Interim Inspection Report

Care Manchester
0185

Date of Inspection: 20th March 2007
Date of Licence Committee: 15th August 2007

CENTRE DETAILS

Centre Address	108-112 Daisy Bank Road Victoria Park Manchester M14 5QH
Telephone Number	0161 249 3040
Type of Inspection	Interim
Person Responsible	Glenn Atkinson
Nominal Licensee	Charmian Russell
Licence Number	L0185/7/a
Inspector(s)	Elliot Lawrence (Lead)
	Tahir Hussain
	Allison Cummings
Fee Paid - date	Not yet invoiced
Licence expiry date	30 September 2009

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About the Inspection:
This inspection visit was carried out on the 20th March 2007 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between November 2006 and 19th March 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 interim 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, recommendations 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.

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 part of the CARE fertility group and is housed within the Manchester Lifestyle Clinic. The centre has been established since 1999 and provides self funding treatments to patients referred from all areas of the North West and occasionally from other regions of the UK and overseas.

The centre has recently undertaken an improvement plan to update the layout and the centres working areas.

The centre is open from Monday to Friday with occasional weekend work for which a rota is provided for staff to work to.

The PR has been with the centre since the start up of the centre and is suitably qualified.

Activities of the Centre (2006)

Licensed treatment cycles	IVF ICSI Egg Sharing - Donor - Recipient Egg Donation - Donor - Recipient	437 393 90 84 7 10
Donor Insemination		26
Unlicensed treatments	IUI GIFT Ovulation Induction Tubal Surgery	127 0 34 0
Research		None
Storage		Yes

Summary for Licence Committee

The centre has seen an improvement in the premises since the last inspection and there is a good history at the centre of regulatory compliance. The recommendations from the previous renewal inspection have been made and work is ongoing to conform to the requirements of the EUTD. The Executive support the continuation of the centres licence.

Risk Assessment

Prior to the inspection, the centre had been allocated a risk score of 11%. Following the inspection, the risk score has not changed.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	X	

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 or Code of Practice

Breach	Action required	Time scale
None identified		

Non-Compliance

Area for improvement	Action required	Time scale
The doors to the consultant's offices were seen to be open and containing patient records when the offices were unoccupied.	All staff need to be informed of their duties to maintain confidentiality.	Immediately.
Donor Info forms were seen to be partly completed by the donor resulting in a donor number with a "C" prefix. This is inconsistent with the donor number transcribed on the treatment forms.	The forms need to be completed correctly and consistently.	Immediately.

Recommendations	Time scale
Staff competencies should be clearly documented and signed off across all areas of the centre.	3 months

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
Staffing levels in the embryology team required review	Additional members have been recruited since
Not all dewars were fitted with low nitrogen level alarms	All dewars are now fitted with low nitrogen level alarms
Patients stated that the counselling services were not accessible	The services are now accessible from reception, through voicemail and also direct contact with the counsellor
Patient information required to be updated	The information has now been updated

Additional licence conditions and actions taken by centre since last inspection

C	
A	**Complied Y/N**
C	
A	**Complied Y/N**
C	
A	**Complied Y/N**

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:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance

The Person Responsible (PR) oversees the management and co-ordination of resources which was evidenced from reviewing minutes of the monthly operational management meetings. The staff interviewed were clear about their own roles and responsibilities.

Monthly unit manager meetings are held between the managers of each department to review the clinic activities and discuss issues. Relevant action points are fed back to the staff via their line manger and/or at the monthly multi-disciplinary team meetings. All members of staff are expected to attend to the multi-disciplinary team meeting. Topics covered include regulatory issues, financial matters, IT, embryology, incidents, complaints, training, quality and governance issues. Meetings are fully minuted and evidence of this was seen during the inspection. Meeting minutes are distributed to all staff via email.

Staff interviewed during the inspection were aware of the HFEA incident alert system. The PR receives the alerts via email from the HFEA and the CARE group and circulates these to all staff. These are signed off by the staff when read. Alerts are discussed at the multi-disciplinary team meetings and relevant departmental meetings.

The unit incorporates three satellite centres (Beaumont, Wigan and Leigh and Halifax). The PR stated that meetings are held twice a year with the satellites however these minutes were not evidenced. The patients at the satellite centres complete CARE consent forms and obtain CARE patient info at the local unit. Treatment details and consent forms are faxed over before satellite patients come to CARE Manchester.

Contingency is in place with CARE Nottingham where staffing cover can be obtained with a days notice. Other services can also be obtained from CARE Sheffield. The group processes and procedures are generic so they are easily transferable. During out of office hours, there are two mobile phones for patients to call if there are issues.

Areas for improvement
No areas identified

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
All areas covered

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:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates

Success rates provided by the centre for the year ending 31/12/06 show the following success rates were obtained: -

	Age <35	Age 35-37	Age 38-39	Age 40-42
Treatment cycles started	26.2	24.5	11.0	7.2
Egg Collections	27.5	26.3	13.0	8.6
Embryo Transfer	29.1	26.3	14.5	9.3
Frozen Embryo Transfer	13.9	21.4	26.7	10.0

All figures above are %

Areas of firm compliance

Evidence was found in patient notes to indicate that a suitable Welfare of the Child assessment had been conducted. Patients are provided with both verbal and written information regarding the treatment options available to them.

There is a robust complaints policy in place which conforms to the requirements of both the HFEA and the Trust. 22 complaints were received in 2006 of which 3 are still open and eight complaints have been received so far in 2007 of which 4 were still ongoing.

Counselling room facilities are undergoing improvement along with the rest of the centre. The counsellor has been with the centre since it opened and is available between 15 and 20 hours weekly. Three free sessions are offered per cycle and couples are offered counselling at various stages throughout treatment. Appointments can be made through the reception area or with direct contact with the counsellor. Due to the donor / recipient services available, the centre is looking to employ an additional counsellor to maintain independence.

Donor selection criteria were considered fit for purpose and detailed all relevant screening requirements.

The centre operates an egg sharing scheme. It was noted that the protocols and patient information provided pre-inspection were considered fit for purpose.

The patients interviewed had decided to use this centre through an open evening information session and had noticed that the centre has become busier over time; however, they have still remained professional. They stated that the staff were friendly, supportive and that they were given timely appointments.

Areas for improvement

None

Executive recommendations for Licence Committee

The counselling services require reviewing to maintain an unbiased view

Areas not covered on this inspection

Protection of children arrangements (for patients under 18yrs)

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:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
During the tour the PR stated that the premises have been significantly improved since the previous inspection and work was seen to be ongoing to better improve the structure. The facilities include: • A suitable male production room. • Admin areas of the building which are shared were seen to have key pad locked doors to ensure security of identifying patient information. • The front reception and waiting area is now divided to ensure patient confidentiality. • The waiting area is awaiting further improvements. The reception area has been fitted with lockable filing cupboards for patient notes. • Three clinical rooms; two of which are used for scanning and IUI's are also performed in these areas. • Emergency trolleys were evidenced to be checked daily. • There are six newly refurbished private recovery rooms which were seen to be fit for purpose.
Areas for improvement
During the tour of the premises it was observed by the inspectorate that the consultant office doors were open with patient records on the desks. These doors were fitted with security pads, however were not closed.
Executive recommendations for Licence Committee
Confidentiality of the patients records should be maintained at all times by ensuring that all access points are secure.
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:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
Twenty sets of patient notes were reviewed for treatments including egg donation, egg recipients, IVF, ICSI, DI and FET. One error was noted where a "Consent to Disclosure" consent had not been obtained and 2 laboratory witnessing errors were noted.
Areas of firm compliance
All patient and donor information is currently in the process of being reviewed along with all protocols for the centre. This is in accordance with the requirements of their Quality Management System, the impending implementation of the EU Tissue and Cells Directive changes and ISO (international organisation for standardisation) standard requirements. All relevant consent forms were found in the notes. The notes were found to be organised well and details required for the purposes of the audit were easily found. All protocols provided and additional information requested during the inspection were considered suitable and fit for purpose by the inspectorate.
Areas for improvement
Treatment forms submitted via EDI with regards to surrogacy arrangements have been seen to be submitted incorrectly. A discussion was held with the HFEA form co-ordinator on the day of inspection. Laboratory staff are currently responsible for completing these and the head of embryology has been made aware. The inspectorate discussed the correct way to complete these forms with both representatives and made available guidance notes for this. Donor Information forms were seen to be partly completed by the donor resulting in a donor number with a "C" prefix. This is inconsistent with the donor number transcribed on the treatment forms. The HFEA form co-ordinator stated that this will be resolved internally.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered

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:

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff (04/07/2007)

GMC registered doctors	3
NMC registered nurses	9.42 (+4.5 HCA's)
HPC registered scientists	4.5
Scientists working towards registration	1.47 (+1.51 laboratory aids)
Support staff (receptionists, record managers, quality and risk managers etc)	12.13

Summary of laboratory audit
This was not requested pre-inspection due to the short notice.
Summary of spot check of stored material
Two embryos were tracked from the records to the tank(s) and vice versa, no discrepancies were noted. Two sperm samples were tracked from the records to the tank(s) and vice versa, no discrepancies were noted.
Areas of firm compliance
In order to meet the requirements of the EUTD, two, class 2, biohazard cabinet are in use. The head embryologist stated the background and cabinet air quality has been assessed as grade B and A respectively. The ten dewars and freezing machine are located in a second laboratory. Access to the laboratories is restricted by digital locks. All dewars are locked and fitted with alarms linked to an auto dial out system. During the week the biomedical scientists are on call for the alarms. The embryologists cover the weekends. A low level oxygen alarm is present in the laboratories and was tested successfully during the inspection. A back-up dewar for storage of sperm and embryos is available in cases of emergency. Key pieces of laboratory equipment were seen to be serviced regularly. Daily monitoring of

temperatures of incubators, hot blocks and heated stages was evidenced from the log books. Monitoring of carbon dioxide levels in the incubators was also evidenced.

Double witnessing in the laboratory was observed and showed that the procedures on the day of the inspection had been signed off. The laboratory manager was able to find all paperwork requested. This indicated a well organised documentation system. Evidence was also seen of monthly embryology meetings, with the last one held in January 07.

A group-wide continuous professional development (CPD) scheme is being developed for the embryologists, to replace the association of clinical embryologists (ACE) CPD scheme. Professional registration details of doctors, nurses and embryologists are kept by the HR for the whole of the CARE group and locally. When registrations are about to expire an email is sent from human resources (HR) to the PR at each centre.

A Deputy Laboratory Manager has been recruited and starts in May and all new staff undergo an induction programme consisting of the CARE training programme and then a continual appraisal system is adhered to.

Areas for improvement

During the interview with the new embryologist, it was seen that an induction programme was available and consisted of being supervised by senior staff for each procedure. However there was no documented evidence of these competencies' being signed off. This practice should be made applicable across all areas. It was felt by some staff that they required additional training relating to HFEA consents and the correct way of obtaining these consents.

Executive recommendations for Licence Committee

None

Areas not covered on this inspection

All areas covered

Evaluation

Some improvement required

Report compiled by:

Name: Tahir Hussain

Designation: Regulation Inspector

Date: 12th April 2007

Appendix A: Centre Staff interviewed

PR – Glenn Atkinson
NL – Charmian Russell

6 centre staff
2 couples

Appendix B: Licence history for previous 3 years

2007
Licence Committee 14th February 2007
Application to export embryos for the purpose to transfer to a surrogate.

2006
Licence Committee 18 December 2006
An incident was brought to the attention of the LC.

Licence Committee 10th July 2006
Renewal inspection report was presented. A three year licence was approved.

2005
Licence Committee 22nd September 2005
Interim inspection report was presented. Licence continued with no recommendations.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……

Name of PR……..

Date of Inspection……..

Date of Response……

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

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

Signed……

Name……

Date……

2. 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).

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

15 August 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 3

CARE Manchester (0185)
Interim Inspection

Members of the Committee:	In Attendance:
Emily Jackson, Lay Member – Chair	Trish Davies, Director of Regulation
Richard Harries, Lay Member	Frances Clift, Legal Adviser
Anna Carragher, Lay Member	Marion Witton, Head of Inspection
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary	Barbara Lewis, Regulation Team Leader
	Claudia Lally, Committee Secretary

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 (25 pages)
- no papers were tabled.

1. The papers for this item were presented by Tahir Hussain and Allison Cummings, HFEA Inspectors. Mr Hussain informed the Committee that the inspection visit had revisited a number of concerns raised at the renewal inspection in 2006. These concerns focused on staffing levels in the embryology team, insufficient numbers of low nitrogen level alarms, difficulties in accessing counselling services and some patient information being out of date. This inspection found that these concerns have now been satisfactorily addressed by the centre.

2. Mr Hussain drew the Committee's attention to a number of recommendations made by the inspection team at this interim inspection visit and detailed on page 6 of the inspection report. He then summarised the response by the Person Responsible to these recommendations, which is appended at page 17 of the report.

3. The Committee noted that the recommendations by the inspection team had been satisfactorily addressed by the Person Responsible and agreed that the centre's licence should continue with no additional conditions.

Signed…… … Date……..
Emily Jackson (Chair)