Licence Renewal Inspection Report

Centre for Reproductive Medicine St Michael's Hospital Bristol

Centre 0276

Date of Inspection: Wednesday 16th January 2008

Date of Licence Committee: 24th April 2008

CENTRE DETAILS

Centre Name	Reproductive Medicine Unit, St Michael's Hospital, Bristol
Centre Number	0276
Licence Number	E0276 / 1 / a
Centre Address	RMU St Michael's Hospital, Southwell St, Bristol BS2 8EQ
Type of Inspection	Licence Renewal
Person Responsible	Dr David Cahill
Nominal Licensee	N / A
Inspector(s)	Gillian Walsh
	Neelam Sood
Fee Paid – up-to-date	Yes
Licence expiry date	30 / 06 / 08
NHS/Private/Both	NHS

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About the Inspection:
This inspection visit was carried out on 16th January 2008 and lasted for 6 hours. The report covers the pre-inspection analysis, the visit and information received between September 2007 and December 2007

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

The report summarises the findings of the 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.

NB: Where there are very minor issues to be addressed these are noted in the "minor issues to be addressed" section for each topic, and this will facilitate the evaluation of 'no improvements required'. 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

The Centre is a small unit located at St Michael's Hospital Bristol, providing IUI treatment to NHS funded couples from the Bristol and Avon area. St Michael's Hospital, formerly known as Bristol Maternity Hospital, is a fully integrated single site obstetric and gynaecology facility. The building also houses the adult ENT wards and out patient clinic. The Centre has strong links with Centre 0024, also in Bristol, which is in the process of amalgamating with another Bristol Centre, 0032 on a new site to create an entirely new Centre in early 2008. Services to Centre 0276 are not expected to be directly affected but will be monitored as services move to the new site.

The centre is a purely outpatient facility, previously conducting up to 120 cycles of IUI treatment in 2005/6. The centre has conducted approximately 70 cycles of treatment in 2007 due to lack of funding. The full effect of local PCT reorganisation on the centre is yet to be fully determined.

The Person Responsible (PR) The PR, Mr David Cahill is Reader in Reproductive Medicine at Bristol University and is Hon. Consultant, Obstetrics and Gynaecology, St Michael's Hospital, Bristol.

St Michael's is inspected by the Healthcare Commission as part of the Trust. The Centre has not been inspected specifically as part of that process.

An Additional Visit was made to the Centre on 11th September 2007 by the HFEA Executive further to the decision made by a Licence Committee of the Authority which met on 17 April 2007, to issue a one year licence to conduct Intra Uterine Insemination with fresh, partner sperm. The Committee decided that the Centre should be inspected by the Executive within 9 months of the licence commencement date.

At that visit the Executive noted and discussed a number of recommendations for continued improvement of service and were agreed by the Centre. (See Changes / recommendations since last inspection.)

Overall the Executive were satisfied with the progress made by the Centre and supported the continuation of the Licence.

Activities of the Centre

Partner Sperm Insemination	NB Semen production and preparation is done at Centre 024 and is transported back to Centre 0276 for insemination by the male partner. The centre does not store or process gametes.
Unlicensed Treatments	Ovarian stimulation

Summary for Licence Committee

The Centre appears well organised and many improvements and developments have been made since the last inspection. The centre has made excellent effort in compliance with new EUTD requirements.

The Executive supports the renewal of a treatment licence to Centre 0276 without condition and recommends the period covered by the licence to be three years.

Risk Assessment

5 % low

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation	✓		
2. Quality of the service	✓		
3. Premises and Equipment	✓		
4. Information	✓		
5. Laboratory and clinical processes		✓	

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
No breaches identified		

Non-Compliance

Area for improvement	Action required	Time scale
Comprehensive risk assessments and validation of equipment and processes has not been completed	Evaluation and assessment of key clinical processes (eg transport of processed gametes to the centre, receipt and witnessing processes) to be conducted.	within two months of licence committee date.

Recommendations	Time scale
Ring fenced administrative support time for Quality Management process	To be monitored at next inspection
Validation and risk assessment of key clinical process	3 months from licence committee date.

Proposed licence variations by last L.C.

No licence variations have been imposed.

Changes/ improvements since last inspection

Recommendations	Action Taken
* Support in the further development of the Quality Manual.	Further development of the QM was reported in the Pre Inspection Questionnaire by the Centre and evidence was seen on inspection.
* Protected time to allow for the administrative support of the development of the Quality Manual.	Though progress has been made, assuring dedicated administrative support time to this function remains a problem for the centre.
* Staff to be made aware when policies are updated and amended.	A more robust system of information sharing has been introduced.
* Comprehensive programme of risk assessments to be instigated.	The development of a risk assessment schedule has begun, greater involvement of Trust risk management officers is ongoing.
* Staff to be made aware of the HFEA Alert system and measures to be put in place to confirm that staff have been made aware of an alert.	Communication within the centre reflects this.
* Risk assessment and validation of procedures, equipment materials to be more comprehensively conducted.	This is being addressed as described above regarding the risk assessment schedule.

* Validation of witnessing and traceability throughout the entire IUI process was to be reviewed to fully reflect current HFEA CoP requirement.	The process for receipt of samples and witnessing have been reviewed.

Additional licence conditions and actions taken by centre since last inspection

Date	Action taken
	There were no additional licence conditions imposed.

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
The Person Responsible (PR) for this centre has successfully completed the HFEA PR entry programme and meets HFEA criteria for the role. (S.4.1.2 / 4 /5) The PR is in attendance at the centre for a minimum of two sessions per week and can be contacted by the team should the need arise at other times. The PR has satisfied the Executive that he is fully conversant with the scope of his responsibilities as PR and his reporting obligations to the HFEA. (S.4.1.7 / 8 / 9 / 11) The centre appears well organised, with good communication within the team at all levels. (S.4.1.1) The premises, equipment, facilities and staff skills appear be appropriate to conduct the number and type of licensed treatments currently offered. (S.4.2.1, S.5.1.2, S6.1.1, S6.2.1) Third Party Agreements are largely managed by Centre 0024 who furnish the Centre with all materials used in the IUI process. An up to date organisation chart was seen to be in place, clearly demonstrating accountabilities and reporting relationships. (S.4.2.5 & S.4.2.6) The centre demonstrated a robust incident reporting policy inclusive of HFEA requirements. Staff asked were aware of this and of HFEA requirements. (S.4.1.8, S.4.2.9, S.6.4.3, S.7.7.1, S.7.7.8, S.9.4 and A.4) and have demonstrated prompt and thorough reporting of an incident to the HFEA on the occasion this was required. The centre demonstrated good contingency plans to accommodate disruption to service by having close working links with the Trust gynaecology service and another Centre. (S.6.3.4 (b)).

Areas for improvement
Risk assessment has not comprehensively been addressed within the centre. Key areas have been assessed by Trust Risk advisors. Clinical processes and procedures require further risk assessment and validation. (S.7.8.10 & S.7.8.3).
Areas for consideration
The Quality Manager undertakes this role alongside other professional duties. It was identified at the previous visit that a period of 'ring fenced' administrative support was required to assist the Quality Management process. The PR should ensure that this time is made available.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
Business planning Clinical Governance

Evaluation
Well run with evidence of improvement.

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
Live birth rates for intra uterine insemination (IUI) with partner gametes are not yet available for 1 year reporting to the HFEA.
Areas of firm compliance
A Quality Manager has now formally been designated and has been working with the centre on the development of the Quality Management System.(S.4.2.1, S.4.2.7, S.5.11 & S.6.1.1) Extensive documentation supporting framework the Quality Management System was seen to be in place. The centre has yet to implement their first annual management review. A quality policy has been developed and is in place and is available to all staff. (S.4.2.2/3 S.5.2.2 / 6) The centre's expectation is that both partners attend at each stage of the treatment pathway. Initial consultation and assessment is conducted by a Consultant or Clinical Felllow during which both partners are seen together and then physically examined separately. Consent is sought by a doctor. Treatment options are discussed with the couple. In conjunction with Trust wide policy, the centre demonstrated and effective complaints policy and mechanism for the monitoring and resolution of complaints. Information on how and to whom a complaint should be addressed, including the HFEA was readily visible and available in patient waiting areas. (S.4.2.9, S.9.2.2). The centre holds scheduled monthly all staff meetings which are minuted and the minutes made available to all staff following. The current schedule and minutes of a number of these meetings were seen at inspection. (S.6.2.2 (g)). A system for managing and monitoring document control and for communicating changes to staff was seen at inspection. (S.5.2.5 / 6)
Areas for improvement
Areas for consideration
Plans for a management review and the development of a comprehensive audit schedule are still to be finalised. (S4.2.8 / 9)

Executive recommendations for Licence Committee
The quality of service provided by the centre appears to be of good quality.
Areas not covered on this inspection
Live birth rates

Evaluation
The quality of service provided by the centre appears to be of good quality.

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 out patient waiting room is shared with general and oncology gynaecology patients. This is a pleasant and spacious, largely open plan area with a central reception desk. The atmosphere appeared friendly and calm. The HFEA Licence was displayed in this area, also information on how to make a complaint, including that to the HFEA. IUI is conducted in a room also used for colposcopy. The room was seen to be well equipped and private. The door could be locked. All areas were seen to be secure, clean, adequately equipped and furnished and fit for purpose. (S.6.3.1/2/3/4) Equipment seen on the day was CE marked. PAT testing had been conducted and was in date. The maintenance of medical equipment is conducted by the Trust Biomedical Engineering Dept. or by specialist engineers as arranged by them. (S.6.4.1/2/3) Counselling is offered to all patients and is conducted away from the centre within the hospital where the counsellor is based. The counsellor communicates regularly with the team, experienced in her role and undertakes regular professional supervision. Patient records are stored within the department's main office in lockable cabinets. Access is restricted and locked out of hours and when unmanned.
Areas for improvement
Risk assessment has not comprehensively been addressed within the centre. Key areas have been assessed by Trust Risk advisors. Clinical processes and procedures require further risk assessment and validation. (S.7.8.10 & S.7.8.3).
Areas for consideration
Executive recommendations for Licence Committee

Areas not covered on this inspection
Air Quality Laboratory facilities Storage of gametes Staff facilities

Evaluation
The service offered by the centre is limited and so not all aspects of this section apply.

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. Information for service users/consents
7. Labelling of packages containing procured gametes
8. Receipt of gametes

Areas of firm compliance
Staff interviewed confirmed that staff are encouraged to attend the regular Unit meetings if available, otherwise minutes are readily available. (S6.3.1) Staff asked were aware of the HFEA alert system. Information regarding a variety of gynaecological conditions was readily displayed in the waiting area, however non of which were specific to fertility treatments. When asked staff said that feedback from patients suggested that there was a reluctance to pick up leaflets on specific fertility treatments when waiting the generic waiting area. Staff also said they felt it was more appropriate to give supportive written information at the time of consultation when treatment options were better known and specifics this could be discussed. (S.7.4.1 S.6.1) The centre has a robust policy on welfare of the child considerations as part of their patient assessment. (S.7.6.4) Patient records are stored within the department's main office in lockable cabinets. Access is restricted and locked out of hours and when unmanned. (S.5.2.5 / Samples are not processed for insemination on this site. Prepared samples of insemination are brought to the centre by the male partner once prepared. Confirmation of identity and of samples is witnessed and confirmed with the partner and staff at the point of receipt and during preparation for insemination, all of which is recorded in the procedure record. (S.7.7.15). A spot check of five sets of randomly selected patient notes showed no inconsistency in recording of these witnessing steps.
Areas for improvement
Areas for consideration
Risk assessment of the receipt of gametes from the processing centre should be undertaken and protocol for the receipt of gametes be reviewed for robustness on transfer to the new processing centre.
Executive recommendations for Licence Committee
Areas not covered on this inspection
Welfare of the child Donor information

Donor Registry
Surrogacy
Procurement and distribution
Packaging and distribution
Transport

Evaluation
Due to the limited nature of the service this centre offers, not all elements of this section apply.

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 procedures
3. Storage of gametes
4. Consent
5. Witnessing
6. Competency and CPD

Summary of laboratory audit / Audit of records
No gametes are stored at this centre.
Summary of spot check of stored material
N/A
Areas of firm compliance
The centre's expectation is that both partners attend at each stage of the treatment pathway. Initial consultation and assessment is conducted by a Consultant or Clinical Fellow during which both partners are seen together and then physically examined separately. Consent is sought by a doctor. Treatment options are discussed with the couple. (S.7.5.1) Semen production and processing for insemination is conducted at centre 0024. Patient / partner identity is confirmed by photo ID when attending centre 0024 having also been checked at centre 0276. The prepared sample for insemination is identified by the unique hospital number for both partners and a unique IUI number generated at centre 024. The nurse conducting the IUI will then further confirm the identity of the couple. . Batch numbers of the insemination catheter and other products used in the assisted conception process are recorded in the patient's notes for the purposes of traceability. (S.7.3.1) Samples for insemination are brought to the centre by the male partner once prepared at centre 0024. Confirmation of identity and of samples is witnessed and confirmed with the partner and staff at the point of receipt and during preparation for insemination, all of which is recorded in the procedure record. (S.7.7.15). A spot check of five sets of randomly selected patient notes showed no inconsistency in recording of these witnessing steps. The senior nurse for the centre has been conducting IUI's for 3 years. Her training was conducted by Dr Cahill who 'signed off' her training when competent. The nurse stated that there was always a member of the medical team in the department when IUI is being conducted should she need them.(S6.2.) Nursing staff were able to confirm that they had received funding for some specialist CPD and that they attended mandatory training with the Trust in Basic Life Support, Health and Safety, Manual Handling and Fire Safety. (S.6.2.12) In the opinion of the Executive, staff numbers and competencies appear appropriate to the treatments being offered by the centre.

Areas for improvement
Full risk assessment and validation of clinical processes is to be completed.
Areas for consideration
Risk assessment of the receipt of gametes from the processing centre should be undertaken and protocol for the receipt of gametes be reviewed for robustness on transfer to the new processing centre.
Executive recommendations for Licence Committee
Areas not covered on this inspection

Evaluation
The team are competent in the skills they employ and appear to offer a considered, dignified service to their patients.

Report compiled by:

Name Gill Walsh

Designation Inspector

Date 20/03/08

Appendix A: Centre Staff interviewed

Person Responsible and three members of the team

Appendix B: Licence history for previous 3 years

Licence award July 07

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number 0276

Name of PR Mr David Cahill

Date of Inspection 16th January 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 (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).

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

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

24 April 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 4

Reproductive Medicine Clinic, St Michael's Hospital (0276)
Licence Renewal

Members of the Committee:
Clare Brown, Lay Member – Chair
Ruth Fasht, Lay Member
Sue Price, Consultant in Clinical Genetics, Oxford Regional Genetics Service
Roger Neuberg, Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary
Chris Barratt, Head of the Reproductive and Developmental Biology research group, University of Dundee

In Attendance:
Debra Bloor, Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice:
Graham Miles, Morgan Cole Solicitors

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 (30 pages)
- no papers were tabled.

1. The papers for this item were presented by Gill Walsh, HFEA Inspector. Mrs Walsh informed the Committee that this centre is a small unit located at St Michael's Hospital Bristol, providing IUI treatment to NHS funded couples. The centre does not do any processing of sperm on site. Rather, this takes place at centre 0024. The centre was visited in September at which time the Executive discussed a number of recommendations for continued improvement of the service. Mrs Walsh explained that no success rates have been provided to the Committee because the centre has not yet submitted a full year's worth of data, and has only completed about 70 cycles since first licensed last year. Mrs Walsh confirmed that she has seen some data for the first treatments carried out during this time and these seemed to be in line with national averages. Mrs Walsh

completed her presentation by recommending that the centre's licence be renewed for three years.

The Committee's Decision.

2. The Committee agreed that they were satisfied as to the suitability of the Person Responsible, the centre premises and the use of suitable practices at the centre. The Committee noted that a signed application had been received from the centre. The Committee further agreed that it was satisfied that it had sufficient and satisfactory information on which to make a decision on the licence renewal.

3. The Committee renewed the centre's licence for a period of three years subject to payment of the licence fee.

Signed…… … Date……..
Clare Brown (Chair)