Licence Renewal Inspection Report for Treatment and Storage Centres

Reproductive Medicine Unit
0167

Date of Inspection: 24 May 2007
Date of Licence Committee: 15 August 2007

CENTRE DETAILS

Centre Address	Elizabeth Garrett Anderson Hospital Huntley Street, London, WC1E 6AU
Telephone Number	020 7380 9759
Type of Inspection	Renewal Treatment and Storage
Person Responsible	Mr Ertan Saridogan
Nominal Licensee	Professor David Fish
Licence Number	L0167-7-b
Inspector(s)	Parvez Qureshi (Lead Inspector)
	Allison Cummings
	Wil Lenton
Fee Paid - date	To be invoiced
Licence expiry date	30 November 2007

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About the Inspection:
This inspection visit was carried out on 24 May 2007 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between August 2005 and 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

The Reproductive Medicine Unit has been licensed since 1997 with no previous conditions on its licence. During 2006 three additional visits were made to the centre to ascertain how the management were addressing the issues highlighted in the last interim inspection. A change of Person Responsible (PR) and Nominal Licensee (NL) took place in July 2006, resulting in improved compliance with the HFEA requirements.

Over the past year a total of 53 donor insemination (DI) cycles were carried out at the unit. Since the previous inspection no major changes have been made to the premises. However, the centre will be relocating to a new site within the University College London Hospitals (UCLH) in 2008.

Opening hours at the centre are Monday - Friday 9am - 5pm. An organisational chart is in place indicating key functions and lines of accountability within the unit.

The Person Responsible (PR) is appropriately qualified to discharge his duties, evident from Person Responsible Entry Programme and as outlined in section 17 of the HF&E Act.

Activities of the Centre

Donor Insemination	53
Unlicensed treatments	Intra-uterine insemination (IUI)
Storage	Yes

Summary for Licence Committee

Since the last inspection, improvements have been made at the centre in particular regarding the auditing and splitting of the long term stored samples. However, additional improvements need to be made to the quality of service being provided.

The inspection team recommends the renewal of the centre's treatment and storage licence for three years.

Risk Assessment

The current risk matrix score for centre is 11%.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvements required	Significant Improvements required
	x	

Evaluations from the inspection

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

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
None.	None.	None.

Non-Compliance

Area for improvement	Action required	Time scale
HFEA alerts.	Development of a procedure for review of practices regarding HFEA alerts.	Within a month from report being presented to the Licence Committee.

Recommendations	Time scale
The PR is to ensure that auditing and splitting of long term stored samples is completed. prior to the centre moving to new premises in 2008.	As soon as possible.
The organisational chart to be updated to include recent staff changes.	Within a month.
The laboratory staff should be represented at the unit meetings.	Immediately.
Induction programmes for new staff and other training undertaken by staff to be formally documented.	On going.
A procedure to be put in place for actioning resolution or investigation of complaints and incidents.	Immediately.
Review current waiting lists to see the counsellor.	Within a month.
Review security of patient notes when the reception area is unattended.	Immediately.
The men's production rooms to be made more comfortable for their intended use.	Within a month.
Review the quality of completing treatment forms returned to the HFEA.	Within a month.

Proposed licence variations

None.

Changes/ improvements since last inspection

Appointment of new PR and NL.
Development of a new Quality Management system.
Auditing and splitting of long term stored samples.

Additional licence conditions and actions taken by centre since last inspection

C	None.
A	None.

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
Documentation including an organisational chart showing main functions and lines of accountability within the unit were supplied for the inspection. Key members of staff have extensive experience of working in the fertility field. A Quality Manager is in place and the PR confirmed that he was aware of the new HFEA Standards and the requirements of the EU Tissue and Cells Directive .The PR also stated that the unit is working towards addressing the issues raised in the recent application to vary the centre's licence to include intra-uterine insemination (IUI) treatment. Minutes of weekly multi-disciplinary team meetings held to discuss practice related issues were seen during the inspection and were found to be satisfactory. Risk assessments are carried out using the Trust's risk management system. Evidence of recent risk assessment for auditing and splitting of stored samples was seen during the visit. Staff are made aware of the HFEA alerts and this was confirmed by staff interviewed. In the event of an emergency, the centre has access to facilities located within the main hospital. The PR confirmed that the Trust's clinical governance policies are in use. Regular audits of practice, patient feedback and of records are carried out by staff. Information from the HFEA finance department showed that there were some concerns over the payment of treatment fees. The PR stated that this will be resolved in due course.
Areas for improvement
The organisational chart needs to be updated to include recent staff changes. Measures need to be put in place by the PR to review practices regarding HFEA alerts.

The laboratory staff are not represented at the unit meetings. This was evident from the minutes reviewed on the day of the inspection.

Induction programmes for new staff and supervision of clinical tasks to ensure competency were not found to be formally documented.

There are incident reporting and complaints management procedures. However the complaints and incidents logs reviewed did not contain all the actions taken for resolution or investigation.

Executive recommendations for Licence Committee
None.

Areas not covered on this inspection
All areas covered.

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:

- 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
Summary of the donor insemination (DI) information from the HFEA Success Rate Assessment (31st March 2002 – 1st April 2005): DI success rate for age band 40-42 significantly lower than National Average Donor Insemination success rate for age band 35-39 lower than National Average Donor Insemination success rate for age band 'Below 35' significantly higher than National Average
Areas of firm compliance
Staff interviewed and a review of the documentation submitted for the inspection showed that 'Welfare of Child' assessment procedures are in place. The centre follows the Trust's confidentiality procedure. All patients' medical records are stored in a secure area with only members of the staff having access to them. Consultations with the patients are held in private rooms and any resulting treatment is documented in their notes. Two patient questionnaires were returned to the HFEA with mixed responses and these were discussed with the centre's staff. There is a suggestion box in the waiting area so that patients' views on the quality of service provided to them can be obtained. Any suggestions made are discussed by staff and where possible improvements are made. Evidence of a recently conducted patient satisfaction survey was made available for the inspection team. A couple were interviewed during the inspection and made positive comments about the quality of service they had received. The PR stated that there are arrangements in place within the obstetric and gynaecology department of the main hospital for patients who require an out of hours service.

The PR confirmed that since the last inspection, seven complaints had been made by patients and all have been resolved.

Counselling is offered by a qualified fertility counsellor who has been associated with the centre for ten years and she is a member of the British Infertility Counselling Association (BICA).
There is no charge for counselling. The counsellor confirmed that her CPD, which is self funded, was up to date and evidence of this was discussed during the inspection. She receives regular supervision from a mentor, regularly attends the centre's MDT meetings and has access to the minutes. The counsellor stated that she was well supported by the staff.

Patients can contact the counsellor via the staff or directly. Currently there is a four to eight weeks waiting list. All counselling sessions take place in a dedicated room and the notes are kept separately from the patients' treatment notes in a secure place.

The counselling audit supplied for the inspection confirmed that there were a total of 180 referrals between April 2006 and March 2007. The uptake rate for counselling is relatively high for the number of patients seeking treatment. Referral data shows that therapeutic/ supportive counselling is the most frequently attended, followed by implications counselling.

Areas for improvement

Currently there is a four to eight weeks waiting list to see the counsellor which can result in patient not being able to take access the service.

Executive recommendations for Licence Committee

None.

Areas not covered on this inspection

Egg sharing and surrogacy.
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
Access to all areas of the centre is via a key pad operated system. Additional security arrangements are in place as a part of the Trust's security policy. Since the last inspection no major changes have been made to the premises. Almost all the areas seen during the visit were found to be clean and well presented. The scientific Inspector considered the current cryostore facilities at the unit to be adequate for the volume of work being carried out. Access to the cryostore area is via the main laboratory. The facilities are fitted with a low oxygen monitoring system. All dewars are alarmed and linked to an autodialler system. There are adequate procedures in place for responding to alarms. The laboratory staff confirmed that since the last inspection, no significant changes have been made to the equipment. Maintenance contracts are in place for key pieces of equipment and evidence of this was seen during the visit. Logs of activities carried out in the laboratory are kept and these were seen by the inspection team and considered to be well organised. The emergency trolley located in the centre was checked and was found to be well maintained. It is checked on a daily basis and entries were seen to be made in an appropriate log. The PR confirmed that in the event of a power failure the centre has access to a back up generator located within the main hospital.
Areas for improvement
There is a controlled access to the unit including the area behind the counter in the waiting room. However, on the day of the inspection the reception area was open to patients but was unattended. As some patient notes are stored behind the front counter, the PR needs to ensure that measures are put in place to maintain the security of patient notes when the reception area is unattended. The men's production rooms which are located near the laboratory were seen by the inspection team and were considered to be cluttered. Currently these rooms are also used as storage areas for various laboratory consumables. Action is required to make the rooms more comfortable for their intended use.

Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
All areas covered.

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
Five patient records were reviewed by the inspection team. The notes were found to be well organised with relevant documents being in place. However, some errors were identified and these were discussed with the centre's staff.
Areas of firm compliance
The information management system seen during the inspection was considered to be well organised. All treatment related information is stored in secure areas. The patient information submitted for the inspection was reviewed and was found to be of a good standard, including information regarding Ovarian Hyperstimulation Syndrome (OHSS). The following information was also seen during the course of the inspection: The Centre's treatment licence. Complaints procedure. HFEA leaflets. Counselling services.
Areas for improvement
Issues raised by the HFEA Registry regarding return of treatment forms by the centre were discussed with the staff. Measures need to be put in place to address the quality of forms returned to the HFEA.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
All areas covered.

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:

- 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	9
NMC registered nurses	4
HPC registered scientists	1
Andrologist / Scientists.	4
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	6

Summary of laboratory audit
As per the recommendations made in the last inspection report, splitting and auditing of samples has been in progress since September 2006. This is an ongoing programme and the PR anticipates the completion of this project before the centre moves to new premises in 2008. All splitting and auditing activities are logged and regular updates are reported to the HFEA.
Summary of spot check of stored material
An audit of two samples from notes to dewars was carried out. No discrepancies were found.
Areas of firm compliance
There are policies in place for assessment of patients seeking treatments and for screening of patients. This was evident from the documentation submitted for inspection and discussion held with staff. The centre has a thorough witnessing procedure in place. Evidence of double witnessing was seen in the laboratory records. The continuous professional development (CPD) for staff is addressed through in-house and external training courses. This was evident from the discussions held with staff who commented that they are encouraged by the PR to attend relevant events.

Regular staff meetings are held at the unit and the outcomes are circulated to all staff, even if they were absent from them.

A Trust-wide policy is in place for the recruitment of staff and their suitability to work in the centre including CRB checks. However, the PR does have some input into the recruitment procedure. The staff turnover at the unit is low as evident from discussions held with the staff.

Areas for improvement

The Nurse Manager stated she was confident that all nursing staff had undertaken mandatory training, including basic life support (BLS). However, a documented record of this was not available on the day of the inspection. Similarly not all other training undertaken by staff is formally documented.

Executive recommendations for Licence Committee

None.

Areas not covered on this inspection

PGD/ PGS.

Evaluation

Some improvements required.

Report compiled by:

Name……Parvez Qureshi…….

Designation……Inspector…….

Date……20 June 2007……

Appendix A: Centre Staff interviewed

The PR and seven other members of staff.

Appendix B: Licence history for previous 3 years

2006

Licence Committee 27 July 2006

The Committee agreed to vary the centre's licence to recognise Mr Ertan Saridogan as the new Person Responsible and Mr David Fish as the Nominal Licensee.

2005

Licence Committee 12 October 2005

The Committee approved Ms Jackie Sullivan as the new Person Responsible.

Licence Committee 17 August 2005

The Committee agreed to the continuation of the centre's licence with no additional conditions.

2004

Licence Committee 12th July 2004

The committee agreed to continue to the licence with ten recommendations, which is due to expire on the 30th November 2007.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……0167……

Name of PR…….Ertan Saridogan ……

Date of Inspection…24 May 2007……

Date of Response…28 June 2007……

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

Recommendations	Response
The PR is to ensure that auditing and splitting of long term stored samples is completed prior to the centre moving to new premises in 2008.	This is an ongoing project, we have made plans to increase auditing and splitting activity to achieve this task
The organisational chart to be updated to include recent staff changes.	This has already been done
The laboratory staff should be represented at the unit meetings.	The laboratory staff now regularly attend the unit meetings
Induction programmes for new staff and other training undertaken by staff to be formally documented.	Induction programmes were already in place and were available on the day. We have now put evidence for 'other training' into our files.
A procedure to be put in place for actioning resolution or investigation of complaints and incidents.	We have now created an electronic spreadsheet file which includes 'actioning resolution' for incidents. A similar file already existed for complaints on the day of inspection.
Review current waiting lists to see the counsellor.	We have applied to our Divisional General Manager to provide resources to increase counsellor sessions.
Review security of patient notes when the reception area is unattended.	The reception area door is now locked at all times even when attended.
The men's production rooms to be made more comfortable for their intended use.	These rooms have been rearranged to make them more comfortable.
Review the quality of completing treatment forms returned to the HFEA.	We have now revised our forms to specify 'donor codes' as registered with the HFEA so that errors are avoided.

Additional note regarding Live Birth Rates Table: We rarely treat couples who are 40 or over, hence the numbers are very small and it is impossible to compare our success rates with the national rates for this age group.

Since the inspection, all copies of BLS training have been received by the HFEA.

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

Signed……

Name…… Ertan Saridogan ……..

Date……28 June 2007……

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

15 August 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

Reproductive Medicine Unit (0167)
Licence Renewal

Members of the Committee:	In Attendance:
Emily Jackson, Lay Member – Chair	Trish Davies, Director of Regulation
Richard Harries, Lay Member	Frances Clift, Legal Adviser
Anna Carragher, Lay Member	Marion Witton, Head of Inspection
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary	Barbara Lewis, Regulation Team Leader
	Claudia Lally, Committee Secretary

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 (41 pages)
- no papers were tabled.

1. The papers for this item were presented by Parvez Qureshi, HFEA Inspector. Mr Qureshi informed the Committee that the recent inspection to the centre had identified a number of improvements since the time of the last inspection. In particular the centre is now addressing the requirement to split and audit oncology samples, which was raised as an issue of concern at a Licence Committee meeting in August 2005. Mr Qureshi reported that the centre is now making steady progress with this issue and is regularly updating the HFEA about what is being achieved. The Person Responsible expects that the process will be complete by the Autumn of 2008, when a move to a new premises is planned. Mr Qureshi informed the Committee that the improvements identified in the inspection report are in part attributable to the fact that the centre's Person Responsible and Nominal Licensee have changed since the time of the last inspection with the new Nominal Licensee playing an active part in the management of the centre.

2. Mr Qureshi reported that the inspection team made a number of recommendations to the centre, detailed at page 7 of the inspection report. He also drew the Committee's attention to the response to these recommendations, appended at pages 20 and 21 of the report. Mr Qureshi reported that on the basis of this response he is content that satisfactory progress is being made with most of the issues discussed at the inspection visit.

3. The Committee noted that the only concern raised in the inspection report which had not been addressed by the Person Responsible was the requirement to develop a way of disseminating HFEA alerts to centre staff. The Committee asked the Executive to check that this is being addressed.

4. Mr Qureshi drew the Committee's attention to the additional comment by the Person Responsible that the centre rarely treats women who are 40 years or over, with the consequence that comparisons with success rates achieved by other centres for patients in this age group are not possible. This point was accepted by the Committee.

5. Mr Qureshi also pointed out that feedback received from patients at the centre has been positive and that counselling uptake is very good for the number of cycles carried out. He informed the Committee that the centre's risk score following the inspection is 11%, putting the centre in the low risk group.

6. Mr Qureshi drew the attention of the Committee to his recommendation that the centre's licence is renewed for three rather than five years. He explained that this recommendation relates to the fact that the Person Responsible has only been in place since last year and the centre is going through a period of change. The recommendation also reflects the fact that the centre has still not completed the process of dividing oncology samples into separate storage dewars. This is a breach of Chair's letter CH(04)03 which required that samples were split before June 2005.

7. The Committee considered the statutory requirements for the granting of licences and agreed that these were all fulfilled with the exception that the licence fee has not yet been paid by the centre. The Committee noted that the centre has not yet been invoiced for the licence renewal fee.

8. The Committee agreed to renew the centre's licence for a period of three years subject to receipt of the licence fee.

Signed……. … Date……..
Emily Jackson (Chair)