliance with standard licence condition A.5.7. This agreement was provided to the inspection team.

The centre also have comprehensive business continuity plans providing instruction on action to take in the event of unexpected difficulties such as, loss of electricity, loss of water, loss of clinical chemistry and infestation. The file of third party agreements was provided on the day of the inspection. One of the agreements was selected at random and was seen to be compliant with the requirements.
Areas for improvement
The centre takes an average of 36 days to pay treatment fees. The HFEA payment terms are 28 days. Payment outside these terms is a breach of standard licence condition A.13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.
Areas for consideration
None
Executive recommendations for Licence Committee
The PR should review whether there are any barriers to the prompt payment of HFEA invoices and take steps to ensure the fees are paid within 28 days in compliance with A.13.3.
Evaluation
Some improvement required
Areas not covered on this inspection
None

2. Quality of service

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

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
In the time period from the 1 April 2003 to 31 March 2006 the centre's outcomes were in line with the national average, except for donor insemination treatment for patients under 35 and frozen embryo replacement treatment for patients under 38 where the outcomes were significantly above the national average.
Areas of firm compliance
The quality review agenda was provided to the inspection team. This states that management are committed to: providing leadership, communicating the importance of meeting requirements throughout the clinic, establishing a quality policy and objectives, conducting management reviews and ensuring the availability of resources. The quality manual included information on recording non-conformities and corrective and preventative action for these. A management review meeting is held annually and minutes of the last meeting were provided. Minutes for other staff meetings are held on the main server to which all staff have access. The Centre achieved ISO 9001:2000 certification in January 2006 and has a well established quality management system in place. The latest ISO inspection report was provided to the inspection team which showed that the centre was recommended for recertification with no non-conformities. Patients' views are collected via a suggestion box which is located in reception. Patients' opinion of elective single embryo transfer and the counselling service has also been obtained as part of the audit schedule. All documents provided to the inspection team were version controlled with authorisation dates and author.
Areas for improvement
None

Areas for consideration
None
Executive recommendations for Licence Committee
None
Evaluation
No improvements required
Areas not covered on this inspection
None

3. Premises and Equipment

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

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
The premises were considered to be fit for purpose. There is a hearing induction loop fitted and also a system for patients to have access to the car park near the clinic entrance before it opens to the general public. A counselling room is situated at the quieter end of a corridor in the unit. There are three individual recovery rooms which ensure privacy for patients. Emergency call buttons were seen to be present in theatres, clinical rooms, recovery rooms, the male production room and toilets. The laboratory facilities were upgraded in 2005 to meet good manufacturing practice (GMP) standard. The laboratory suite comprises of a series of laboratories which have grade B air throughout. The laboratory area is restricted to laboratory personnel and senior heads of department via a proximity card reader. The cryopreservation laboratory is located within the laboratory suite and has a further proximity reader at the door. All dewars were seen to be locked and fitted with low nitrogen level alarms. A low oxygen monitor was seen to be in place. The laboratory has a facility monitoring system which monitors the room pressure; particles; incubator temperature and carbon dioxide levels; fridge and freezer temperature, liquid nitrogen low levels in dewars, oxygen depletion in the laboratories and gas pressure in pipes. Service schedules ensure that equipment is adequately maintained. The staff offices were seen by the inspection team and there is also a small kitchen for staff use. Patient records are stored in the notes store located behind the reception. This was seen to be a secure area. The PR informed the inspection team that they are considering archiving some records off-site. Centre staff are aware of the confidentiality requirements for patient records and will develop a protocol for this prior to adopting this practice. Centre staff are also aware of the time periods for which treatment records must be retained.
Areas for improvement
None
Areas for consideration

The inspection team were informed that one of the scan rooms could be used as a recovery room if necessary. If this situation is likely to occur, then the suction equipment should be kept ready for use.
Executive recommendations for Licence Committee
None
Evaluation
No improvements required
Areas not covered on this inspection
None

4. Information

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

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Audit of records
An audit was conducted on five sets of patient notes. All sets of notes contained the relevant consent forms. Welfare of the child assessments were seen to be in place and were seen to had been checked by staff. Appropriate witnessing had been performed.
Areas of firm compliance
Since the last inspection, patient information has been updated as required and evidence of this was seen by the inspection team. However, as this was an interim inspection the complete set of patient information was not reviewed. The clinical nurse specialist informed the inspection team that patients are given information about treatment at the first consultation so they have two-three weeks to consider all the information before they need to sign the consent forms. Patient records are stored in paper copy and on the IDEAS database system. Paper records are stored in a records room behind the reception. This room is lockable and the key held by senior members of staff. Electronic records are password protected and the database is backed up on a secure server.
Areas for improvement
None
Areas for consideration
The HFEA register department have reported problems with the submission of forms. This is at least in part due to a problem with the two computer systems. Centre staff are aware of this problem and have stated their commitment to work on this. If this situation continues the centre could be in breach of directions D.2008/6.
Executive recommendations for Licence Committee
The centre should monitor the situation regarding submission of HFEA forms to ensure that they do not breach directions D.2008/6.
Evaluation
No improvements required

Areas not covered on this inspection
None

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	3.2
NMC registered nurses	6.4
Non NMC registered clinical staff	2.4
HPC registered scientists	2.8
Scientists working towards registration	3.0
Support staff (receptionists, record managers, quality and risk managers etc)	11.0
Counsellors	1.0

Summary of laboratory audit
A summary of the stored embryo audit was provided to the inspection team. No discrepancies were noted. The centre perform an audit of stored material every two years as required by standard S.7.8.12
Summary of spot check of stored material
This was not performed on the day of the inspection.
Areas of firm compliance
The PR and medical director are both on the GMC register, the clinical nurse specialist is registered with NMC and the lead scientist is registered with the Health Professions Council. The induction SOP has been amended to include the requirement for all staff to report promptly all criminal convictions to the PR. This was shared with the inspection team. In discussions, staff were seen to be aware of the emergency contact number in the hospital. The three embryos transfer log was provided to the inspection team. All the three embryos

transfers were seen to have been performed for women aged 40 or over in line with guidance.

A protocol for the transport of gametes and embryos was provided to the inspection team. This covered all the key areas and was compliant with the requirements of HFEA alert 21.

The method for tracing media and consumables that have come into contact with gametes and embryos was demonstrated to the scientific inspector.

Equipment has been validated and evidence of this was seen during the inspection.

Witnessing of the disposal of embryos was seen to be in place. The quality manager provided evidence of an audit of witnessing practice, which has recently been reviewed following a change to electronic witnessing.

The laboratory participates in a programme of quality assurance. Evidence of participation in the NEQAS scheme was provided. Key performance indicators are closely monitored and graphically analysed by the quality manager who is also the principal embryologist.

The latest counselling audit was provided to the inspection team. The service is well attended and the results of the counselling questionnaire, provided to the team, illustrated the valuable contribution that this service makes to the treatment centre. There is no charge for the counselling and no limit on the number of sessions available to patients.

Areas for improvement

The daily checks on the emergency trolley were seen to be performed at the specified frequency. Some items should be checked weekly according to the centre's policy but these checks had not always been performed weekly.

Although the donor information complies with directions and guidance G.4.11.1 has been complied with, the actual reimbursement made to donors is not compliant. Donors are given £15 for each sample. This is a breach of standard licence condition A.2.6 and directions D.2006/1 which limits reimbursement to reasonable expenses and loss of earnings only.

Screening of egg donors is not in line with professional guidelines. The BFS guidelines state that egg donors should be screened for gonorrhoea and chlamydia. This is non-compliance with code of practice guidelines G.4.9.1.

Areas for consideration

None

Executive recommendations for Licence Committee

The centre should follow their own protocol as well as Trust and national guidelines for checking the emergency trolley.

Donors should be reimbursed in line with directions D.2006/1.

The centre should follow professional guidelines for screening egg donors.

Evaluation
Some improvement required
Areas not covered on this inspection
None

Report compiled by:

Name……Vicki Lamb…….

Designation……Inspector……..

Date……5 December 2008……

Appendix A: Centre staff interviewed

PR and six members of centre staff.

Conflicts of interest – the PR is also a member of the HFEA Authority.

Appendix B: Licence history for previous 3 years

Licence	Status	Type	Active From	Expiry Date
L0196/7/a	Active	Treatment with storage	01/10/2007	30/09/2012
L0196/6/a	Expired	Treatment with storage	05/07/2007	30/09/2007
L0196/5/b	Replaced by new version	Treatment with storage	01/11/2005	30/09/2007
L0196/5/a	Replaced by new version	Treatment with storage	01/09/2005	30/09/2007

Appendix C: Response of Person Responsible to the inspection report

Centre Number……196……

Name of PR…….William Ledger……..

Date of Inspection……12.11.08……..

Date of Response……22.12.08……..……

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

Signed……by email……..……

Name……William L Ledger……

Date……22.12.08……..……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

None

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

We suggest that the section entitled “Areas for some improvement” be relabelled. Inspections will always identify some inadvertent errors in practice – this is one of the useful outcomes of inspection. However the Authority, and the public should be able to distinguish minor from more major errors in the report. A differentiation between ‘minor’ and ‘major’ areas for improvement would provide useful information without being overly taxing to the inspectors.

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

The report will be discussed fully at our unit ‘awayday’ in January 2009 and necessary action taken thereafter

HFEA Licence Committee Meeting

23 February 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 2

Interim Inspection, Centre for Reproductive Medicine and Fertility, Sheffield (0196)

Members of the Committee:	
David Archard, Lay Member (Chair) Sally Cheshire, Lay Member Jennifer Hunt, Senior Infertility Counsellor, IVF Hammersmith Hossam Abdalla, Director, Lister Fertility Clinic Attending via conference telephone: Neva Haites, Professor of Medical Genetics, University of Aberdeen	Committee Secretary: Claudia Lally Legal Adviser: 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: letter from the Principle Embryologist dated 23 February 2009.

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009.

1. The Committee noted that this centre has been licensed since 2001 and provides a variety of licensed treatments to self-funded and NHS patients. The Committee noted the report of the interim inspection, dated 12 November 2008, and the areas for improvement identified at pages 6 to 7. These issues related to:

- late payment times for treatment fees payable to the HFEA
- sperm donor reimbursement, which was found not to be in line with Directions D.2006/1
- screening of egg donors which had not been taking place in line with professional guidelines
- problems which had been identified with the submission of HFEA register forms; and
- weekly checks of the emergency trolley, which had not always been performed.

2. The Committee noted that late payment of treatment fees and sperm donor reimbursement constituted breaches of standard licence conditions.

3. The Committee considered the response of the Principal Embryologist, as set out in the letter to Vicki Lamb, dated 23 February 2009. The Committee agreed that this letter addresses all of the issues identified in the report, other than the screening of egg donors, of which no mention is made. The Committee agreed that it expected the centre to address this issue immediately, in accordance with the recommendation of the inspection report.

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

Signed…… … Date……..
David Archard (Chair)