Interim Inspection Report

Manchester Fertility Services
0033

Date of Inspection: 17th October 2007
Date of Licence Committee: 28 January 2008

CENTRE DETAILS

Centre Address	The Bridgewater Hospital 120 Princess Road Manchester M15 5AT
Telephone Number	0161 227 0010
Type of Inspection	Interim
Person Responsible	Brian Lieberman
Nominal Licensee	Daniel Brison
Licence Number	L0033-11-b
Inspector(s)	Wil Lenton (Chair, HFEA) Janet Kirkland (HFEA) Tahir Hussain (HFEA
Fee Paid - date	N/A
Licence expiry date	30th April 2009

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About the Inspection:
This inspection visit was carried out on 17th October 2007 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between 1st January and 31st December 2006.

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

Manchester Fertility Services was first licensed by the HFEA in1986. It currently provides IVF, ICSI, FET, DI, IUI, Egg donation and storage facilities. It is a large sized centre and provides approximately 1100 licensed treatment cycles per year to fee paying patients. It has no NHS contract with local PCT's. The centre has a policy of not replacing more than two embryo's even in exceptional circumstances. The centre was licensed to perform treatment and storage in new premises in May 2006, with a re-inspection by the executive being carried out in June 2006. It recently successfully varied its current licence to incorporate the requirements of the EUTD with a low risk score of 5%. The PR is an experienced consultant, who has successfully completed the PR assessment workbooks, and has a similarly experienced senior management team.

Activities of the Centre

Licensed treatment cycles	IVF	236
	ICSI	196
	FET	256
	DI	417
	Egg Donation	5
Unlicensed treatments	Ovulation induction	
Research	Yes	
Storage	Yes	

Summary for Licence Committee

The overall level of compliance was considered to be good, however during the course of the inspection a number of regulatory issues were identified and are summarised below:

- Some third party agreements are in place, but more work is required in order to cover all services/suppliers.
- Although incidents are logged internally, no incidents have been reported to the HFEA since 2005. The centre may want to re-assess its grading of reportable incidents to the Authority.
- There was no information within the patient waiting area giving details of either,
  i. the centre's complaints procedure or
  ii. access to counselling.
- A very brief counselling audit was supplied prior to the visit. This should be expanded in the future to include a better breakdown of client groups seen, gender of clients, couples or individuals, number of sessions attended etc.

- The first floor reception, which is located within a mixed patient waiting area, was found to be insecure and staff were heard to refer to patients by name whilst answering telephone calls.

- Air quality within the laboratory is not presently being monitored/recorded.

- Some items such as catheters and ICSI needles are currently logged for traceability, but every item such as culture dishes, centrifuge tubes, pipettes etc which come into contact with gametes/embryo's needs to be similarly recorded.

- A home-procurement protocol needs to be formulated.

- Some witnessing steps need to be included/amended in order to ensure that practice complies to HFEA guidance.

The inspection team support the continuation of the centre's licence**.**

Risk Assessment

Following the inspection, the risk assessment as calculated via the HFEA Risk Tool is low at 16%.

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
Air quality within the laboratory is not presently being monitored/recorded ***(CoP7 – S.6.3.6/S.7.8.5)***	A protocol needs to be developed in order to monitor /recorded to comply with the Standard	**3 months following LC**
The first floor reception, which is located within a mixed patient waiting area, was found to be insecure and staff were heard to refer to patients by name whilst answering telephone calls. ***(CoP7 – S.6.3.1)***	The security of confidential information, both written and verbal needs to be reviewed	**Immediately**
Some third party agreements are in place, but more work is required in order to cover all services/suppliers. **(CoP7 – S.4.2.10)**	All third party agreements need to be formulated.	**3 months following LC**
Some witnessing steps need to be included/amended in order to ensure that practice complies to HFEA guidance. **(CoP7 – S.7.8.15)**	Revision/amendment of witnessing protocol to ensure that each step where gametes are moved is witnessed appropriately as per HFEA guidance	**Immediately**
Every item which come into contact with gametes/embryo's needs to be traceable from records. ***(CoP7 – S.7.3.1/2)***	Development of present protocol/practice to ensure that each item which comes into contact with gametes/embryo's is traceable.	**3 months following LC**
A 'home-procurement' protocol needs to be formulated. **(CoP7 – S.7.7.9)**	A written protocol needs to be developed to comply with the Standard	**Immediately**

Non-Compliance

Area for improvement	Action required	Time scale
N/A		

Recommendations	Time scale
The counselling audit should be expanded	By the next inspection
There was no information within the patient waiting area giving details of either the centre's complaints procedure or access to counselling.	Immediately

Proposed licence variations

None

Changes/ improvements since last inspection (19th January 2006)

Recommendation	Action taken
Patients notes stored in filing shelves in counselling area which aren't always secured – need to check that this practice has been amended	No notes now kept within the counselling area.
Patient records stored in area which is small	Patient notes store area relocated July 2007 to larger room.
Low nitrogen alarms not fitted to all cryodewars? – centre agreed to alarm main storage dewars by time of next inspection	All alarms now in place.
Centre needed to develop written protocol for 'coasting' patients	Protocol now in place.
Centre undertaking review of patient letters	Review of patient letters undertaken.

Additional licence conditions and actions taken by centre since last inspection

C	N/A

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. General organisation of the centre
2. Quality management system
3. Continual improvement
4. Corrective action
5. Preventive action
6. Internal audit
7. Establishment and review of contracts with third parties and transport
8. Transportation, labelling of shipping container and recall
9. Incident Reporting
10. Alerts
11. Notification of serious adverse reactions
12. Equality and Diversity
13. Risk Management
14. Donors
15. External reviews
16. Contingency arrangements

Areas of firm compliance
Four organisational charts provided on the day of inspection were found to adequately define working relationships and management structure. There appeared to be adequate numbers of appropriately qualified and trained staff in order to deliver the service to patients. Regular minuted clinical meetings take place every week to discuss completed cycles, upcoming cycles, outcomes and any other issues arising. Monthly, minuted quality management meetings also take place. Minutes of meetings were made available via the password –protected electronic quality management system (QMS). HFEA Alerts are discussed at departmental meetings before being signed off as read by individual staff. Risk assessments concerning the clinical areas were seen to have been performed together with regular Health and Safety checks of the ground/first floor premises. Contingency arrangements are in place with centre 0067 and Liv' Women's 0000 ?
Areas for improvement
Although incidents are logged internally, no incidents have been reported to the HFEA since 2005. The centre may want to re-assess its grading of reportable incidents to the Authority. Some third party agreements are in place, but more work is required in order to cover all services/suppliers.

Minor issues to be addressed
None
Areas not covered on this inspection
Equality and Diversity

Evaluation
Some 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. Live Birth Rates
2. Confidentiality and access to health records
3. Needs and requirements of users
4. Assessment of user satisfaction
5. Quality objectives and plans
6. Quality Manager
7. Quality Review
8. Counselling
9. Welfare of the Child
10. Monitoring and resolutions of complaints
11. Staff suggestions
12. Patient choice
13. Egg Sharing and Surrogacy

Live Birth Rates (Centre's own figures 01/01/06 to 31/12/06)
IVF/ICSI clinical pregnancy rate/cycle started = 20% FET clinical pregnancy rate/cycle started = 17% DI clinical pregnancy rate/cycle started = 11%

Areas of firm compliance
The quality manager has been in post since August 2006 and has utilised the Q-Pulse system to develop the centre's QMS. All documentation is accessible to centre staff with an appropriate pass-word. Incidents and complaints were seen to be logged and monitored via the system. A hard copy of the quality manual is available in the clinic and laboratory, but is available electronically too. Three experienced, part-time counsellors are employed by the centre and are available on different days of the week, as and when required. A brief counselling audit for 2006/7 was supplied prior to the visit, which showed that a total of 273 patients had used the service during this period, the vast majority (71%) for implications counselling. Complaints were seen to be logged and managed via the QMS system on the day of inspection. The centre has formulated, sent out and evaluated its own patient questionnaire in order to address patient concerns. HFEA patient questionnaires collated prior to the inspection indicated that a majority (90%) of respondents were happy with the service that they had received at the centre.

Areas for improvement

There was no information within the patient waiting area giving details of either,

i. the centre's complaints procedure or
ii. access to counselling.

A very brief counselling audit was supplied prior to the visit. This should be expanded in the future to include a better breakdown of client groups seen, gender of clients, couples or individuals, number of sessions attended etc.

Minor issues to be addressed

Patient suggestion box missing from waiting room (lost during transfer of premises)

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. Any Changes
2. Suitable premises
3. Safe working with environment
4. Clinical facilities
5. Counselling facilities
6. Laboratory facilities
7. Storage facilities for gametes and embryos
8. Air quality
9. Staff facilities
10. Suitable equipment
11. Management of equipment and materials
12. Alarms
13. O2 alarms
14. Handling and manipulation of gametes and embryos
15. Dewars

Areas of firm compliance

Since June 2006 the theatre and laboratory facilities have been relocated onto the present site and were re-inspected for licensing purposes on 14th June 2006, at which time they were found to be fit for purpose by the Executive.

The centre is now on one site within the Bridgewater hospital. The facilities are spread over two floors. The theatre, embryology laboratory and cryostorage room are located on the ground floor, whilst the consulting, scan, treatment, administration and mens production rooms, are on the first floor. Patients are directed up to centre from the main hospital reception.

The medical notes store has been relocated to a more appropriate room which was seen to be secure and fit for purpose.

The cryostorage room has restricted swipe-card access. Each dewar was seen to be fitted with a low nitrogen alarm and there was a low oxygen monitor within the room, connected to an external audio/visual alarm. The temperature of each dewar was monitored via a pc link.

All patient-sensitive areas such as theatre, embryology laboratory, notes room, administrative office and the nurses office had restricted access and were seen to be secure.

Areas for improvement

The first floor reception, which is located within a mixed patient waiting area, was found to be insecure and staff were heard to refer to patients by name whilst answering telephone calls.

Air quality within the laboratory is not presently being monitored/recorded.

Minor issues to be addressed
None.
Areas not covered on this inspection
None.

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. Meetings and communication
2. Information management
3. Quality manual
4. Document control
5. Control of Records
6. Donor registration
7. Receipt of gametes
8. Home Procurement documentation
9. Traceability
10. Material donated to research
11. Information for users This includes: Access to data
12. Tracking live birth events
13. Storage records
14. Information to the HFEA
15. Counsellor records
16. Import/export
17. 3 embryo transfer
18. Donor Information
19. Storage and release of gametes and embryos
20. Storage forms
21. Anonymity
22. Labelling of packages containing procured gametes
23. Screening
24. Audit
25. Consents

Outcome of audit of records
Eight sets of patients notes were reviewed on the day of inspection and no problems were encountered.
Areas of firm compliance
A current HFEA treatment & storage and research licence, together with a Healthcare Commission certificate were observed in the patient waiting area. All patient information reviewed was clear and accurate and is held within the centre's QMS. All centre documentation is held electronically as part of the QMS and can be accessed as 'read only' files by centre staff with the appropriate password. Information is regularly reviewed and updated as required by designated centre staff before being signed off by the quality manager. It is centre policy not to perform any three-embryo ET's.

Areas for improvement

Some items such as catheters and ICSI needles are currently logged for traceability, but every item such as culture dishes, centrifuge tubes, pipettes etc which come into contact with gametes/embryo's needs to be similarly recorded.

Home-procurement protocol needs to be formulated.

Minor issues to be addressed

None.

Areas not covered on this inspection

Labelling of packages containing procured.
Material donated to research.

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. Staffing Personnel Records
2. Criminal convictions
3. Initial /basic training and update training
4. Competence
5. Annual joint review
6. Continuing education and professional development
7. Procedures
8. Clinical Processes
9. Clinical treatment
10. Procurement, Distribution (including packaging and transportation), and receipt of gametes and embryos
11. Viral positive patients
12. Cross infection
13. Laboratory Processes
14. Selection and Validation of laboratory procedures
15. Screening
16. Emergency procedures
17. Handling and manipulation of gametes and embryos
18. Witnessing
19. Assuring the Quality of procedures
20. Participation in inter-Centre comparisons and inter-Laboratory comparisons

Full time equivalent staff

GMC registered doctors	6
NMC registered nurses	6
HPC registered scientists	2
Scientists working towards registration	4
Support staff (receptionists, record managers, quality and risk managers etc)	9

Summary of laboratory audit
1. Embryo audit. (30/04/07 to 02/05/07) 8 discrepancies found and all resolved successfully 2. Sperm audit (31/07/07 to 02/08/07) 14 discrepancies found and all resolved successfully
Summary of spot check of stored material
1 sperm sample tracked from records to tank and vice versa 1 embryo sample tracked from records to tank and vice versa No discrepancies found

Areas of firm compliance

New laboratory staff undertake specific training which includes, familiarisation with SOP's, observing practice and supervised practice, prior to being signed off as competent by the supervisor. Training logs are kept by staff. The CPD log for the laboratory manager was seen to be up-to-date. Individual outcomes are recorded for IUI's, ICSI's, ET's, etc in order for ongoing competency assessment. Annual appraisals are performed and kept by the unit manager.

Minuted laboratory meetings take place every month during which HFEA Alerts and incidents are discussed. Minutes of such meetings were viewed on the QMS.

The laboratory was established in 2006 with new equipment, most of which was still under manufacturers warranty, but maintenance/service contracts were seen to be in place.

All critical-use equipment such as incubators, flowhoods and cryodewars are monitored electronically via a link to a pc which was observed during the inspection.

KPI's such as;

- Number of eggs collected
- Fertilisation rate
- Cleavage rate
- Clinical pregnancy rate

are measured on a regular basis and evidence was seen via the QMS.

The laboratory participates in the NEQAS external QC scheme.
Sperm donors are screened in accordance to current HFEA/BAS guidelines.

Areas for improvement

Some witnessing steps need to be included/amended in order to ensure that practice complies to HFEA guidance.

i. checking of patient information when transferring eggs into patient dishes following egg-collection
ii. written protocol required for active identification of sperm provider
iii. witnessing step required when sperm pellet transferred to clean tube during processing
iv. witnessing step required when removing embryo's from storage.

Minor issues to be addressed

None.

Areas not covered on this inspection

Validation processes

Evaluation

Some improvements required.

Report compiled by:

Name…….Wil Lenton……..

Designation…… Inspector……..

Date…… 28/11/07……

Appendix A: Centre Staff interviewed

PR + 5 other staff

Appendix B: Licence history for previous 3 years

2007

Licence Committee 26 April 2007
Variation of licence to incorporate requirements of the EUTD.

2006

Licence Committee 24 May 2006
Change of premises approved pending a satisfactory visit on 14 June 2006. Treatment licence issued to centre on 15 June 2006.

Licence Committee 22 March 2006
Licence renewed for three years with no conditions and no recommendations

2005

2004

Licence Committee 11 November 2004
Daniel Brison recognised as the new Nominal Licensee.
GIFT treatment removed from licence as requested by centre.
Licence continued with no conditions and 1 recommendation.

Licence Committee 13 May 2004
Incident #164 discussed and agreed no further action was needed.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……0033……

Name of PR……Professor Brian Lieberman……

Date of Inspection……..17 October 2007……..

Date of Response……03 December 2007……

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

Non-Compliance	Action Taken	Timescale
Air quality within the laboratory is not presently being monitored/recorded	A protocol will be developed and Planer will be validating and monitoring the air quality at the same time as servicing the controlled rate freezer at six monthly intervals	
1st Floor Reception	We are in negotiation with the Bridgewater Hospital Management who have agreed to provide a discrete, secure and separate reception area for our patients	Immediately
Third Party Agreements	Quality Manager is in the process of formulating agreements with all third parties	On-going
Information in the waiting area	The complaints procedure was clearly displayed in the waiting area at the time of inspection. Document entitled, 'Helping us to Help you' The name and contact	

	details of the complaints officer is now also displayed on the patient notice board Information on our counselling service is now displayed on the patient notice board	
Counselling Audit	Counselling audit will be expanded (see attached Counselling Statistic Form) A Patient Suggestion Box has now been purchased and is situated in the waiting area	
Witnessing Steps	See amended Witnessing Forms	
Traceability of items	In the process of implementing traceability of all items which come into contact with gametes/embryos	Within 3 months
Home Procurement protocol	See Form Andrology OP-AN-23v1	

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

Signed……

Name ……Professor Brian Lieberman……

Date……03 December 2007……

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