Renewal Inspection Report

Manchester Fertility Services

0033

Date of Inspection: 04 December 2008
Date of Licence Committee: 23 February 2009

Centre Details

Person Responsible	Brian Lieberman
Nominal Licensee	Daniel Brison
Centre name	Manchester Fertility Services Ltd
Centre number	0033
Centre address	The Bridgewater Hospital 120 Princess Road Manchester M15 5AT
Type of inspection	Renewal
Inspector(s)	Wil Lenton (Lead, HFEA) Ellie Suthers (HFEA) Bryan Woodward (External Inspector)
Fee paid	Yes - 04/07/2008
Licence No. & expiry date	L0033- 12-a (30th April 2009)
NHS/ Private/ Both	Private

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About the Inspection:

This inspection visit was carried out on 4th December 2008 and lasted for 8 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 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

- Manchester Fertility Services was first licensed 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.
- The centre has a policy of not replacing more than two embryo's even in exceptional circumstances and has been part of the DH initiative on multiple births.
- 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 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[1] for the time period from (HFEA Register data Jan – Dec 2007)

In vitro fertilisation (IVF)	255
Intracytoplasmic sperm injection (ICSI)	153
Frozen embryo transfer (FET)	247
Intra uterine insemination (IUI/DI)	430
Gamete intrafallopian transfer (GIFT)	0
Research	Yes
Storage gametes/embryos	Yes

Summary for Licence Committee

The centre was found to be cohesive and well organised, with an experienced senior management team in charge of service delivery.

A number of regulatory issues were identified during the course of the inspection and are summarised below:

- Amendment of SOP (OP-EM-8v1) for removal of embryo straws from cryo-storage
- Amendment of SOP (OP-EM-8v1) to ensure all records updated contemporaneously
- Risk assessment of current practice for the splitting of patients frozen embryo's between cryodewars

The inspection team support the renewal of the centre's licence.

[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.

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
None		

Non-Compliance

Area for improvement	Action required	Time scale
None		

Recommendations

Area for improvement	Action required	Time scale
Embryo thawing SOP (OP-EM-8v1) to be amended to ensure; i. the removal of embryo straws (from their canes) to be performed over a flask of liquid nitrogen and not over the open dewar. ii. all records are contemporaneously updated. **CoP7 – S.7.8.5(b)(c)/S.7.8.10(d)**	Amendment of SOP (OP-EM-8v1)	Immediately
The practice of not splitting all patient's frozen embryo's into two different cryodewars to be risk assessed.	Risk assessment of current practice	To be completed by end of June 2009

Changes/ improvements since last inspection

Recommendations	Action Taken
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
Third Party Agreements	Quality Manager is in the process of formulating agreements with all third parties
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
Home Procurement protocol	See Form Andrology OP-AN-23v1

Additional licence conditions and actions taken by centre since last inspection

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 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
From the organisational charts provided prior to the inspection, together with information received and observations made during the inspection, 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. A good clinical governance framework was seen to be in place with both complaints and incidents being logged and managed via the QMS. Contingency arrangements are in place with centre's 0067 & 0007
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

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]

HFEA Clinic Profile for period Jan 01, 2003 to Dec 31, 2006

Relative Live-birth Success Rates (compared to national average)

Age Group		**DI**		**FET**		**IVF/ICSI**
Below 35	13.855%	No difference	20.062%	No difference	26.483%	No difference
35 - 37	12.234%	No difference	15.58%	No difference	21.02%	No difference
38 - 39	9.623%	No difference	13.253%	No difference	14.05%	No difference
40 - 42	5.078%	No difference	10.417%	No difference	6.645%	No difference
Over 42	3.571%	No difference	8%	No difference	2.5%	No difference

Areas of firm compliance

The quality manager has been in post since August 2006 and is continuing to develop the centre's QMS via the Q-Pulse system. All documentation is accessible to centre staff with an appropriate password. A hard copy of the quality manual is available in the clinic and laboratory, but is available electronically too.

The quality manager is attending regular quality management training as part of her ongoing CPD.

Evidence of a document control system with annual review was seen as part of the QMS, with incidents and complaints being logged and monitored via the same system.

An annual quality management review is taking place and audits such as a patient questionnaire are being devised, distributed and analysed as part of the continual improvement process.

Third party agreements were seen to be in place.

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
Since the previous inspection the patient reception has been relocated to a different area on the first floor to give greater patient confidentiality. 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. All clinical facilities seen during the inspection were appropriate and fit for purpose.
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

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

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. Information concerning access to counselling, complaints procedure, quality assurance policy as well as HFEA literature, patient satisfaction survey and a suggestion box were also available. 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.
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

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 wte (7 clinicians)
NMC registered nurses	4 wte (7 nurses)
Non NMC registered clinical staff	0
HPC registered scientists	2
Scientists working towards registration	4
Support staff (receptionists, record managers, quality and risk managers etc)	6
Counsellors	0.5 (2 counsellors)

Summary of laboratory audit
Sperm audit: 16,17, 24 & 28 October 2008 Seven discrepancies found – administrative errors - all successfully resolved Embryo audit: 16 September & 22 October 2008 Five discrepancies found – administrative errors - all successfully resolved
Summary of spot check of stored material
Two sets of embryos were tracked from the database to the cryostore and vice versa, with no discrepancies. Two sets of semen samples were similarly tracked, again with no discrepancies.
Areas of firm compliance

From both the staff-list supplied and observation during inspection, it appeared that there are adequate numbers of trained staff in order to deliver the laboratory service.

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

An SOP is in place for the monitoring of laboratory air quality. An external company measures air quality via particle counts at six-monthly intervals and settle plates are evaluated quarterly. Results were seen to fulfil present regulatory requirements.

A traceability log of all media, consumables and equipment which comes into contact with patient gametes/embryo's was viewed via the QMS and found to be compliant.

The witnessing procedures presently in place within the laboratory are compliant with present Authority guidelines.

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.

All critical-use equipment is regularly maintained and service contracts are in place. Monitoring of critical equipment.

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.

A home-procurement SOP is presently in place and was found to be compliant with current regulatory requirements.

It is centre policy not to perform any three-embryo ET's and therefore no 3-embryo ET log is maintained and no such practices undertaken at the centre.

Two experienced part-time counsellors are employed by the centre and are available on different days of the week, as and when required. A counselling audit for 2007/8 was supplied prior to the visit, which showed that a total of 172 patients had used the service during this period, the vast majority (82%) for implications counselling.

Areas for improvement

Embryo thawing SOP (OP-EM-8v1) to be updated to ensure;

i. the removal of embryo straws (from their canes) is performed over a flask of liquid nitrogen and not over the open dewar (learning from incident IN00911)

ii. all records are contemporaneously updated (learning from recent audit)

Areas for consideration

The practice of not splitting all patient's frozen embryo's into two different cryodewars to be risk assessed. (this is only presently undertaken if the couple have 8+ embryos to store)

Executive recommendations for Licence Committee

Embryo thawing SOP (OP-EM-8v1) to be updated to ensure;

i. the removal of embryo straws (from their canes) is performed over a flask of liquid nitrogen and not over the open dewar (learning from incident IN00911)

ii. all records are contemporaneously updated (learning from recent audit)

Evaluation

Some improvements required

Areas not covered on this inspection

None

Report compiled by:

Name……Wil Lenton…….....

Designation…….Inspector…….....

Date……...04 December 2008……

Appendix A: Centre staff interviewed

Person Responsible
Quality manager
Unit manager
Principal scientist
Counsellor
Junior scientist

Appendix B: Licence history for previous 3 years

2008

Licence Committee 28 January 2008
Presentation of interim inspection – no licence conditions

Research Licence Committee 9 January 2008
Presentation of research inspection

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

Appendix C: Response of Person Responsible to the inspection report

Centre Number…….0033……

Name of PR…Professor Brian Lieberman……

Date of Inspection…4th December 2008……..

Date of Response…23rd January 2009……

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

Signed……. Bliebermar ……

Name……Professor Brian Lieberman……

Date……...23rd January 2009……

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.

nil

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

nil

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

Embryo thawing SOP OP-EM-8 was updated as recommended on the 15.12.08

We welcome comments about the inspection on the inspection feedback form, a copy of which should have been provided at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

HFEA Licence Committee Meeting

23 February 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 1

Licence Renewal, Manchester Fertility Services (0033)

Members of the Committee:	
David Archard, Lay Member (Chair)	Committee Secretary:
Sally Cheshire, Lay Member	Claudia Lally
Jennifer Hunt, Senior Infertility Counsellor, IVF Hammersmith	Legal Adviser:
Hossam Abdalla, Director, Lister Fertility Clinic	Mary Timms, Field Fisher Waterhouse
Attending via conference telephone:	
Neva Haites, Professor of Medical Genetics, University of Aberdeen	

Declarations of Interest: Sally Cheshire informed the Committee that she is Deputy Chair of the NHS Northwest Strategic Health Authority. The Chair agreed that this is not an interest that gives rise to a conflict. Other 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 (28 pages)
- no tabled papers.

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 is a large centre which provided approximately 1,100 licensed treatment cycles per year to privately funded patients.

2. The Committee considered whether they were satisfied that the Person Responsible was a suitable person. They decided that they were, on the basis of the statement at page 5 of the inspection report that the Person Responsible was an experienced consultant who has successfully completed the Person Responsible Entry Programme (PREP) assessment.

3. The Committee considered whether they were satisfied as to the suitability of the centre premises. They decided that they were, on the basis of the evaluation at page 12 of the inspection report that no improvements were required to the centre premises or equipment. The Committee also noted the statement on the same page that all clinical facilities seen during the inspection were appropriate and fit for purpose.

4. The Committee considered whether they were satisfied as to the suitability of the practices carried on at the centre. The Committee noted that no breaches of the Act, Code of Practice or licence conditions were identified at the inspection. Furthermore, the Committee took into account the actions, listed at page 7 of the inspection report, which were being taken in response to recommendations made at the previous inspection of the centre. In the light of these two factors, the Committee decided that they were satisfied as to the suitability of practices at the centre.

5. The Committee agreed that it had sufficient and satisfactory information upon which to make a decision.

6. The Committee noted that a suitably completed and signed renewal application had been received by the centre and that the licence renewal fee had been paid.

7. The Committee agreed that they did not want to impose an additional condition on the licence. However, the Committee asked that the centre note the recommendations identified in the report and address these in accordance with the timescales given. Furthermore, the Committee asked that the centre fully implement, as soon as possible, the outstanding recommendations from the previous inspection.

8. The Committee decided that, taking into account that no breaches of the Act or Code were identified at the renewal inspection, the centre's licence should be renewed for a period of five years.

9. The Committee further decided that an interim inspection should take place after two years.

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