Licence Renewal Inspection Report for Treatment and Storage Centres

Homerton University hospital
0153

Date of Inspection: 30th January 2007
Date of Licence Committee: 16th April 2007

CENTRE DETAILS

Centre Address	Fertility Unit Homerton University Hospital Homerton Row London E9 6SR
Telephone Number	0208 510 7660
Type of Inspection	Renewal Treatment and Storage
Person Responsible	Nancy Hallett
Nominal Licensee	Nancy Hallett
Licence Number	L0153-10-a
Inspector(s)	Tahir Hussain
	Tony Knox
	David Gibbon
Fee Paid - date	Due to be billed in July 07
Licence expiry date	31st August 2007

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About the Inspection:

This inspection visit was carried out on the 30th January 2007 and lasted for 6 hours. The report covers the pre-inspection analysis, the visit and information received between May 06 and January 07.

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 IVF unit has been licensed for treatment since 1995, and is located on the site of the Homerton University Hospital NHS Trust, which has Foundation status. The unit occupies a portacabin at the rear of the premises. Adequate signs are in place within the main hospital to direct patients to its current location. The unit occupies two floors. The ground floor includes the reception, the main waiting area, offices, the laboratory, procedure room, nurses' office, male producing room / toilet, a female toilet and consulting room in which scanning operations are performed. The second floor includes two consulting rooms, one of which is used as a counselling room.

Egg collections and some difficult embryo transfers are conducted within the Day Surgery Unit of the main hospital. This unit comprises a waiting area where patients are prepared for theatre, a well equipped operating theatre, including a flow hood for the preparation of eggs collected prior to transport to the laboratory within the unit, and two recovery areas.

The centre is currently looking to re-locate to new, purpose built premises within the main hospital by end of December 2007. The unit staff have had input into the new build to ensure that all regulatory requirements will be met when the new premises are commissioned.

Activities of the Centre

Storage of Sperm (Patient & Donor)	IVF IVF with Donor eggs / Sperm	Mechanical Assisted Hatching
Storage of Embryos	ICSI with Donor sperm / eggs	IUI – Intra Uterine Insemination using partners sperm - unlicensed
Donor Insemination	Chemical Assisted Hatching	Ovulation Induction - unlicensed

Summary for Licence Committee

The inspectors recommend the renewal of the Centres' licence for three years.

The centre has made many improvements since the last inspection with more planned. There have been significant improvements made in the laboratory, however, it was noted that some suggested improvements from the last inspection have not been fully implemented within the laboratory area to meet with acceptable standards and adherence to the Code of Practice.

Risk Assessment

The current risk matrix score for the centre is 26 %

This has increased from 21% due to the change of PR since the previous inspection.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	√ This overall evaluation is based on the performance and state of the embryology laboratory as well as breaches from the last inspection not fully completed.	

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 or Code of Practice

Breach	Action required	Time scale
An autodialler has been purchased and installed, however has not been commissioned.	The autodialler needs to be commissioned and working.	End of February
Not all dewars within the laboratory were alarmed as required at the last inspection. The PR stated that these have been purchased and should be in place by end February 2007.	Alarms to be installed on all the dewars.	End of February
The producing room was considered unfit for purpose at the last inspection and staff were recommended to provide an alternative. See Code of Practice 2.7.	No change was noted to the facilities during this inspection.	As soon as possible. The unit is due to re-locate to within hospital in December 2007 and these premises will have a purpose built production room.

Non-Compliance

Area for improvement	Action required	Time scale
The low oxygen level monitor was not in place in the laboratory as the battery had failed. It was stated by Raj Joshi (Lead Embryologist) that this could take up to 3 weeks to replace. It was pointed out to the centre that this was a risk and an alternative plan should be put into place.	The oxygen level monitor should to be placed in the maintenance register to ensure that the area is alarmed at all times.	Immediately
Witnessing at weekends is not carried out and this is performed retrospectively	This should be conducted at the time of the procedure being carried out to eliminate any mistakes	Immediately

Recommendations	Time scale
Training folders be maintained for all staff	Ongoing

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
Audit stored samples against patient notes	All stored samples are now within the date of expiry
All policies and procedures to be version controlled and to contain date of issue as well as review date.	Documents now meet the criteria
Update the Incidents and complaints procedure	Document updated and fit for purpose
Develop an in-house training procedure	Developed and under way

Additional licence conditions and actions taken by centre since last inspection

C	
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
An organisational chart showing main functions and lines of accountability within the unit was submitted for the inspection. Key members of the staff have extensive experience of working in the fertility field and have been at the centre for a number of years. The inspection team considered the unit to be appropriately staffed for the current volume of work being carried out. All staff interviewed during the inspection stated that they were well supported by the PR in all aspects of their work. In the event of any emergency, the centre staff have access to facilities located in the main hospital. The unit also has contingency cover with St Barts and uses the facilities as and when required. There are draft third party agreements in place with each other. Information from the HFEA finance department showed that there were no issues with the centre over the payment of treatment fees. The average days for payment of fees to the HFEA were 53 days Communication was seen to be effective throughout the centre and it was seen that all staff attend regular meetings. The leadership team have regular input into the meetings and welcome feedback from all levels.
Areas for improvement
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered
Evaluation
No 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
The live birth rates provided are for the period preceding the appointment of the current PR. Live birth rates are below the HFEA produced national averages with the exception of donor insemination treatment. This is reflected within the risk matrix score above.
Areas of firm compliance
Review of documentation submitted for the inspection together with discussions held with the staff and the review of the patient notes showed that 'Welfare of Child' assessments are being conducted in accordance with the regulations at the centre. The inspection team noted that the medical records are stored in a dedicated room with only members of the centre having access to them. All consultations with the patients are discussed in private rooms and any treatment offered is documented in their notes. Audits of practice success results, patient feedback and records are carried out by centre's staff. There are incident reporting and complaints management protocols in place and these were discussed during the inspection. The centre was well organised and the patient treatment notes were seen to be in good order and improved from the previous inspection (including all relevant consents and the WoC form). The complaints procedure was seen during the inspection. There were 4 complaints received since the last inspection of which one was still noted as open and was under review. The counselling service is well promoted in the patient information leaflets. The counsellor is easily accessible and appointments can be booked via the centre's staff or directly. No separate charge is made for counselling sessions. The counselling audit was seen and witnessed and it was seen that there was no waiting list. The counsellor is a member of the British Infertility Counselling Association (BICA) and has extensive experience of working in infertility counselling.

Counselling sessions take place in a dedicated room in the centre and the notes are kept separately from the patients' treatment notes in a secure place only accessible by the counsellor.

Two couples receiving treatment were interviewed during the visit. They were complementary of the service received, the information provided about their treatment, counselling available and drugs. Both couples stated that the staff were friendly and approachable.

Areas for improvement
Patients expressed some dissatisfaction with delays in being seen on the day of their appointment. The unit manager stated that they endeavour to see patients on time; however the occasional consultation can take longer than anticipated and they would rather see a patient for a little longer on these occasions than make them come back for another appointment. The admin staff will always update and apologise to patients in the waiting room and offer to rebook them if they can not wait.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Donor selection Egg sharing and surrogacy Protection of children arrangements (for patients under 18yrs)

Evaluation
Some improvement 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 no major changes have been made to the premises. All areas seen during the inspection were found to be clean and well presented. Access to the unit is restricted to staff only. A closed circuit television system is in operation within the hospital which further enhances the centre's security. Since the last inspection, no significant changes have been made to the equipment. Maintenance contracts are in place for all critical equipment and these were seen during the inspection. Logs of activities carried out in the laboratory are kept and these were made available for the inspection. In the event of a power failure the centre is covered by a back up generator. The unit manager stated that the fertility unit has access to a theatre in the main hospital which is used for egg collections. The unit is due to relocate to an area in the main hospital building and this is planned to occur in December 2007. The new facilities will be purpose built and the fertility unit staff have regular input into the design.
Areas for improvement
The male sample production room, which is also the gentleman's toilet, is unfit for purpose. It was pointed out that the majority of patients produce the sample at home and it was noted that provision has been made for a more suitable production room in the new unit.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered

Evaluation
Some improvement 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
On the day of inspection, 20 records were selected from the unit. These records were checked for welfare of child (WoC), correct consents and HFEA forms as well as completeness of information. All records contained the correct information and were in good, clear and concise order. The three embryo transfer log was viewed and 6 have been performed this year, all were for women over the age of 40 and all have supporting notes from a doctor.
Areas of firm compliance
During the inspection the following documents were evidenced and fit for purpose (it was also noted that they are now version controlled: • Patient information on IUI, DI, • Operational policy • Hospital induction programme • Complaints procedure and notice • Incidents log Other documentation reviewed included: • Appraisal Form for a Nurse – contained PIN number, achievements, areas for improvement and development. Also objectives, training and development plan. • Folder for new starter – junior embryologist – included the corporate induction programme, appraisal, PDP and certificates including ACE membership.
Areas for improvement
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered
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	5
NMC registered nurses	4
ACE registered scientists	1
Seminologist	0
Support staff (receptionists, record managers, counsellor, quality and risk managers etc)	8

Summary of laboratory audit
A full internal audit is performed by the Embryologists yearly and it was seen by the inspectors that no embryos or sperm samples in the store had passed their expiry date. All details have been input electronically into a database which will flag up a list of patients samples that are nearing their annual expiry. A written list is also maintained as a back-up. The patients are contacted before their samples expire to ensure that there are no samples in storage past their consented storage point. It was seen by the inspectors that this was very time consuming and some administrative assistance would be useful.
Summary of spot check of stored material / Witnessing
Sperm – two samples from tank to records and two records to tank were checked Embryos – two samples from tank to records and two records to tank were checked No discrepancies were noted. Five records in total were examined for witnessing, two for IVF, one for IUIH, one for sperm freeze and one for embryo freeze. All records were complete and evidence of witnessing was seen for all the required steps, however this was not true of all weekend witnessing.
Areas of firm compliance
The laboratory has now began to perform the following internal QC checks: • Temperature of fridges and incubators • Batch number of reagents

It was found that the service records checked were complete and up to date for all critical equipment viewed in the laboratory. The embryologist stated that the micro-manipulator cannot be serviced in the UK, however a different manufacturer is being considered for the relocation. It was noted that all equipment has been PAT tested and a regular schedule is maintained.

The backup generator had failed to start in December 06 which caused disturbance in the laboratory. It was witnessed by the inspectors that this has now been rectified by the installation of new sockets and the system was successfully tested 2 weeks later.

Staff were interviewed and the CPD was checked for all. It was seen that an appraisal process and development of PDP was available for all staff and staff interviewed felt well supported.

Areas for improvement

It was raised by the inspectorate that air quality has not been monitored to date in the existing laboratory areas and this should be undertaken before the move to the new premises to ensure compliance with the EUTD.

The embryologists are working alone on weekends and it was noted that witnessing is performed retrospectively. It was pointed out to the PR that this should be performed at the time of the actual step.

Three dewars did not have alarms, the inspectors were told these have been ordered and should be in place by end of February 2007. This was an outstanding breach from the previous inspection. It was explained that Trust Funding for this equipment had only recently been approved.

The alarmed dewar was:

- Embryo

The non alarmed dewars were:

- Donor Tank
- Quarantine Tank – this was empty when examined
- Sperm – (however it was noted that this alarm was broken and sent for repair)

It was seen that there was insufficient storage for backup and for additional samples that are being stored within the centre as the workload increases. The current dewars were seen to be reaching their maximum capacity.

An auto-dialler was in place but not commissioned. The PR plans to bring this into operation when the new alarms arrive for the dewars and are working. The on call rota and an SOP is required.

The low oxygen level monitor was not in place in the laboratory as the battery had failed. It was stated by Raj Joshi that this could take up to 3 weeks. It was pointed out to the centre that this was a risk and an alternative plan should be put into place.

Currently the laboratory alarms only sound in the laboratory area. If the alarms activate out of office hours, they can potentially be unchecked until the next working day. Centre staff did state that there are security patrols of the centre throughout the night who will hear the alarm if it sounds.

The staffing levels require attention due to the current senior embryologist leaving and a new one starting in February. There are two trainees, however they cannot work unsupervised. The rota should be updated to cover all eventualities.

It was found that a incubators used for viral positive samples are not separated from the negative samples. This must be addressed.

It was noted that training folders were not available for all members of staff and a sign off sheet for competencies is recommended. The PR must have systems in place to ensure that all staff are competent.

Executive recommendations for Licence Committee

- An autodialler to be fully commissioned and linked to all dewars within the laboratory in the case of an emergency.
- Alarms must be connected to all dewars within the embryology laboratory.
- Weekend witnessing should be performed at the time of the event

Areas not covered on this inspection

All areas covered

Evaluation

Significant improvements have been made since the last inspection, however more are required.

Report compiled by:

Name Tahir Hussain

Designation Regulations Inspector

Date 2nd February 2007

Appendix A: Centre Staff interviewed

Nancy Hallett (PR)
4 staff
2 couples

Appendix B: Licence history for previous 3 years

- **Renewal Inspection 30th January 2007**

- **Renewal Inspection 18th May 2006**
- **Licence Committee 27th July 2006**

Licence continued with no conditions

- **Unannounced inspection 20th April 2006**

- **Licence Committee 12th October 2005**

Licence continued with no conditions

- **Licence Committee 17th August 2005**

Change of PR approved.

- **Licence Committee 14th July 2004**

Request to export sperm where the donor had not given consent to export. This request was approved.

- **Interim Inspection 4th August 2004**
- **Licence Committee 5th October 2004**

Licence was continued with four recommendations

- **Centre was first licensed in 1995**

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……

Name of PR…….

Date of Inspection……..

Date of Response……

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

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

16 April 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

Homerton University Hospital (0153)
Licence Renewal

Members:
Walter Merricks, Lay Member – Chair
Ruth Fasht, Lay Member
Jennifer Hunt, Senior Infertility Counsellor, Hammersmith Hospital
Hossam Abdalla, Director of Lister Fertility Centre

In Attendance:
Trish Davies, Director of Regulation
Frances Clift, Legal Adviser
Claudia Lally, Committee Secretary

Observing:
Roger Neuberg, Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary

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 Tony Knox, HFEA Inspector. Mr Knox informed the Committee that this centre was first licensed in 1995. The centre currently has a risk score of 26%, reflecting the change of Person Responsible since the last inspection. Mr Knox drew the Committee's attention to the areas of non-compliance set out at page 7 of the inspection report, in particular, the fact that the autodialler part of the low-nitrogen alarm system was not working at the time of the inspection and the fact that not all dewars in the laboratory had been fitted with low-nitrogen alarms. In addition, the production room was considered unfit for purpose, a low oxygen level monitor was not in place in the laboratory and witnessing at weekends is performed retrospectively.

2. The Committee noted that a number of these issues constituted breaches of the Act and/or Code of Practice. In particular, the requirement that all dewars

should be alarmed and fitted with an auto-dialler is stated in CH(04)03, and retrospective witnessing of laboratory procedures is a breach of Directions D.2004/4.

3. Mr Knox read out the response to the inspection report by the Person Responsible. This response confirmed that the majority of these issues have now been rectified. In particular, all dewars are now fitted with low-nitrogen alarms linked to a working auto-dialler. In addition, double witnessing is now always being done, including at weekends. With respect to the low oxygen level alarm the centre had explained that there usually was one in place in the laboratory but it was in the process of having its battery replaced. The centre agreed to consider purchasing a second alarm to ensure that there was always a working alarm present in the room.

4. Mr Knox drew the Committee's attention to the large number of improvements seen since the time of the previous inspection. In particular, a new system has been put in place to ensure that no samples are being stored whose statutory storage period has expired, all the centre's policies and procedures are now version controlled, and a new incidents procedure has been introduced. Mr Knox summarised these developments by saying that he had seen a marked improvement in the way the centre was being run.

5. The Committee asked Mr Knox to confirm whether an action plan, requested by a Licence Committee on 27 July 2006, had been submitted by the centre. Mr Knox confirmed that it had.

6. The Committee noted that a Licence Committee sitting in October 2005 had requested a risk assessment from the centre to determine the possibility of accidents during the move to its new premises. Mr Knox confirmed that this has not been received by the centre and agreed to request it from them.

7. The Committee decided to renew the centre's licence for a period of three years. This decision reflected the fact that although the centre has made many improvements since the last inspection, there is still some work to do to achieve complete compliance with the Code of Practice.

Signed……. … Date……..
Walter Merricks (Chair)