Interim Inspection Report

St Mary's Manchester
0067

Date of Inspection: 17 October 2008
Date of Licence Committee: 12 January 2009

CENTRE DETAILS

Centre Name	St Mary's Hospital, Manchester
Centre Number	0067
Licence Number	L0067- 15-a
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
Inspector(s)	Wil Lenton (HFEA, Lead) Vicki Lamb(HFEA) Allison Cuimmings(HFEA) Jean-Marc Lam-Hing (HFEA, Observer)
Fee Paid – up-to-date	N/A
Licence expiry date	31st July 2010
NHS/Private/Both	NHS

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About the Inspection:
This inspection visit was carried out on 17/10/2008 and lasted for 8.5 hours.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

Where recommendations are made the HFEA will provide details of <u>what</u> needs to be addressed but not <u>how</u> they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website <u>www.hfea.gov.uk</u> .

Brief Description of the Centre and Person Responsible

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 senior management team has produced a multiple births minimisation plan, in order to reduce the incidence of multiple births, in line with recent professional body guidelines.

The centre successfully moved into new 'state-of-the art' laboratories and theatre facilities during February 2008.

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 (HFEA Registry verified data Jan-Dec 2006)*

Licensed treatment cycles	IVF	332
	ICSI	196
	FET	386
	Egg donation	6
	Egg recipient	6
	DI	69
Research	Yes	
Storage	Yes	

*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.

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:

- Payment of fees to the Authority takes 58 days on average.
  CoP7 A.16.3
- Verified data has not been forwarded to the Authority within given timeframes.
  D2008/6; 5-10
- The emergency trolley within the department was found to have equipment missing and had only been checked twice during October (up to the day of inspection – October 17th)
  CoP7 S.6.3.4(b)
- Present nursing staffing levels may not be adequate to provide a good quality of service.
  CoP7 S.6.2.1
- Not all Third Party Agreement's are presently in place.
  CoP7 S.4.2.10
- Competencies for all staff groups need to be determined and recorded
  CoP7 S.6.2.9/A.10.11

The inspectorate supports the continuation of the centres licence.

Risk Assessment

N/A – Process under review

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
Payment of fees to the Authority takes 58 days on average. ***CoP7 A.16.3***	Payment of fees to the Authority to comply with standard licence conditions	Immediately
Verified data has not been forwarded to the Authority within given timeframes. ***D2008/6; 5-10***	Verified data to be forwarded to the Authority within required timeframes.	Immediately
The emergency trolley within the department was found to have equipment missing and had only been checked twice during October (up to the day of inspection – October 17th) ***CoP7 S.6.3.4(b)***	The emergency trolley should be checked as required by HFEA Standards	Immediately
Present nursing staffing levels may not be adequate to provide a good quality of service. ***CoP7 S.6.2.1***	Risk assessment of present nursing staffing levels to be undertaken	Immediately and report forwarded to Executive
Not all Third Party Agreement's are presently in place. ***CoP7 S.4.2.10***	The centre to formalise any outstanding agreements	6 months

Competencies for all staff groups to be determined and recorded. ***CoP7 S.6.2.9/A.10.11***	SOP's for determining and recording staff competencies to be formalised.	Before next inspection

Non-Compliance

Area for improvement	Action required	Time scale
The centre should formalise a record of staff signatures, for those staff involved in witnessing procedures. ***CoP7 G.13.2.2***	A record of staff signatures to be formalised.	Before next inspection

Recommendations	Time scale
Review of the clinical service by external consultants in order to identify factors which may influence outcomes for patients.	6 months

Proposed licence variations by last L.C.

None

Changes/ improvements since last inspection

Recommendations	Action Taken
1.Document control system doesn't presently cover all aspects of the centres documentation	This related to the staff list which was not version controlled. The staff list is now held on Qpulse as a controlled document
2.The centre does not currently monitor air quality within the laboratory	Air quality is monitored on a regular and scheduled basis in the new premises
3.The laboratory does not currently record details of all plasticware and other materials which come into contact with gametes and/or embryos	Equipment is now noted with each patient record. A system has been discussed and is being implemented to enable traceability of all consumables which come into contact with gametes and/or embryos
4.The HFEA was not informed of an incident concerning potential loss of patient material (sperm sample) during a recent audit	The incident was not reported as it was thought that the cane containing the straws had dropped to the bottom of the tank. On inspection the cane was found.
5.A reinspection of the new laboratory, theatre and recovery facilities is recommended once they have been fully commissioned.	Inspected on 13th March. No non-compliances noted.
6. the reporting of some treatment cycles to the Authority has been problematic	Being resolved by Nick Pulsford and data being collated by Dept to send Sep 2008

Additional licence conditions and actions taken by centre since last inspection

Date	Action taken	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. Leadership and management
2. Organisation of the centre
3. Resource management
4. Risk management
5. Incident management
6. Contingency arrangements
7. Business planning
8. Clinical governance
9. Payment of treatment fees

Areas of firm compliance
An organisational chart and staff list were provided which detailed the centre's lines of communication, reporting structure and staff complement. An induction process is in place for new staff to follow, which covers both NHS Trust and unit specific policies & procedures. Regular minuted meetings occur. The minutes from recent general management and quality management meetings were reviewed on the day of inspection. The PR has managerial cover arrangements in place within the centre for instances when she is unavailable. The centre has formulated a 'multiple births minimisation plan' in line with professional body guidelines and minutes of a meeting which took place in September 2008, giving details of the plan, were reviewed during the inspection. The centre currently has a multiple birth rate of 24%, which is within devised professional body guidelines for 2009. A written contingency agreement is in place with centre 0033
Areas for improvement
On the day of inspection it was noted that the nurse manager was on long-term sick leave and the centre had recently lost a health care support worker. High levels of staff sickness were noted amongst the nursing staff. The overall situation concerning the resourcing of nursing staff was of concern, and required risk assessing, in order to determine whether

adequate resources were available for the service requirement and to ensure that patient safety was not being compromised.

Payment of fees to the Authority is taking an average of 58 days instead of 28 days required.

Competencies for all staff groups are not being determineded/recorded.

Areas for consideration

The centre has been part of the department of health (DH) initiative to promote single embryo transfer (SET) and does not perform any 3-embryo transfers. The PR and senior management team feel that this willingness to promote SET has contributed in some part to their relatively low live birth rates in some patient groups and are actively reviewing their present policy. The centre currently has a SET rate of 37%.

The centre has also been involved in a collaborative study with researchers at the University of Manchester, to determine the impact of a SET policy on clinical outcomes. The main conclusion from the study was that, 'the use of SET to reduce twin rates will lead to a significant reduction in treatment success. Around half of this reduction could be mitigated with careful selection of patients and cycles, including embryo quality' The paper is due to be published in a peer-reviewed scientific journal before the end of 2008.

Executive recommendations for Licence Committee

Risk assessment of nursing staffing levels to be undertaken and the report and action points to be forwarded to the Executive

Payments to the Authority to be within required timescales

Competencies for all staff groups to be determined and recorded

Areas not covered on this inspection

None.

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. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality objectives and plans
5. Quality Management review/evaluation
6. Monitoring and resolution of complaints
7. Staff suggestions
8. Document control
9. Live Birth Rates

Live Birth Rates (HFEA Clinic Profile for period 01/04/ 2003 to 31/03/ 2006)

Age Group (years)	DI		FET		IVF/ICSI	
<35	18.792%	n	10.059%	s	15.733%	s
35-37	13.235%	n	8.279%	s	8.155%	s
38-39	8.333%	n	7.5%	n	6.818%	s
40-42	-		6.154%	n	13.636%	n
>42	-		0%		-	

n = no difference from the national average
s = significantly below national average

As indicated above for the time period shown, some outcomes for certain age-groups of patients, within certain treatment types fall below the national average.

Areas of firm compliance

A quality manager has been in post since 2006 and has a functional quality management system in place, which is based on the QPulse system and is available to staff via a password protected IT network.

A quality manual is in place which describes the systems within the QMS

All processes are subject to continuous review via a system of planned internal audits

A complaints log and incident log were reviewed on the day of inspection and found to be appropriate.

The centre participates in inter-centre evaluations such as UKNEQAS, and external review via the CPA.

Recent internal audits include,

- Document control
- OHSS
- Assessment of User Satisfaction and Complaints
- Semen analysis
- Sperm preparation for IVF procedures

Key performance indicators, covering areas such as laboratory outcomes (number of patients; number of eggs collected; fertilisation rates; number of embryos; embryo quality; clinical pregnancy rates; number of embryos frozen) are collated on a weekly basis and then presented/discussed at monthly team meetings. Minutes of such meetings were reviewed at inspection and a graph of laboratory KPI's for 2008 made available.

The senior management team are aware of the relatively disappointing live birth rates associated with some age-groups of FET and IVF/ICSI patients, and are actively addressing this area of the service, by weekly/monthly measurement of KPI's and review of any 'out of conformity' situations. This was evidenced by a thorough management review of low fertilisation rates in March 2008, which culminated in a review of sperm parameters to be used for ICSI cases.

Since the last inspection there have been reviews and changes in the following areas of the clinical service;

- OHSS policy (September 2007) – cycle cancellation criteria revised
- ICSI criteria (March 2008) – stricter sperm criteria for IVF cases
- Change of IVF/ICSI culture media (September 2008)

There are plans to perform a review of the clinical service by external consultants, in order to elucidate any further factors which may be influencing the quality of service.

Areas for improvement

Not all Third Party Agreement's are presently in place, but the centre is working with the purchasing department to ensure that the outstanding agreements are formalised.

Review of the clinical service by external consultants in order to help identify factors which may influence outcomes for patients.

Areas for consideration

None.

Executive recommendations for Licence Committee

All third party agreements to be formalised

Review of the clinical service by external consultants in order to help identify factors which may be influencing outcomes for patients

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. General Suitable premises
2. Clinical facilities
3. Counselling facilities
4. Laboratory facilities
5. Air quality
6. Storage facilities for gametes and embryos
7. Staff facilities
8. Management of equipment and materials
9. Control of records
10. Risk assessments

Areas of firm compliance
The centre has recently moved into new laboratory and theatre facilities (February 2008), which includes a 'facilities monitoring system' which provides constant monitoring of all critical laboratory equipment such as incubators, gas-cylinders and cryo-dewars. All critical equipment is regularly maintained and service contracts were evidenced during the inspection. Cryo-dewars containing patient material were seen to be secure and fitted with low liquid nitrogen alarms, connected to an auto-dialler system for out-of-hours incidents. A written protocol was in place to cover such situations. A low Oxygen monitor was in place within the cryostorage area, with an external audio/visual alarm. Air quality within the laboratory is being monitored and found to be compliant with HFEA requirements. Notes were seen to be kept securely within filing cabinets in the general administration area All critical care areas have restricted staff access and are kept secured when not in use.
Areas for improvement
The emergency trolley within the department was found to have equipment missing and had only been checked twice during October (up to the day of inspection – October 17th)
Areas for consideration
None

Executive recommendations for Licence Committee
The emergency trolley should be checked as required by professional guidelines.
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. General Information
2. Meetings and communication
3. HFEA Alerts
4. Welfare of child
5. Confidentiality and access to health records
6. Traceability and coding
7. Coding/ identification of samples
8. Information for service users/consents
9. Donor information
10. Donor registration
11. Surrogacy
12. Procurement and distribution of receipt of gametes and embryos
13. Home procurement report documentation
14. Packaging &distribution
15. Labelling of packages containing procured gametes
16. Transportation, labelling of shipping container and recall
17. Receipt of gametes

Areas of firm compliance
A HFEA treatment & storage licence together with two research licenses were prominently displayed within the main waiting area, together with details of the centre's complaints procedure, quality policy, counselling service, research work and information on local/national support groups. HFEA alerts were disseminated and discussed at regular monthly meetings, where staff were also able to highlight any other issues and report back any concerns to the team. During staff interviews it was noted that personnel were aware of welfare of the child, patient confidentiality, dignity and respect issues.
Areas for improvement
The centre should ensure that required data is verified and forwarded to the Authority within given timeframes.
Areas for consideration
The reporting of treatment cycles to the Registry has continued to be problematic during the past twelve months, due mainly to problems encountered by the centre as they installed a new database system (changed from Acusys to Acubase). After much dialogue between the IT consultant from the database company, the centre and the Registry, the problems concerning 2006 data submission now appear to have been successfully resolved.

Unfortunately the centre were unable to supply all the data required, in the given time, for publication of their 2007 success rates, but following discussions during the inspection involving the PR and the Registry QA manager it was concluded that these issues are close to being resolved.

Executive recommendations for Licence Committee

Verified data to be forwarded to the Authority within required time-frames.

Areas not covered on this inspection

Surrogacy

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. Laboratory processes
2. Selection and Validation of laboratory procedures
3. Laboratory's documented procedures
4. Storage of gametes and embryos
5. Counselling
6. Witnessing

Full time equivalent staff

GMC registered doctors	6
NMC registered nurses	7.5 (plus 2 health care support workers)
HPC registered scientists	13
Scientists working towards registration	4
Support staff (receptionists, record managers, quality and risk managers etc)	13
Counsellors	2

Summary of laboratory audit / Audit of records
Audit of stored sperm: (17/12/07) 20 containers audited, with 51 errors noted which were mainly administrative, concerning discrepancies between the card record system and electronic record system. All resolved and findings discussed at laboratory meeting. *Audit of stored embryos: (July 2008)* 100 containers audited, with 31 errors noted which were mainly administrative, concerning discrepancies between the card record system and electronic record system. All resolved and findings discussed at laboratory meeting.
Summary of spot check of stored material
No spot check of cryostored material was undertaken on this occasion
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. The two most recently employed laboratory staff confirmed that they had attended a Trust induction scheme and the documentation for one of the staff was viewed.

Weekly minuted laboratory meetings occur, where HFEA Alerts, incidents and clinical issue are discussed. (viewed as part of QMS)

Staff have access to ongoing CPD which was confirmed via interview during the inspection. This includes formal training such as the ACE certificate as well as attendance at regional/national conferences.

The traceability log has been extended to include all equipment that is used during the processing of gametes and embryos. The recording of traceability was evidenced during the review of patient notes.

A comprehensive audit of the counselling service provided by the centre was reviewed and found to be satisfactory. The service is free to patients and is split between two experienced counsellors. The counsellors also assist in the training of new staff and attend unit meetings.

Areas for improvement

The centre should formalise a record of staff signatures, for those staff involved in witnessing procedures.

Areas for consideration

None.

Executive recommendations for Licence Committee

A record of staff signatures should be formalised for all staff involved in witnessing procedures.

Areas not covered on this inspection

Spot check of cryostored material

Evaluation

Some improvements required

Report compiled by:

Name……Wil Lenton…….

Designation……Regulatory Inspector…….

Date……17/10/2008……

Appendix A: Centre Staff interviewed

PR plus seven other staff

Appendix B: Licence history for previous 3 years

November 2007: Licence Committee

September 2007: Interim Inspection

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.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number…….0067……

Name of PR……..Cheryl Fitzgerald…….

Date of Inspection……17th October 2008……

.

Date of Response……17th December 2008……

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

Signed……

Name……..

Date……

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.

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

At the time of the inspection, we mentioned that we may consult externally over the next few months regarding laboratory and clinical issues, but this has now been written into the inspection report as a recommendation that needs to be fulfilled within six months. This was not discussed with us at the time of the inspection. The inspection contains our live birth data in which shows us to have results significantly below the national average, these data refer to 2003 to the early part of 2006. This issue was discussed with HFEA last year, in particular our results from 2004. We agreed that our results at that time were unacceptable low and discussed steps that have been put in place in order for them to improve. We have shown year on year improvement since that time as discussed on the day of the inspection, but obviously cannot change data from three to six years ago. The clinical pregnancy and live birth rates from fresh embryo transfers continue to improve. However, we still have comparatively low pregnancy rates for the under 35 age group. As discussed at the inspection, we feel that this is largely a result of our single embryo transfer policy (37% of all fresh embryo transfers currently SET) which targets that group more than

others, with a consequent reduction in fresh pregnancy rate. We have recently published about the impact of SET on the pregnancy rate from fresh embryo transfer and have shown that dependent upon patient selection SET will reduce fresh pregnancy rates by 10-25% (Roberts et al 2009), this can be largely offset by embryo freezing. We have recently reviewed our SET policy to include the factors shown in the modelling paper.

The data table also shows that the results from FET are poor for the three year period from 2003. The success rate from frozen embryo transfer is dependent upon freezing and thawing policy, i.e. how readily embryos are frozen and the number of embryos thawed for a transfer. It is impossible to compare data across centres as discussed by Granne et al (2008) as they merely reflect these differences, not differences in standard of care. We have always been pleased with our frozen embryo transfer programme as demonstrated by the very high number of pregnancies that occur considering the number of fresh IVF cycles that we undertake.

Roberts S, Fitzgerald CT, Brison D. Modelling the impact of single embryo transfer in a national health service programme. Human Reproduction 2009; 24(1):122-131 (EPub Oct 2008)

Granne I, Child T & Hartshorne G (on behalf of BFS). Embryo cryopreservation: Evidence for practice. Human Fertility 2008; 11(3):159-172

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

The timely payment of HFEA fees has been raised with the Trust management and assurance has been given to us that this will now happen.

We have had significant issues surrounding the transfer of data to HFEA since the introduction of electronic data transfer which coincided with the introduction of a new database within the unit, ACUBase. There remains one outstanding “outcome” form from 2007 which is now with HFEA as the problem appears to be one that we are unable to correct. We are awaiting further information from you. We have recently received several hundred “errors” with HFEA forms submitted in 2007 and 2008. We have contacted Nick Pulsford (database designer) as the majority of these errors have been created by problems within the software, not entry errors. Nick Pulsford is currently working on these errors, but until the software issues are resolved we are unable to correct these. We have stressed to Nick Pulsford the urgency with which he needs to address these problems. This remains a difficult issue, but I can give assurance that we are doing all that we possible can to resolve these problems.

The nurses acknowledge that the emergency trolley needs to be checked regularly and this is now being done. We recognise the importance of the emergency trolley, but would also like to add that if a patient collapsed within the unit, the emergency crash team for the hospital would also be called, in line with Trust policy.

We have experienced problems within our nursing complement this year due to the long term illness of our most senior sister, in addition our next most senior sister has been on maternity leave. One of our other senior nurses has been “acting up” in their absence and has carried out the role extremely competently. The number of patients undergoing treatment at any time is always agreed after consultation with all areas within the unit. We have therefore limited the number of patients going through treatment at some times during the last year in order to prevent this situation having any impact on patient care. Whilst this has not impacted on patient care, we appreciate that this has put some of our nurses under additional pressure. Both of our senior sisters have now returned and I hope that the pressure on the nurses will lessen.

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

12 January 2009
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 6

St Mary's Manchester, 0067
Interim Inspection

Members of the Committee:

David Archard, Lay Member – Chair
Sally Cheshire, Lay Member Jennifer Hunt, Senior Infertility Counsellor, IVF Hammersmith
Hossam Abdulla, Director, Lister Fertility Clinic

In Attendance:

Debra Bloor, Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice to the Committee:

Graham Miles, Morgan Cole Solicitors

Conflicts of Interest: Sally Cheshire informed the Committee that she is Deputy Chair of the NHS North West Strategic Health Authority with responsibility for 63 Trusts. The Committee agreed that this is not an interest that gives rise to a conflict but asked that this interest be recorded in the minutes. 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 (26 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 large centre has been licensed by the HFEA since 1992 and provides approximately 1,000 licensed treatment cycles per year, to NHS patients. Mr Lenton reported that the centre is participating in a Department of Health initiative to promote single embryo transfers and carries out no three embryo transfers. He added that the centre's newly commissioned laboratories and theatre facilities were "state of the art".

2. Mr Lenton drew the Committee's attention to the findings of the inspection, summarised at pages 6 and 7 of the report. Improvements were recommended in relation to the following areas:

    - payment of fees
    - timely submission of verified data
    - the emergency trolley
    - nursing staff levels
    - third party agreements
    - assessment and recording of staff competencies, and
    - review of clinical service by external consultants.

3. Mr Lenton updated the Committee on action taken by the centre to address the inspection findings. He directed the Committee to the response by the Person Responsible appended at pages 22 to 24 of the report. Mr Lenton drew the Committee's attention to the ways in which the centre management are addressing the payment of fees, submission of verified data, the emergency trolley and nursing staff levels. Mr Lenton also drew the Committee's attention to the Person Responsible's comments about the centre's comparatively low pregnancy rates for the under 35 age group. On this issue, Mr Lenton added that the data seen during the inspection appears to show that success rates at the centre are improving.

The Committee's Decision

4. The Committee noted the areas for improvement identified in the inspection report and the measures adopted by the Person Responsible to comply with the recommendations of the inspection team. The Committee agreed that they were satisfied with the overall response to the issues raised.

5. The Committee agreed that they were concerned that live birth rates for the centre were not improving at the rate that they would expect and remained significantly below the national average, notwithstanding the problems experienced at the centre in 2003.

6. The Committee endorsed the recommendation by the inspection team that a review of the clinical service should be conducted by external consultants in order to identify factors which may influence outcomes for patients. The Committee agreed that the team to conduct the review should comprise at least a clinician and an embryologist and that the report of the team's findings should be submitted within 6 months to the HFEA, when it will be considered by a Licence Committee.

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

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