Licence Renewal Inspection Report for Treatment and Storage Centres

Glasgow Centre for Reproductive Medicine
0250

Date of Inspection: 10 May 2007
Date of Licence Committee: 26 July 2007

CENTRE DETAILS

Centre Address	21 Fifty Pitches Way, Cardonald Business Park, Glasgow G51 4FD
Telephone Number	0141 891 8749
Type of Inspection	Renewal
Person Responsible	Professor Richard Fleming
Nominal Licensee	Dr Marco Gaudoin
Licence Number	L0250-1-A
Inspector(s)	Allison Cummings Tahir Hussain Victoria Lamb
Fee Paid	Due for payment August 2007
Licence expiry date	11 October 2007

Index

Page

About the Inspection:
This inspection visit was carried out on 10 May 2007 and lasted for seven hours. The report covers the pre-inspection analysis, the visit and information received between 1 November 2006 and 10 May 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, 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

This purpose-built IVF centre was designed to conform to the European Union Tissues & Cells Directive (EUTD). It is situated in a business park on the outskirts of Glasgow, close to the Southern General Hospital. The centre was initially granted a licence for treatment and storage on 1 November 2006 and provides treatment to self-funded patients.

The Person Responsible (PR) is new to his role and has the appropriate qualifications and experience to fulfil this successfully. He has completed the Person Responsible Entry Programme (PREP) and is also the Scientific Director of the centre. Additionally, the PR is an Honorary Professor at Glasgow University.

Activities of the Centre

Licensed treatment cycles	In Vitro Fertilisation (IVF),	51
	Intra Cytoplasmic Sperm Injection (ICSI)	27
	Donor Insemination (DI)	2

This information has been obtained from the HFEA register for all fresh cycles initiated between 1st November 2006 and 10th May 2007.

Summary for Licence Committee

The centre was found to be well managed and working towards achieving compliance in all of the areas inspected.

The Executive recommends that the centre be granted a HFEA licence for three years.

Risk Assessment

A risk matrix tool has recently been completed and the centre scored 5%. The centre is therefore considered to be low risk.

As a result of the upcoming implementation of the EUTD, the centre was also risk assessed on the basis of progress towards achieving compliance. Based on the information submitted in the centre's application received in December 2006, it scored a low risk rating of 11%. On the day of inspection, it was found that the centre had progressed significantly towards achieving compliance.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvements required	Significant Improvements required
	✔	

Evaluations from the inspection

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

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
None		

Non-Compliance

Area for improvement	Action required	Time scale
None		

Recommendations	Time scale
Ensure contingency arrangements are in place for continued patient service, including the storage of dewars, in the event of a staffing and/or premises emergency.	3 months
Implement a protocol for the provision of managerial cover in the PR's absence.	3 months
The induction programme for new staff members should be formally documented to include evidence of supervised practice and competency based assessment for those performing specialised clinical tasks.	3 months

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
The PR should ensure that all staff are made aware of scheduled meetings and minutes are documented. It was recommended the counsellor is involved in the departmental meetings.	It was evident that all staff attend both bi-weekly clinical review meetings and a separate team meeting for any other business. Minutes from these meetings were seen. The counsellor attends meetings when possible.
It was recommended that a system to obtain patient views on the effectiveness of the counselling services is established.	The PR has amended the centre's own patient questionnaire to include opportunity to express views on the effectiveness of the counselling service.
It was recommended improvements should be made to the premises so that: (1) Conversations in the consultation rooms could not be overheard from the ladies toilets. (2) Patient recovery rooms are patient focussed rather than clinical. (3) The men's production room is used for that purpose only i.e. also not used as a male toilet.	The following actions were observed: (1) Conversations could not be overheard from the ladies toilets. The installation of air conditioning appears to have resolved this issue. (2) Comfortable chairs have been placed in the recovery rooms and in the male production room. (3) The male production room is now for this purpose only. The toilet facilities for disabled people are now shared with male patients/visitors.

Additional licence conditions and actions taken by centre since last inspection

C	There are no licence conditions.
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:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
The PR and Nominal Licensee (NL) confirmed that they are present at the centre most days and that arrangements are in place to be contacted by mobile phone if they are absent from the centre. The PR stated the Quality Management System (QMS) is an integral part of the service. The senior management team are considering International Standards Organisation (ISO) accreditation in the future. The PR stated that all disciplines of staff are involved in centre matters. Team meetings are held every Monday to discuss administrative and managerial issues. Clinical review meetings are held bi-weekly on Tuesdays and Thursdays, each designated meeting is planned to discuss clinical cases from the previous week and for the forthcoming week. Every lunch hour, all staff meet for patient assessment. Monthly executive meetings are held and these are attended by the Directors and the Centre Manager. Minutes of meetings were evidenced on the day of inspection except for the patient assessment meetings as these are documented in the patient records and on the centre's database. The pre-inspection questionnaire submitted by the PR stated that risk is managed through health and safety audits and regular incident meetings. It also noted that fire and electrical safety, laboratory and security risk assessments have taken place since the centre opened. An incident log was witnessed on the day of inspection and although there were a number of these recorded, the Executive found that these were minor. Active incident monitoring and reporting was apparent and evidence of action taken following an incident was seen on the tour of the premises. It was also noted that no incidents have been repeated. The PR stated there is a formal agreement with the lead clinician at Southern General Hospital, Glasgow, for arrangements to cover all medical emergencies. This is in the form of a letter rather than a Service Level Agreement (SLA).

A clear organisational chart was included with other pre-inspection information and this is included in the quality manual.

Payment of treatment fees to the HFEA is timely.

Areas for improvement

Both the PR and the NL confirmed there are currently no written guidelines for managerial cover in the PR's absence. In discussion with both the PR and the NL, they acknowledged this will be important for the future as they are aware that at times it will not be possible for either of them to provide cover.

The PR stated that he had written to another fertility centre in an attempt to formalise contingency arrangements for both the storage of dewars and continuation of fertility treatment if the centre could not provide a service. The PR is aware of the need to make alternative arrangements.

The Laboratory Director stated the HFEA alerts are kept in a folder in the main office for staff to refer to. The PR stated that both he and the Laboratory Director discuss alerts at staff meetings. However, two of the staff members interviewed were aware that the HFEA sends out alerts but were not familiar with the most recent ones.

Executive recommendations for Licence Committee

Note that contingency plans have not yet been formalised to ensure continued service, including the storage of dewars, in the event of a staffing and/or premises emergency.

Areas not covered on this inspection

Business planning was not covered on the day of inspection.

Evaluation

Some improvements needed.

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:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates
As the centre has only been operational since November 2006, there is no live birth data to report.
Areas of firm compliance
Welfare of the Child (WoC) assessments were discussed with the Medical Director. He affirmed that the gathering of information on which this assessment is based takes place with the patient at their first consultation and this procedure forms part of the primary checklist when gaining the patient's history. This checklist was evidenced on the day of inspection. The Nurse Manager stated that the patient is then given a social questionnaire to complete at the screening visit and that time is allocated to discuss concerns with the nursing staff. Patient records are held securely in locked cabinets within the administration area. The door leading into the administration area may be open throughout the day but the Executive were reassured this area is constantly manned with licensed staff. A log of complaints was reviewed by the Executive and it was noted that two complaints have been received and resolved since the centre has opened. The Executive was satisfied with the centre's complaint handling process. A couple interviewed on day of the inspection who raised a complaint were also satisfied with the outcome. Twelve patient questionnaires have been received by the HFEA prior to the inspection. The responses were overall positive and many commented on the professional, supportive and friendly manner of staff. Privacy and dignity were maintained at all times. All patients were made aware of counselling service and one patient expressed that the service was very supportive and accessible. There were mixed views about patient information – most patients stated they were well informed, in both written and verbal format. Continuity of care was raised on two occasions. In some questionnaires, the patients expressed a preference for seeing the same staff, including through to the embryo transfer procedure, as they felt anxious if new faces provided care at this stage. Patients responded positively to the premises, stating it was both clean and relaxing.

The patients interviewed on the day of inspection were positive about their experiences at the centre. They had been offered counselling before and throughout their treatment and commented that the staff were positive, helpful and friendly. They expressed satisfaction with the flexibility offered for appointment times and waiting time at the centre was minimal. Patient information on the administration of drugs has recently been amended in light of a patient recommendation.

The fee schedule provided in the patient information pack indicates that patients do not incur a charge for independent counselling (during and up to two months after a treatment cycle). The Counsellor told the Executive that she is available to see patients on Mondays and Fridays but is flexible with these arrangements. She stated that patients can contact her independently of the centre to make appointments. Centre staff interviewed on the day of the inspection affirmed they verbally promote counselling alongside the information presented in patient information packs. In the event the Counsellor is concerned with a couple's response to counselling she stated that she obtains their consent so that she can seek guidance from appropriate colleagues. The Executive was told about arrangements to cover for the Counsellor in her absence.

The PR stated that the centre has started to recruit sperm donors but previous attempts have attracted unsuitable candidates. At present they purchase donor sperm from Manchester. The laboratory staff were aware of the Sperm, Egg and Embryo Donation (SEED) requirements. Verbal confirmation was received that egg donors are only paid legitimate expenses.

The centre offers an egg sharing service. In these situations, the staff strongly advise patients to take up counselling.

Areas for improvement
None.

Executive recommendations for Licence Committee
None.

Areas not covered on this inspection
Choice of treatments, Protection of children arrangements (for patients under 18yrs).

Evaluation
No 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:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
Since the last inspection, the premises and equipment continue to be of a high standard. Recommendations in the last inspection report have been implemented (refer to section on 'changes/ improvements since last inspection' at the beginning of the report). The Laboratory Director stated that permanent CCTV monitoring is in place. The premises are monitored outside of office hours by the contracted security company. The Executive were shown the roller security shutters that additionally protect the administration areas where the computer database, monitoring systems for equipment and patient notes are kept. The Laboratory Director also pointed out that doors to all laboratory areas are locked after hours and that no confidential documents or materials are kept outside these secured areas. The Scientific Inspector found that the dewars are independently alarmed and are stored in a secure key-pad locked room. The Laboratory Director stated that four staff members have access to the room and that they have been made aware of the procedures in the event the low-oxygen alarm is initiated. The system of monitoring is continuous and applied to the incubators, fridges, dewars, low oxygen monitor and air quality. Evidence of this was seen. The monitoring system can be accessed by the Laboratory Director off site. If there is a deviation from normal, the system will alert the three Directors. The service log for laboratory equipment was witnessed by the Executive and was up to date. The Laboratory Director said that CE marked products are purchased where possible, in line with EUTCD requirements. The Executive were informed that Chubb supply the fire extinguishers and maintain the fire alarm. The Laboratory Director told the Executive that he performs the fire training for all centre staff.
Areas for improvement
The Nurse Manager told the Executive that the emergency trolley is checked weekly. The Executive found that a diary has been used to record the signature of those staff that have checked the trolley, rather than a formal checklist. Implementation of a formal checklist would assist the process of ensuring that continuous maintenance is apparent.
Executive recommendations for Licence Committee
None.

Areas not covered on this inspection
Prevention of incidents/accidents.

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:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
Ten patient records were audited for consent forms. A Discrepancy was found in one record and this related to an incomplete section on posthumous wishes on the HFEA male treatment form. A further five records were examined for evidence of witnessing and some discrepancies were noted. These are discussed in section five of the report. Overall, records audited by the Executive were kept in a neat and organised manner. Checklists for forms and audit results were kept at the front of each record.
Areas of firm compliance
Since the last inspection, the Centre Manager (who is also the Quality Manager) stated that Standard Operating Procedures (SOP's) have been completed and are held electronically and in hard copy format for all staff to access. She told the Executive that hard copies were updated simultaneously to any amendments made to electronic copies. A number of SOPs were provided to the Executive prior to the inspection and these proved to be document controlled, including the version, date and approval signatures. The Quality Manager stated she has been responsible for developing the Quality Manual. To date, HFEA registration and treatment forms have been submitted in a timely manner.
Areas for improvement
None.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
None.

Evaluation
No 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:

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	2
NMC registered nurses	3
HPC registered scientists	2
Scientists working towards registration	None
Support staff (receptionists, record managers, quality and risk managers etc)	4

Summary of laboratory audit
To date, a laboratory audit has not been completed by the centre due to the length of time the centre has been operating.
Summary of spot check of stored material
There were no discrepancies noted on the spot check of stored material (sperm and embryos). The Executive checked one embryo sample from the records to the tank; one embryo from tank to records, one sperm sample from the records to the tank; and one sperm sample from the tank to the records. The Executive was told that the sperm samples are split between two dewars. The dewars were all locked and alarmed and connected to the continual monitoring system. The keys for the dewars were kept in a locked key cabinet. The cryostore door is locked by a keypad. Evidence of these security measures was seen. The Laboratory Director explained that all of the stored sample records will be entered on to the ACU database. It would then be possible to sort them by expiry date to ensure that no samples are stored beyond their consented storage period. There is a low level extractor in the cryostore which is in continual operation. The dewar top up record was seen and was up to date.
Areas of firm compliance
Evidence of suitable practices to monitor air quality was seen and explained to the scientific Inspector.

A new staff member was interviewed on the day of inspection and in addition to mandatory training, it was noted that she also received training on witnessing and how to safely operate equipment used throughout the centre. This training log was witnessed. She told the Executive that her induction included supervision of her clinical practice by senior staff members and time allocated to allow her to visit other departments to gain an understanding of the roles and responsibilities of other staff members.

The PR told the Executive that all staff receive mandatory training which includes fire, health and safety, security and basic life support. A sample of mandatory training records was witnessed on the day of inspection and deemed fit for purpose.

The Counsellor maintains her Continued Professional Development (CPD) by participating as a member of the British Infertility Counselling Association (BICA) Executive Committee and attending events related to her membership of the British Association of Social Workers (BASW) and the Association for Family Therapy (AFT). She said that her practice is supervised for two hours of the month.

The Medical Director told the Executive that he maintains his CPD, as required by the Royal College of Obstetricians and Gynaecologists (RCOG). He also discussed upcoming training opportunities for staff, including the European Society of Human Reproduction & Embryology conference.

The Executive reviewed individual PDPs for the Centre Manager, Nurse Manager and the Senior Embryologist.

Areas for improvement
Whilst it was noted that staff receive training tailored to their needs, induction programmes were not formally documented, including competency based assessment of particular tasks such as IUIs.

Executive recommendations for Licence Committee
Note that induction programmes for new staff members should be formally documented, including evidence of supervised practice and competency assessment for those performing specialised clinical tasks.

Areas not covered on this inspection
Assessment of patients and donors, Safe handling systems. PGD/PGS is not performed at this centre.

Evaluation
Some improvements required.

Report compiled by:

Name: Allison Cummings

Designation: Inspector

Date: 8 June 2007

Appendix A: Centre Staff interviewed

The PR and seven other staff were interviewed throughout the course of inspection.

Appendix B: Licence history for previous 3 years

An initial application for treatment and storage was received in August 2006.

After a site visit was conducted by the HFEA Executive on the 6th October, the findings were presented to the Licence Committee on the 11th October.

A one year treatment and storage licence was granted by the HFEA on the 1 November 2006.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number 0250

Name of PR Professor Richard Fleming

Date of Inspection 10th May 2007

Date of Response 11th July 2007

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

Responses to Inspection Report 11/07/07
Centre Number 0250, GCRM

We appreciate the opportunity to review the report being submitted to the licensing committee. We consider its contents to be broadly fair, and below are some details of responses to the original report that are pertinent to changes planned and taking place as part of evolutionary processes.

Research
The position has changed now in this respect.
We are participating in a lab-based study of RFs PhD student. The activity was approved by our ethics committee – and previously by the committee at the GRI. It does not involve gametes or embryos - only cells from follicular fluids. So far, 12 cases at GCRM have volunteered for the study. The exercise is planned to discontinue in the autumn.

Contingency arrangements
For continued patient service, including storage Dewars in even of staffing and/or premises emergency For catastrophic emergency requiring relocation of storage Dewars - we have written to the local Ross Hall Hospital, with whom we have a number of arrangements, to determine the possibility of a SLA for temporary storage. They have responded positively in the first instance, and we are preparing paperwork for their further examination.

For continued service of patients on treatment, we have no realistic alternative, and our standard response will be to discontinue treatment.

Managerial cover in PR's absence
We have added the following statement to the Quality Manual:

Continuous Management Responsibility
The Person Responsible and the Nominal Licensee undertake never to be absent simultaneously for extended periods.

The Laboratory Director will be fully involved in these matters, and along with the Centre Manager will ensure full managerial cover at all times. This is implicit in their specified roles.

Induction programme for new staff members
Documentation of supervised practice and competency for specialised tasks. The induction programmes will be extended to include specialised clinical tasks in nursing and medical practices.

HFEA Alerts
Advice to ALL staff Lab director / PR disburse advice of alerts by email to all staff (all staff have email addresses) – also see next item.

Changes made in response to alerts
There is now a standing item for incidents and HFEA Alerts in the 'Team Meeting' agenda.
Alert 23. Witnessing procedures are being reviewed - based upon the new CoP (v7) and Alert 23 by means of process mapping and risk-assessment. Our procedures appear to be robust at present and revisions will take place following the review.

"Areas for improvement"
The Emergency Trolley now has log sheet for recording weekly checks.

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

26 July 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

Glasgow Centre for Reproductive Medicine (0250)
Licence Renewal

Members:	In Attendance:
Clare Brown, Lay Member – Chair	Marion Witton, Head of Inspection
Ruth Fasht, Lay Member	Claudia Lally, Committee Secretary
Roger Neuberg, Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary	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 (34 pages)
- no papers were tabled.

1. The papers for this item were presented by Allison Cummings, HFEA Inspector. Ms Cummings informed the Committee that this purpose-built IVF centre was built relatively recently allowing for it to be designed to ensure compliance with the requirements of the EUTD. The centre is situated on the outskirts of Glasgow and offers treatments to self-funded patients. The centre's initial licence was granted on 1 November 2006, and this renewal inspection visit to the centre took place on 10 May 2007. Because the centre has been operating for a relatively short period of time there are no figures yet available for the centre's live birth rate, however pregnancy rates to date are listed at page 24 of the Committee Papers. Ms Cummings also highlighted that the centre's current risk score has been calculated to stand at 5%, putting the centre in the low risk range.

2. Ms Cummings drew the Committee's attention to the fact that the Person Responsible had acted quickly to address the recommendations made at the initial inspection last year. These included the recommendation that soundproofing was improved and that the male production room was converted to a single-use room.

3. Ms Cummings listed the three recommendations which had been made to the centre during the renewal inspection visit (detailed at page 6 of the inspection report). She informed the Committee that these have now largely been addressed, with the exception that the centre have not yet been successful in identifying another centre with whom to draw up an agreement about taking over the treatment of patients in the event that adverse circumstances make it necessary to close the centre at short notice.

4. The Committee discussed the fact that the centre has not been able to draw up a contingency plan with another centre. The Committee considered the response of the Person Responsible on this issue (at page 22 of the Committee papers), which states that no realistic alternative is available and that discontinuing treatment would be the standard response by the centre in these circumstances. The Committee expressed concern about the possibility that patients' treatment might have to be abandoned mid-cycle in the event of an emergency and they agreed that the centre should be urged to pursue a more satisfactory answer to this problem. The Committee agreed that until a solution is found, patient information should include reference to the fact that no arrangements have been made for the continuation of their treatment in the event of the closure of the centre. The Committee asked that the centre update the Executive on any progress with this issue by 1 November 2007.

5. The Committee agreed to renew the centre's licence for a period of 3 years, with no additional conditions.

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