



New Premises Site Visit Report

Name of Applicant	Dr. Richard Fleming
Address of Proposed Premises	Glasgow Centre for Reproductive Medicine, 21 Fifty Pitches Way, Cardonald Business Park, Glasgow G51 4 FD
Has the applicant been licensed before	NO
If yes: Centre Number and Address of previous premises	
Inspector(s)	Dr. Neelam Sood
	Dr. Marion Witton
	Dr. Vicki Lamb
Date of visit	6/10/2006
Date of any previous visits to these premises	25/07/2006

About the Site Visit

The purpose of the site visit report is to confirm to the PR the findings of the inspection highlighting areas of firm compliance and good practice, as well as areas where further improvement is required. The report may be shared with other regulators on a need to know basis, such as the HC and HTA.

Brief Description of the Centre

This purpose built new IVF Centre is situated on the Fifty Pitches Way close to the Southern General Hospital. The Glasgow Centre for Reproductive Medicine is well signposted and easily approachable. The building has two floors and the Centre is on the ground floor. There is a common entrance to the building. The Centre has an independent security code at its entrance on the ground floor. Patient's registration desk is on the side of the main door and a staff member serves visitors. Overall the building design is impressive, meeting EUTD requirements for air quality. It is well decorated and had latest laboratory equipment. The tour of the facilities was guided by the PR and other members of the staff.

Summing up meeting notes

The Glasgow Centre for Reproductive Medicine is a well organised unit. Although building design complements a purpose built IVF unit the furnishing needs some improvement to provide a more relaxed and comfortable atmosphere for patients.

The men's production room that also serves as a toilet was found to be functional rather than comfortable. The PR explained that the male toilet facility will move to the disabled toilet when the male production room comes into service.

The post recovery rooms were found lacking comfortable easy chairs for attendants. Trolleys were being used instead of beds for patients. The PR stressed that the recovery trolleys are specifically designed for purpose, and are made of comfortable materials intended for protracted use. They obviate the need for sedated or anaesthetised patients to be transferred or made to walk.

Conversation in the ladies toilet could be overheard from the adjacent consultation rooms. The PR and the staff are aware of and concerned about the privacy and dignity of patients.

The patient's questionnaire on counselling services needs to capture their views about the effectiveness of the counselling services.

The information leaflet needs to provide clear information regarding payments and the number of free counselling visits.

The counselling room would benefit if comfortable easy chairs are provided for the patients.

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 of: *(Delete areas not reporting on)*

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident Management
- Contingency arrangements
- Business planning
- Clinical governance
- Knowledge of the legal requirements and COP

Summary of Findings

The unit was assessed as organised. The evidence included accurate and clearly documented SOP's of risk management, clinical governance structure, business plan and contingency arrangements.

Staff interviewed was aware of the process involved in reporting incidents and HFEA alerts. The staff confirmed that the systems are known and work in practice.

The PR demonstrated awareness of his responsibilities under the HFE Act, and is aware of the new standards document issued by the HFEA and the requirements of the EUTD. The centre appears well organised and appropriately staffed for the planned cycles for the first year.

Areas for improvement

The PR should ensure that dates are advertised for scheduled meetings and include a list of the names of attendees.

It is recommended that counsellor is involved in the departmental meetings.

Points to consider/action for next inspection

None

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection: *(Delete areas not being reported on)*

- 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)

Summary of Findings

The PR explained that treatment choices will be offered to the patient and the main focus will be on the patient's need.

Welfare of child arrangements were discussed and the staff found to be aware of the services. Patient information leaflet reflects current requirements.

Single embryo transfer procedure was discussed and the clinician showed interest for single embryo transfers in some suitable cases.

Highlighted areas of firm compliance

The complaints procedure was displayed in the reception area. There was an evidence of an individual in-charge of adverse incidents and complaints. The complaint procedure was considered suitable for purpose by the inspectors. Notice was on display in the waiting area showing how patients can access this service.

All staff members interviewed were aware of the confidentiality requirements of patients and their notes and their privacy and dignity. Patient records would be kept in locked cabinets in secure area.

During the inspection one patient was interviewed. She was found to be happy with the treatment and overall professionalism of the staff and with the ambience of the clinic. The patient stated that staff are enthusiastic and have a positive attitude towards her treatment. The information received by her, both written and oral, was clear and concise.

Patients are required to provide the photographic identification (passport or driving licence) as proof of identify before starting into a treatment programme.

Evidence has been provided regarding questionnaires for feedback on satisfaction of patients along with the information leaflets.

The counsellor was interviewed. Counselling is provided by a dedicated counsellor who is contracted to provide one session a week. She reported that she works at the Glasgow Royal Infirmary and on Mondays she has a session at the GSRM. She would be flexible regarding her consultation time according to the need of patients. Although counselling is included in the overall fees the counsellor considers that it should only be provided to people with an identified need. She prefers to see couples rather than patients individually although she explains they have different needs. Couples undergoing donor treatment are advised to have counselling but it is not presented as a pre requirement to the treatment.

Most couples are expected to have two sessions with the counsellor but they may see the counsellor after two months of cessation of treatment as part of the overall fees with an option to pay for further sessions independently.

Areas for improvement

It is recommended that a system to obtain patient views on the effectiveness of the counselling services is established.

The counsellor reported that she has been in discussion with the PR regarding team meetings and her contribution to the decision making about the centre. No arrangements are in place at present for regular team meetings.

Points to consider/action for next inspection

None

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection: *(Delete areas not being reported on)*

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

Summary of Findings

The Glasgow Centre for Reproductive Medicine has a new purpose built suitable premises designed to meet EUTD requirements for air quality. Some parts of the building are still under construction.

Overall building is well decorated and maintains good standards of hygiene. Storage facilities for embryos and gametes were found to be satisfactory. There are two rooms for consultations and one is primarily used for patient examinations and scanning.

Highlighted areas of firm compliance

The laboratory space and cryofacilites are well planned and spacious thus reducing the likelihood incidents and accidents.

Male, female and disable toilets, sperm production room and three recovery rooms for post recovery patients are with en-suite facilities.

The spacious patients waiting area with television was found to be impressive. A meeting/ seminar room, general office/ reception and cabinets for patient's notes were found to be fit for the purpose.

All dewars within the cryostore were independently alarmed, locks were ready to use and the autodial facility was being connected on the day of inspection. The low oxygen alarms, which were seen in situ, were also being connected to the autodialler.

Emergency backup power is supplied to the unit by a battery operated uninterrupted power supply and a backup generator.

All the equipment in the laboratory was found to be satisfactory with the exception of wrong incubators which were supplied to the centre but since the inspection the incubators have been replaced with the correct ones.

Areas for improvement

Conversations may be overheard in the ladies toilets from the consultation room. The patient's recovery rooms are clinical rather than patient focussed, for example there are trolleys instead of beds in the rooms and there are no comfortable chairs in the rooms for the partners. The men's production room is also used as a male toilet and other visitors wishing to use the toilet might have to use the disabled toilet.

Points to consider/action for next inspection
None
The standard of the premises and equipment
No improvement required

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and to the HFEA

Summary of findings from inspection: *(Delete areas not being reported on)*

- Information management
- Information to patients and donors
- Information to the HFEA
- Protocols
- Record keeping (including consents)

Summary of Findings
There is a robust accubase system computer programme for patients' records. Patients' information is to be stored on the hard disk and also saved as hard copies which will be kept in the locked cabinets.
Outcome of audit of records
The PR informed the inspection team that audit of records will be carried out by the Quality Manager.
Highlighted areas of firm compliance
Patient information leaflets were found to be satisfactory. A patient interviewed stated that the both verbal and written information provided was complete and understandable. All policies, protocols were found to be up to date and of high standards. A quality manager has been appointed but is not yet in post. The post holder will be responsible for developing the quality manual, SOP's and protocols which has already been drawn up. A system needs to be established for assessing the quality of the service which results from the SOP's.
Areas for improvement
No improvement required.
Points to consider/action for next inspection
None
The standard of information provided
Information provided for patients is up to date, understandable and complete.

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: *(Delete areas not being reported on)*

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

Full time equivalent staff

GMC registered doctors	Two
NMC registered nurses	Two
HPC registered scientists	Four
Support staff (receptionist, centre administrator, Centre manager, quality and risk managers etc.)	Three

Summary of Findings

The staff are competent and sufficient for a safe clinical and laboratory practice for the number of cycles planned for the current year. The PR informed the inspection team that they are planning to do approximately 200 cycles in the coming year.

The Clinicians are registered with GMC, nurses are registered with RCN, Counsellor is registered with BICA and embryologists are registered with HPC as evidenced from the documents submitted for the inspection.

The training and CPD of staff for the next year has been organised by the PR and it is fully funded by the unit.

Highlighted areas of firm compliance

The laboratory director informed the inspection team that viral positive patients would not be treated initially. The Centre's policy for screening patients was seen on inspection.

The laboratory director has a clear overview of the whole laboratory from the inspection window in his office so that he may oversee the daily work and the safe handling systems in the laboratory.

There is a separate andrology laboratory for all initial semen analysis.

The laboratory director informed the inspection team that all screened samples of embryos and sperms would be split and kept in separate tanks. The lab staff will not accept any unscreened samples.

Areas for improvement
No improvement required.
Points to consider/action for next inspection
The provision and quality of staff
No improvement required.

Topic 1

(a) The applicant meets the requirements for **organisation**

Topic 2

(a) The applicant meets the requirements for **quality**

Topic 3

(a) The applicant meets the requirements for **premises**

Topic 4

(a) The applicant meets the requirements for **information**

Topic 5

(a) The applicant meets the requirements for **laboratory and clinical practices**

Next Action

Actions Taken immediate after inspection

The incorrect incubators have been replaced by those ordered in the first place.

Patient Questionnaire: amendments have been made regarding assessment of the counselling service and new documents received.

New comfortable chairs for the quiet consulting room have been ordered, as recommended at inspection. Other comfortable chairs have also been organised for the recovery room.

Window blinds and duvets are now in place in the recovery room, which softens the clinical atmosphere significantly.

Sound proofing: some remedial measures in the process to reduce the degree of sound transmission, but PR is waiting that the commissioning of the air conditioning to determine just how much is required.

The laboratory commissioning (air handling systems) have started, and will continue over the next week. The external (independent) auditing company required to validate the system is booked for October 18th.

Actions Intended to be Taken

Team Meetings. The SOP for patient management (clinical meetings), The PR has planned three clinical team meetings each week. It is anticipated that these will precede formal 'team meetings' at least weekly in the first few months. Aim to involve the counsellor whenever she feels that the agenda is appropriate.

The SOP for team meetings will list individuals, and minutes will be circulated to all members of staff.

Summary of findings for Licence Committee
(If final visit before Application considered by LC)

The inspection team recommends that the Centre is licensed for storage and treatment for one year.

Appendix A: The inspection team and staff interviewed

The inspection team interviewed the PR, Mr Richard Fleming and seven other members of staff.

The inspection team

Dr Neelam Sood	Chair, Inspector, HFEA
Dr Marion Witton	Inspector, HFEA
Dr Vicky Lamb	Inspector HFEA

Report compiled by _____ Dr Neelam Sood _____

Signed _____

Designation __ HFEA inspector _____

Date _____

RESPONSE OF PERSON RESPONSIBLE TO THE SITE VISIT

Centre
Number.....250.....

Name of PR.....Dr Richard Fleming
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Date of
Inspection.....05/10/06.....

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Date of
Response...09/10/06.....

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

All actions we anticipate have been included in the report. We found the comments of the inspection team constructive.

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).

[Empty rectangular box for providing factual corrections or comments.]

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 this section of the report to:

Dr Marion Witton

Head of Inspection, HFEA

21 Bloomsbury Street

London

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