Interim Inspection Report

Reproductive Medicine Unit
0167

Date of Inspection: 28 August 2008
Date of Licence Committee: 27 October 2008

Centre Details

Person Responsible	Mr Ertan Saridogan
Nominal Licensee	Mr David Fish
Centre name	Reproductive Medicine Unit Department of Obstetrics & Gynaecology University College London Hospitals
Centre number	0167
Centre address	Elizabeth Garrett Anderson & Obstetric Hospital Huntley Street London, WC1E 6DH
Type of inspection	Interim
Inspector(s)	Parvez Qureshi Wil Lenton Paula Nolan (observing)
Fee paid	Not due
Licence expiry date	30 November 2010
NHS/ Private/ Both	NHS

Index

About the Inspection:

This inspection visit was carried out on 28 August 2008 and lasted for 7 hours.

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

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

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

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

Where recommendations are made the HFEA will provide details of 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 Reproductive Medicine Unit is part of the University College London Hospitals NHS Foundation Trust. It is anticipated that the unit will be relocating to a new site within the University College London Hospital grounds in November 2008 subject to HFEA approval.

Over the past year a total of 78 donor insemination (DI) treatment cycles and 202 cycles of intra uterine insemination (IUI) were provided at the unit. The centre also provides a storage service for patients who have had treatment that may impair their fertility.

No changes have been made to the premises since the last inspection. Currently preparation of semen for use in IUI is taking place at UCH (centre 0044) under the auspices of a third party agreement pending the outcome of a review of the laboratory services currently being undertaken by an external expert.

The centre treats NHS patients only. Opening hours at the centre are Monday - Friday 9am - 5pm.

The Person Responsible (PR) has completed the HFEA PR Entry Programme. He is registered with the General Medical Council (GMC) and is on the Obstetric and Gynaecology specialist register.

Activities of the Centre[1] for the time period from 27/05/2007 to 28/05/2008.

In vitro fertilisation (IVF)	0
Frozen embryo transfer (FET)	0
Donor Insemination (DI)	78
Intra uterine insemination[2]	202
Gamete intrafallopian transfer (GIFT)	0
Research	n/a
Storage	Yes

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

[2] Treatments provided in the time period from 5 July 2007 and 31 December 2007

Summary for Licence Committee

There have been no significant changes in the centre in terms of activity, patient demographics and premises since the last inspection in May 2007. However the centre will be moving to new premises later this year.

Issues highlighted in the previous inspection have been addressed. However, some improvements are recommended to the following areas of practice:

- Payment of fees to the HFEA
- Air quality
- Continual professional development

The inspection team supports the continuation of the centre's licence.

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
The average time for the payment of treatment fees to the Authority is 71 days. This is a breach of Standard licence condition A.13.3 which states that the Person Responsible agrees that s/he will pay to the Authority any additional fees, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.	The Person Responsible should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.	At the centre's discretion. Progress to be Monitored at the time of the next inspection.

Air quality in the environment in which gametes are processed has not been demonstrated to meet the required standards.	The processing of gametes while exposed to the environment should take place in an environment of at least Grade C air quality with a background environment of at least Grade D air quality as required by standard licence condition A.10.19. The PR should ensure that where the environmental air quality has dropped below Grade D in the course of a procedure involving the manipulation of gametes or embryos, those gametes or embryos should only be used in treatment if the centre can assure itself that no additional risk to the woman to be treated or to any resulting child is entailed as a result. in compliance with G.9.4.5.	The assessment of risks associated with the use of gametes processed in air of quality less than grade D should be complete as required and the assessment documented in patient records.
Continuing education and professional development (CPD) for laboratory staff is not maintained.	Laboratory staff should maintain their CPD and this training should be documented and monitored I compliance with S.6.2.11. and A.10.11.	Ongoing

Non-Compliance

Area for improvement	Action required	Time scale
None.	None.	------

Recommendations

Area for improvement	Action required	Time scale
None.	None.	-------

Changes/ improvements since last inspection

Recommendations from previous report	Action
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.	Auditing and splitting of samples is now complete as confirmed by PR on the day of inspection.
The organisational chart to be updated to include recent staff changes.	Evidence made available for the inspectorate to review confirmed this had been actioned.
The laboratory staff should be represented at the unit meetings.	Evidence from review of recent minutes of team meetings confirmed that laboratory staff now regularly attend the unit meetings.
Induction programmes for new staff and other training undertaken by staff to be formally documented.	Seen during inspection.
A procedure to be put in place for actioning resolution or investigation of complaints and incidents.	Procedure now in place and evidence witnessed by inspectorate.
Review current waiting lists to see the counsellor.	The counselling audit (April 2007 – April 2008) confirms that the waiting list now at 4 weeks.
Review security of patient notes when the reception area is unattended.	The reception door is now locked this was witnessed on inspection.
The men's production rooms to be made more comfortable for their intended use.	Improvement noted on inspection.
Review the quality of completing treatment forms returned to the HFEA.	The centre has now revised the forms to specify 'donor codes' as registered with the HFEA so that errors are avoided.

Additional licence conditions and actions taken by centre since last inspection

The previous licence was issued without additional conditions.

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 the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
Documentation submitted for inspection, including an organisational chart showing key responsibilities and lines of accountability, were reviewed by the inspection team and were considered to be appropriate. The PR has implemented changes as recommended in the report of the previous inspection. Processes are in place for the identification, notification and investigation of incidents: incidents have been reported within the prescribed timeframes and have been investigated and resolved effectively. The centre's complaints log was reviewed by the inspection team and evidence of actions taken to resolve complaints were noted. The PR stated that in the event of an emergency the centre has direct access to the trust's facilities. In addition, there are arrangements in place for patients who need to contact staff outside working hours. The centre has a contingency arrangement in place with UCH London centre 0044 for continuation of service. Third party agreements are in place and were made available to the inspection team to review. A sample of agreements were reviewed and were compliant with HFEA guidelines. Minutes of weekly multi-disciplinary team meetings held to discuss practice related issues were seen during the inspection. Issues such as in house training, updating patient information, fire policy and HFEA alerts were noted.
Areas for improvement
The average time for the payment of treatment fees to the Authority is 71 days. This is potentially a breach of standard licence condition A.16.3.

Areas for consideration
None
Executive recommendations for Licence Committee
The Person Responsible should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.
Evaluation
Some improvement required.
Areas not covered on this inspection
Risk management Resource management Clinical governance

2. Quality of service

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

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Staff suggestions
- Document control
- Live birth rates

Live birth rates[1]
Outcomes of DI treatments for the time period from 1 April 2004 to 31 March 2007 were in line with national averages for all age groups. In the time period from 5 July 2007 and 31 December 2007 the centre provided 202 cycles of IUI and report that 29 clinical pregnancies resulted from the treatments.
Areas of firm compliance
The centre has a quality policy and manual in place which was reviewed by the inspectorate and was considered to be appropriate. The centre has implemented quality management procedures. The PR and Head of Laboratory are currently sharing the role of quality manager. This role will be taken over by the newly appointed unit manager. Some quality performance indicators have been established and evidence of monitoring clinical and laboratory practices was provided in the course of the inspection. The centre holds quarterly quality management meetings when issues discussed include: patient satisfaction; staff suggestions; outcomes; compliance with quality indicators. The outcomes of these discussions are documented in minutes. Three patient questionnaires were returned to the HFEA: two respondents made positive comments about the treatment they received. 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 discussion of patient feedback was recorded in minutes of multi disciplinary team meetings. It was noted by the inspectorate that there is an effective document control procedure in place. This was evident from the documents reviewed by the inspection team and discussions held with the staff.

Areas for improvement
None
Areas for consideration
In feedback provided to the HFEA one patient reported that they had not been provided with ample information or opportunities to ask questions. It is acknowledged that this was the only negative response but it is suggested that the PR considers gathering feedback from a wider patient cohort in relation to the provision of information.
Executive recommendations for Licence Committee
None.
Evaluation
No improvements required.
Areas not covered on this inspection
All areas covered.

3. Premises and Equipment

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

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Storage of records

Areas of firm compliance
Since the last inspection no major changes have been made to the premises. The areas seen during the visit appeared to be clean and well presented. The centre will be relocating to new premises within the trust in November subject to a licence committee decision on the new premises. 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 centre's current cryostore facilities appeared to be adequate for the volume of work being conducted. The cryostore is fitted with a low oxygen level monitor. All dewars are alarmed and the centre has a procedure 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 monitoring activities carried out in the laboratory are kept and these were seen by the inspection team and considered to be well organised. When health records are not in use are stored in locked cabinets.
Areas for improvement
The air quality in a class II hood was checked in July 2007 during servicing, however an air quality monitoring system is not in place. The centre's expects to relocate to new premise in November 2008 pending a decision on licensing of the facilities.
Areas for consideration
None.
Executive recommendations for Licence Committee
The processing of gametes while exposed to the environment should take place in an environment of at least Grade C air quality with a background environment of at least Grade D air quality as required by standard licence condition A.10.19.

The PR should ensure that where the environmental air quality has dropped below Grade D in the course of a procedure involving the manipulation of gametes or embryos, those gametes or embryos should only be used in treatment if the centre can assure itself that no additional risk to the woman to be treated or to any resulting child is entailed as a result. In compliance with G.9.4.5.
Evaluation
Some improvements required.
Areas not covered on this inspection
Staff facilities.

4. Information

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

Summary of the findings from the inspection of the following areas of practice:

- Consent
- Access to health records
- Welfare of the child
- Provision of information to the HFEA register

Areas of firm compliance
Five patient records were reviewed by the inspection team. The notes were found to be well organised: all records contained evidence of completion of a welfare of the child assessment and consent forms were compliant with the treatment provided. The centre has appropriate procedures in place for obtaining consent to treatment, as noted in the patient records reviewed. This was confirmed by staff who met with the inspection team. The centre reports that they have a procedure for responding to patient requests for access to their health records through the local NHS trust policy. Discussions held with staff confirmed that the centre has appropriate procedures in place to ensure that proper account is taken of the welfare of the child when considering treatment. The provision of information to the HFEA register is done in a timely manner.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
No improvements required.
Areas not covered on this inspection
Information for service users.

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit

Full time equivalent staff

GMC registered doctors	5
NMC registered nurses	4
Non NMC registered clinical staff	1
HPC registered scientists	1
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	12
Counsellors	1

Summary of laboratory audit
The splitting and auditing of all stored sperm samples (2,500) was competed in the last year.
Summary of spot check of stored material
No spot check audit was carried out.
Areas of firm compliance
The continuous professional development (CPD) for staff is addressed through in-house training and external training courses. Staff training files were examined on the day of the inspection and included orientation and induction courses as well as mandatory training such as basic life support and manual handling. There are policies in place for the assessment of patients seeking treatments and for screening of patients. This was evident from the documentation submitted for inspection and a discussion held with staff. The centre has witnessing procedures in place. Documentation reviewed in the course of the inspection were considered to be appropriate. . Traceability of consumables used in the laboratory is logged in a hard copy book.

Counselling service have remained the same since the last inspection. However it was noted that the waiting list for counselling has now decreased from eight to four weeks. 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 96 referrals between April 2007 and April 2008 indicating a good uptake for the number of treatment cycles done.

Areas for improvement

Training records viewed on the day of inspection indicate that the laboratory staff have not been provided with training opportunities since February 2008. The PR should ensure laboratory personnel are provided with adequate opportunity for relevant professional development and the training should be documented in compliance with the requirements of A.10.11.

Areas for consideration

None.

Executive recommendations for Licence Committee

During a review of the documentation of witnessing it was observed that the documentation of a witnessing step had been omitted. The omission was at a stage where the centre had included an additional witnessing step beyond the requirements of HFEA guidelines however, it is recommended that the centre monitors compliance with witnessing procedures.

Evaluation

Some improvements required.

Areas not covered on this inspection

Screening of donors.

Report compiled by:

Name……..…Paula Nolan/Parvez Qureshi…….

Designation……Inspectors……..…….

Date……06 0ctober 2008……..……

Appendix A: Centre staff interviewed

The PR and nine other members of staff.

Appendix B: Licence history for previous 3 years

2007

Licence Committee 15 August 2007

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

Licence Committee 26 April 2007

The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

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.

Appendix C: Response of Person Responsible to the inspection report

Centre Number……0167……

Name of PR…….Ertan Saridogan…….

Date of Inspection……28 August 2008……..

Date of Response……15 October 2008……

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

Signed……

Name……Ertan Saridogan ……..…….

Date……..15 October 2008……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

None.

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

None.

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

(Comments taken from PR response received). • Delayed payments: Unfortunately this has been happening due to frequent change of staff in the Finance Department at our Trust, although the PR has intervened personally on several occasions. Our General Manager is now negotiating with the Finance Department to put a system in place to avoid this happening in the future. • Air Quality: This issue was highlighted by us during inspections of 2006 and 2007 in

view of the fact that the trust was building new premises for the Centre. Our new premises have been designed to meet the air quality standards in the EUTCD and we have certified compliance prior to the inspection. In our current premises, all sperm preparations are carried out in Grade II Laminar Flow Cabinets, furthermore, all sperm preparations for IUI are currently performed by UCH ACU (Centre 0044) Laboratory under a Third Party Agreement.

- CPD for laboratory staff: Organisation, management and quality issues at our Laboratory are currently under external review with an intention to resolve outstanding problems and improve overall quality in all aspects. We anticipate that this review will finish within the next few weeks and we will take action accordingly.

We welcome comments about the inspection on the inspection feedback form, a copy of which should have been provided at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF