Interim Inspection Report

St Mary's Manchester
0067

Date of Inspection: 26th September 2007

Date of Licence Committee: 21st November 2007

CENTRE DETAILS

Centre Address	Department of Reproductive Medicine St Mary's Hospital, Manchester M13 OJH
Telephone Number	0161 276 6340
Type of Inspection	Interim
Person Responsible	Dr Cheryl Fitzgerald
Nominal Licensee	Dr Mike Deegan
Licence Number	L0067- 15-a
Inspector(s)	Wil Lenton (HFEA, Chair) Parvez Qureshi (HFEA) Emer O'Toole (HFEA, Observer)
Fee Paid - date	N/A
Licence expiry date	31st July 2010

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About the Inspection:
This inspection visit was carried out on 26th September 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

The Regional IVF and DI unit at St Mary's Hospital in Manchester was first licensed by the HFEA in 1992. It currently provides IVF, ICSI, egg donation, DI, IUI, freezing and storage facilities. This is a large, active centre providing over 1000 treatment cycles in the last year. NHS funded treatment is provided here for patients from Greater Manchester and the surrounding areas. It is part of the Department of Health initiative to promote single embryo transfer (SET) and does not perform any 3 embryo transfers. The centre has a good history of regulatory compliance and recently successfully varied its licence to incorporate the requirements of the EUTD, with a low risk score of 7%.
The Central Manchester Trust is currently in the process of a PFI (private finance initiative) development, and the centre is scheduled to move into this new facility later in 2007.
The PR has been in post since August 2006 and is appropriately qualified to discharge her duties as outlined in S.4 of CoP7. She is familiar with all aspects of the service provided such as, clinical, nursing, laboratory, administrative and managerial responsibilities as she was previously the accredited consultant at the centre.

Activities of the Centre (Register data Jan – Dec 2006)

Licensed treatment cycles	IVF	331
	ICSI	197
	FET	388
	Egg donation	6
	Egg recipient	6
	DI	68
Research	Yes	
Storage	Yes	

Summary for Licence Committee

St Mary's Manchester has been licensed by the HFEA since 1992. It currently provides over 1000 licensed treatment cycles to NHS only patients from Greater Manchester and surrounding areas. It is part of the Department of Health initiative to promote single embryo transfer (SET) and does not perform any 3 embryo transfers. The centre has a good history of regulatory compliance and recently successfully varied its licence to incorporate the requirements of the EUTD, with a low risk score of 7%. The centre is about to move into new laboratory, theatre and recovery facilities by the end of 2007.

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

- The document control system does not presently cover all aspects of the centres documentation.
- The centre does not currently monitor air quality within the laboratory.
- The laboratory does not currently record details of all plasticware and other materials which come into contact with gametes/embryos
- The HFEA was not informed of an incident concerning potential loss of patient material (sperm sample) during a recent audit

In addition to these issues it is recommended that a re-inspection of the new laboratory, theatre and recovery facilities occurs once they have been fully commissioned.
(The Executive to be advised by the centre as to the timing of this action)

Risk Assessment

The risk score is currently 11% which is considered as low.

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
The document control system does not presently cover all aspects of the centres documentation. *CoP7 –S.5.2.5/6*	Further development of the document control process to include all documents used within the centre.	6 months following LC
The centre does not currently monitor air quality within the laboratory. *CoP7 – S.6.3.6/S.7.8.5*	Monitoring of air quality	3 months following LC
The laboratory does not currently record details of all plasticware and other materials which come into contact with gametes/embryos. *CoP7 – S.7.3.1/2*	Traceability records for all equipment and materials used during the transit of gametes/embryos through the centre	3 months following LC
The HFEA were not informed of an incident concerning potential loss of patient material (sperm sample) *CoP7 – S.6.4.3c*	Resolution of sperm tank audit issue from April 2007 concerning potential loss of stored sperm and reporting of incident to Authority	1 month following LC
The reporting of some treatment cycles to the Authority has been problematic. *CoP7 – S.6.5.1/2*	Centre to work with Registry to fully resolve outstanding issues	3 months following LC

Non-Compliance

Area for improvement	Action required	Time scale

Recommendations	Time scale
Re-inspection of new facilities (laboratory, theatre, recovery and cryostore) once they have been fully commissioned.	To be advised by centre.

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
Long term storage samples to be split	Completed Jan 2007
Written arrangements with satellite centre to be put in place	Written agreement with satellite centre in place and reviewed on 6 monthly basis
Screening of all stored sperm samples to occur.	This is due to commence with move into new facilities by November 2007
The cryostore door to be kept secure	This has been actioned

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
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
The PR and senior management team attend regular minuted meetings which include unit and quality management meetings. HFEA alerts and incidents are discussed during unit meetings. There are also regular individual discipline meetings (administrative, clinical, laboratory, nursing and research). Minuted notes were observed during the inspection of a meeting between 0067 and staff at Leigh infirmary to discuss satellite arrangements. A quality manager is in post and the quality management system (QMS) is being developed via the Q-Pulse system. Information such as; • Minuted meetings • Risk assessments • Key performance indicators • Standard operating procedures (SOP's) • Incident reports • Audits & management reviews are now stored/accessed electronically. The development of a document control system was evidenced both by documentation sent prior to the inspection and paperwork requested on the day.

A major building program is in process involving the embryology laboratory, theatre and recovery areas. Plans of the new facilities were supplied prior to the inspection and progress to date was seen on the day. It is expected that the new facilities will be in use by the end of November this year.

Risk assessments were observed on the day and are undertaken as part of the CPA process and kept on the QMS.

Incidents are actively reported to the Authority.

A written contingency agreement is in place with centre 0033

Areas for improvement

Areas not covered on this inspection

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:

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

Clinical Pregnancy Rates (HFEA data 01/01/06 to 31/12/06)
Fresh IVF + ICSI (per cycle started) = 18% Fresh IVF + ICSI (per embryo transfer) = 24% FET CPR (per cycle started) = 16% (per embryo transfer) = 18%
Areas of firm compliance
The HFEA treatment and storage licence, together with two research licences were evidenced in the waiting room. There was also a notice giving information about the centres complaints procedure, counselling service and information on current research projects. Since the last inspection the PR and senior management team have implemented new initiatives to improve its quality of service, continued to audit the centre's activities and have seen year-on-year improvements to quality of patient care as indicated by improved success rates. A quality manager is in post and the QMS is being developed via the Q-Pulse system, with all documentation being stored and updated via the quality manager. A document control system is in place as evidenced from paperwork seen on the day, but this needs to be further developed to cover all documentation. The unit carefully monitors patients treatment cycles and practices a 'freeze-all' policy if the patient is showing any signs of OHSS. In the reporting period there were 49 instances of patients having all viable embryos frozen instead of proceeding to embryo transfer (and a higher risk of OHSS.) The units' philosophy is to safeguard the welfare of the patient at all times, whilst ensuring that they have a good chance of producing a viable pregnancy via subsequent frozen embryo transfer (FET)

The unit does not carry out any 3 embryo transfers and is part of the department of health (DH) initiative to promote single embryo transfer (SET). This policy is now well established and patients are carefully counselled about the health risks associated with multiple pregnancies, both to the woman and unborn child. Last year SET accounted for 34% of all fresh embryo transfers and 58% of all FET's.

An extensive audit of the counselling service was supplied with the pre-inspection documentation, which showed;

- Total sessions offered – 741
- Total number of sessions delivered – 574, of which

i. implication counselling – 169
ii. support/therapeutic counselling – 374
iii. WoC – 31

- Cancelled sessions – 66
- DNA – 101

Both practitioners have extensive experience of providing fertility related counselling and are members of the British Infertility Counselling Association (BICA). Patients requiring genetic counselling are referred to specialists within the NHS Trust.
Evidence of the counsellors ongoing CPD was seen during the inspection and monthly supervision sessions by mentors are undertaken.
Currently there is no waiting list for the counselling service, for which there is no separate charge.
Patients attend sessions in a dedicated counselling room which was seen to be fit for purpose. Counselling notes are kept secure in locked cabinets.

Thirty-six patient questionnaires were received prior to the inspection with 92% of respondents stating that they had experienced a good quality of service.

Patient records were seen to be kept securely locked within filing cabinets in the main office area during the inspection.

No complaints from patients had been received by the HFEA during the last twelve months.

Areas for improvement

Further development of QMS and document control

Areas not covered on this inspection

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
The centre is set out over three floors. Main patient reception, embryology laboratory and theatre suite are presently on the ground floor. Steps up to the first floor give rise to the main waiting room, nurses office, scan and consulting rooms. The main day-case gynaecological ward is situated on the second floor. Extensive building work is presently being carried out to provide new facilities which will include laboratory, theatre and recovery areas which will have graded quality air as specified by the EU Tissues and Cells Directive (EUTD). This work is scheduled to be completed and fully commissioned by the end of November 2007. A re-visit by the Executive, at a mutually convenient date was discussed, in order to inspect the new facilities once they have been completed and fully commissioned. All cryodewars situated within the Andrology laboratory were seen to be alarmed and secure. A low oxygen monitor was in place, with external audio/visual alarm and an auto-dialler for out of hours contact if an incident occurs. Patient-sensitive areas such as theatre, embryology laboratory, ultrasound-scanning rooms and notes office had restricted access and were seen to be secure.

Areas for improvement
The Executive to inspect new laboratory/theatre/recovery facilities once completed and fully commissioned.
Areas not covered on this inspection

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. Coding
12. Information for users This section includes: Access to data
13. Tracking live birth events
14. Storage records
15. Information to the HFEA
16. Counsellor records
17. Import/export
18. 3 embryo transfer
19. Donor Information
20. Storage and release of gametes and embryos
21. Storage forms
22. Anonymity
23. Labelling of packages containing procured gametes
24. Validations
25. Screening
26. Audit
27. Consents

Outcome of audit of records
Ten sets of patients notes were reviewed on the day of inspection. No discrepancies were identified by the inspection team. All appropriate consents were seen to be in place.
Areas of firm compliance
A complaints procedure, counselling notice and HFEA licences for treatment and storage and research were on display in the waiting room. Information concerning current research projects was also available, together with a suggestion box and patient questionnaire.

Patient information seen on the day was deemed to be relevant, clear and accurate. Most of the information, SOP's and data retrieved from the QMS during the day was document controlled, but data showing KPI's and some minuted meetings were not.

Areas for improvement

Document control to be developed to include all documentation used within the centre.

Some reporting of treatment cycles to the Registry has been problematic in the past due to problems with the interface between the centre's database system and the EDI system. Dialogue has taken place between the Registry and an IT consultant from the database company. A solution to resolve the discrepancy between the systems has been proposed and the Registry is presently actively involved with both the centre and the IT consultant in the resolution of the issue.

Areas not covered on this inspection

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	3
NMC registered nurses	8
HPC registered scientists	11
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	15

Summary of laboratory audit
Audit of stored sperm: (11/04/07) 30 errors identified – all but 1 resolved – to be resolved when transfer to new cryostorage facility as tank to be emptied and contents transferred to new vessels. *Audit of stored embryos (5-11/04/07)* 11 errors identified – all resolved
Summary of spot check of stored material
One frozen semen sample was tracked from the electronic database to the cryostorage dewar and the vice versa. No discrepancies were found. One frozen embryo was tracked from the electronic database to the cryostorage dewar and the vice versa. No discrepancies were found.

Areas of firm compliance
There are adequate numbers of appropriately trained staff in order to deliver the service. Minuted laboratory meetings take place weekly during which HFEA alerts, incidents, new equipment and clinical issues are discussed. Minutes from such meetings were seen during the inspection. Staff turnover is low, but there is a written induction policy for new staff and present staff maintain compulsory NHS training as well as specific training such as attendance at local/national/international conferences. The laboratory manager maintains a CPD log, which includes ongoing ACE participation. He has recently completed his affiliation as a member of the Royal College of Pathologists (MRCPath.) Written witnessing procedures were discussed and observed within the patients notes. Traceability of items such as ET/IUI catheters, syringes and cryopreservation straws is recorded in a hard-log. This will be extended to include all laboratory plasticware once the new facilities are commissioned. Daily monitoring of incubator parameters such as temperature, $\%CO_2$ and humidity occurs and is kept in a hard-log. All manipulation of gametes/embryos occurs within class II work-stations, but air quality is not presently monitored. This will be accommodated within the new laboratory facilities. KPI's are monitored within the laboratory and include number of oocytes collected, fertilisation and cleavage rates, clinical pregnancy and live birth rates. The Andrology laboratory participates in the UK NEQAS scheme and is CPA accredited.
Areas for improvement
Resolution of outstanding sperm tank audit issue. Air quality monitoring. Traceability of laboratory plasticware. It was agreed during the inspection that a follow-up site visit would occur once the new laboratory/theatre/recovery facilities had been fully commissioned at which point all these issues will be addressed.
Areas not covered on this inspection

Evaluation
Some improvements required

Report compiled by:

Name……Wil Lenton……

Designation… Inspector……

Date…… 25/10/07……

Appendix A: Centre Staff interviewed

PR + 5 other staff interviewed

Appendix B: Licence history for previous 3 years

June 2007: Representations hearing
Dr Fitzgerald presented evidence of measures put in place by the centre which have lead to improvements in success rates. Also noted that one piece of data presented to LC in Jan 2007 inaccurate – Additional licence condition removed. Licence approved for 3 years.

May 2007:
Successful variation of licence to include the requirements of the EUTD

March 2007: Licence Committee
Following revisit to centre additional data presented to LC by Executive. LC still not convinced that measures put in place effective. Additional condition imposed.

January 2007: Licence Committee
LC not satisfied that primary focus of inspection (success rates) had been addressed. Asked Executive to revisit centre to collect more evidence of improvements.

September 2006: Renewal Inspection

August 2006: Licence Committee
The Committee approved Dr Cheryl Fitzgerald as PR.

March 2006: Licence Committee
The Committee agreed the continuation of the centre's licence with no additional conditions.

March 2005: Licence Committee
The Committee agreed the continuation of the centre's licence with no conditions.

February 2004: Licence Committee
The Committee agreed to renew the centre's licence for 36 months with no additional conditions and one recommendation regarding retraining staff in completing HFEA consent forms.

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

21 November 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 3

St Mary's Hospital, Manchester (0067)
Interim Inspection

Members of the Committee:	In Attendance:
Anna Carragher, Lay Member – Chair	Trish Davies, Director of Regulation / Deputy Chief Executive
Rebekah Dundas, Lay Member	Stephanie Sullivan, Interim Head of Inspection
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary	Claudia Lally, Committee Secretary
	Providing Legal Advice: Sarah Ellson, Field Fisher Waterhouse

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 (37 pages)
- no papers were tabled.

1. The papers for this item were presented by Wil Lenton, HFEA Inspector. Mr Lenton informed the Committee that this is a large, active centre having provided over 1,000 treatment cycles in the last year. The centre provides treatments to NHS funded patients from Greater Manchester and surrounding areas. The centre also participates in the Department of Health initiative to promote single embryo transfers and does not perform any 3 embryo transfers. The centre has a good history of regulatory compliance and a low risk score of 7%.

2. Mr Lenton informed the Committee that the centre will be moving into new facilities at the end of 2007 with a new laboratory, theatre and recovery facilities. The Executive will be visiting the centre again when these new facilities are ready.

3. Mr Lenton reported that the interim inspection visit to this centre took place on 26 September. He discussed the inspection report with the Committee and

mentioned the breaches of the Code of Practice identified during the inspection visit. Mr Lenton informed the Committee that the centre is actively addressing these breaches together with the recommendations made by the inspection team.

4. Mr Lenton discussed the issue of the centre's success rates. He briefly summarised the measures which have been put in place by the centre to address these. He also informed the centre that the success rates are constantly reviewed by the Person Responsible who continues to apply herself to task of ensuring that the rates improve. Mr Lenton drew the Committee's attention to the fact that the centre's success rates improved in 2005 and according to most recently available data appear to have made another improvement in 2006.

5. The Committee noted that the centre is continuing to address the issue of success rates and asked the Executive to continue to monitor the rates on an on-going basis. The Committee suggested that to facilitate this monitoring the centre should have another interim inspection next year.

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

Signed…… … Date……..
Anna Carragher (Chair)