Interim Inspection Report for Treatment & Storage Centre

Homerton University Hospital
0153

Date of Inspection: 26 February 2008
Date of Licence Committee: 25 June 2008

CENTRE DETAILS

Centre Name	Homerton University Hospital Fertility Unit
Centre Number	0153
Licence Number	L0153/13/b
Centre Address	Fertility Unit Homerton University Hospital Homerton Row London E9 6SR
Telephone Number	0208 510 7660
Type of Inspection	Interim – Treatment & Storage
Person Responsible	Anil Gudi
Nominal Licensee	Nancy Hallett
Inspector(s)	Tahir Hussain (HFEA Chair)
	Wil Lenton (HFEA Scientific)
	Helen Kendrew (External Clinician)
Fee Paid – up-to-date	All fees paid up to date of inspection
Licence expiry date	31/08/2010
NHS/Private/Both	Both

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About the Inspection:
This inspection visit was carried out on 26 February 08 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between February 07 and February 08.

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.

NB: Where there are very minor issues to be addressed these are noted in the "minor issues to be addressed" section for each topic, and this will facilitate the evaluation of 'no improvements required'. 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 IVF unit has been licensed for treatment since 1995, and is located on the site of the Homerton University Hospital NHS Trust. The unit is based partly within porta-cabins and partly in a permanent building.

The centre is expecting to re-locate to new, purpose built premises within the main hospital by the end of September 2008 and substantial work has been carried out since the previous inspection to facilitate the move.

The current PR, has been in place since December 2007 and has completed the PR entry Programme satisfactorily. The PR is registered with the General Medical Council and is on the obstetrics and gynaecology specialist register.

Activities of the Centre - data for the calendar year 2007 was extracted from the HFEA register[1]

Licensed treatment cycles	IVF / ICSI (Fresh & Frozen)	368
Donor cycles	Insemination Egg Donor Egg Recipient	37 2 1
Research	No	
Storage	Yes	

Summary for Licence Committee

The centre was seen to be working towards many of the issues raised and the Executive recommend that the licence continue with no additional conditions.

Risk Assessment

Following the inspection, the risk has been calculated at 21% which is in the medium range.

Evaluations from the inspection

[1] These data have not been verified by the centre and may be subject to change

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, 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	Reference	Action required	Time scale
The centre has stored cryopreserved material without written consent.	**S.7.8.11** At paragraph 1 of schedule 3 of the 1990 Human Fertilisation and Embryology Act it states that a consent under this Schedule must be given in writing.	The protocol for disposal of samples past their expiry date should be reviewed and a more robust system should be considered. The PR should review the procedures for disposing of cryopreserved material for which there is no valid consent to storage as a matter of urgency. Any changes in procedure implemented as a result of the review should be communicated to the relevant staff and protocols should be amended as required. The PR should advise the HFEA when the issue is resolved and of the outcome of any review of practice.	The review of the procedures for disposing of cryopreserved material should be completed by end of Sept 2008. The centre should obtain written to consent to storage for all cryopreserved material. Where continued storage is not required, or if it is not possible to obtain written consent and all reasonable efforts have been made to obtain the consent, embryos for which there is no valid written consent to storage should be allowed to perish by 13 April 2008.
Transfer of cryopreserved material is not witnessed	**G.13.1.1**	Witnessing at the time of transfer of cryopreserved material should be implemented	with immediate effect

The laboratory does not have any internal or external quality assurance (QA) processes in place	**S.7.8.13** **S.9.2.6**	The centre should ensure that internal Quality control procedures are in place and that records of the results of quality control/assessment activities, non-conformities detected and action taken are kept. The centre should participate in inter-Centre comparisons and the results should be evaluated and documented and relevant findings be used to improve the service.	To be monitored at the time of the next inspection
There was no formal procedure or documentation for home procurement	**S.7.7.9** **S.7.7.10** **S.7.7.2. (d)**	The centre should develop a procedure for home procurement and appropriate documentation to ensure compliance with the relevant standards	**3 Months**
Staff reported that workloads can be difficult to accommodate.	**S.6.2.1**	It is recommended that the PR undertake a risk assessment to ascertain how many cycles of treatment can be safely accommodated considering the staffing levels, skills mix, premises and equipment and that measures are taken to ensure that the centres capacity is not exceeded.	**Before the move to the new site.**

Non-Compliance

Area for improvement	Action required	Time scale
Almost all sperm samples for treatment are produced at home. This is potentially non compliant with guidelines at G 2.3.1 of the Code of Practice.	As documented above, the centre should ensure that appropriate procedures are in place for home procurement.	**3 months**

Recommendations	Time scale
There was no external audio or visual alarm for the Low oxygen level. This should be considered and put into place when the new premises are being built.	**Before the move to the new site.**

Proposed licence variations by last L.C.

None

Changes/ improvements since last inspection

Recommendations	Action Taken
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 are now installed on all the dewars.
The low oxygen level monitor was not in place in the laboratory as the battery had failed.	The oxygen level monitor has been placed in the maintenance register to ensure that the area is alarmed at all times.
The producing room was considered unfit for purpose at the last inspection and staff were recommended to provide an alternative.	Provision has been made for this in the new build and the plan is to move to all samples being produced fro treatment within the centre.
Witnessing at weekends is not carried out and this is performed retrospectively	Is now conducted at the time of the procedure being carried out to eliminate any mistakes
An auto-dialler has been purchased and installed, however has not been commissioned.	This has now been commissioned and is fully operational.

Additional licence conditions and actions taken by centre since last inspection

Date	Action taken
	Complied Y/N

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:

1. Leadership and management
2. Organisation of the centre
3. Resource management
4. Risk management
5. Incident management
6. Contingency arrangements
7. Business planning
8. Clinical governance
9. Payment of treatment fees

Areas of firm compliance
The newly appointed PR appears to be taking an active role in the management of the unit with support from the unit manager. Staff at the centre stated that both have ensured that the centre is well organised and maintained especially and that the recent changes in the PR have provided consistency for the unit. Communication was seen to be effective throughout the centre: staff attend regular meetings and this was seen in the minutes file. The leadership team have regular input into the meetings and welcome feedback from all levels. The incident log was reviewed and was considered comprehensive as it contained actions and follow up notes relevant to each incident. There has been one incident reported to the HFEA since the previous inspection and the investigation conducted was comprehensive with the PR obtaining external advice to ensure independence. Business planning was discussed with the Nominal Licensee and the unit's main aim this year is to move into the newly built premises and maintain the service. There may be plans to increase the number of treatments but this will be dependant on funding. The main hospital treats a large number of patients with HIV and the NL stated that there are a higher proportion of patients who attend seeking assisted conception who have HIV than other units. They are fully prepared for this scenario and would like to be a leading centre in the country. There is also a population of refugees and immigrants in the surrounding area who attend the clinic and the hospital policy is to treat, even if other centres have refused treatment. This has been planned for and the staff have received training. In the event of an emergency, the centre staff have access to the facilities located in the main hospital. The unit also has contingency cover with St Bartholomew's Hospital (0094). Information from the HFEA finance department showed that invoices have been paid within prescribed timeframes.

Areas for improvement
The Unit Manager, who works closely with the Quality Manager and the nursing teams, performs a number of key roles. The Unit Manager and the Quality Manager reported finding it difficult to fulfil all the responsibilities of their roles. The laboratory is staffed by two embryologists but one member of the team is leaving the unit soon. Workload can impact on the effective and safe running of a centre and consideration should be given to resource management. It is recommended that the PR undertake an assessment of how many cycles can safely be accommodated taking into consideration, the staff, skills mix, premises and any other factors that could impact on the quality of service and that workload is planned to ensure that the capacity for the unit is not exceeded.
Areas for consideration
None.
Executive recommendations for Licence Committee
Resources should be reviewed to ensure that staffing is adequate for the number of cycles and the centre should be operating safely.
Areas not covered on this inspection
Alerts. Clinical governance.

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:
1. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality objectives and plans
5. Quality Management review/evaluation
6. Monitoring and resolution of complaints
7. Staff suggestions
8. Document control
9. Live Birth Rates

Areas of firm compliance
The quality manager is part of the administration team and has additional assistance from the unit manager. The quality manual and other procedures and policies are held as a master paper copy, and electronically on a secure NHS Trust server, password protected so as to be accessible to all centre staff, only by the quality manager, the unit manager and the PR have editing rights. The Quality Manual includes an appropriate Quality Policy and was reviewed in the course of the inspection. The Inspectorate considered that the Quality Manual and procedures were comprehensive, broad ranging, well written and compliant to the relevant guidance for each area. There has been a lot of work carried out since the application for the EUTD licence in 2007, with a drive to include clinical pathways into the quality manual. The Unit Manager is the nominated complaints officer and the centre has a documented complaints procedure. The complaints policy is displayed in the waiting room. The complaints log was reviewed in the course of the inspection and was considered comprehensive. All the policies and procedures Quality Management System (QMS) were uniquely identifiable with all the required fields including title, version number and issue date etc. this is managed by the Quality Manager by using the shared network drive, however, the centre is looking to purchase management software.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
Staff suggestions

Live birth outcomes

Evaluation
No 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:

1. General Suitable premises
2. Clinical facilities
3. Counselling facilities
4. Laboratory facilities
5. Air quality
6. Storage facilities for gametes and embryos
7. Staff facilities
8. Management of equipment and materials
9. Control of records
10. Risk assessments

Areas of firm compliance
There have been no changes to the premises since the last renewal inspection and all areas seen during the inspection appeared tidy and well presented. Access to the unit is restricted to staff only. Laboratory doors are fitted with digital locks and a closed circuit television system is in operation within the hospital. A tour was taken of the site where the new facilities will be housed and substantial work has been carried out since the previous renewal inspection. During the building work it was noticed by the centre staff and management that there may be a shortage of space so an additional extension has been added. Comprehensive plans and architect drawings were provided to the inspectorate and it was seen that the work was on track to be completed by the due date. Since the last inspection, no significant changes have been made to the equipment and environment and maintenance contracts are in place for all critical equipment and logs of activities carried out in the laboratory are kept and were reviewed at inspection. Air quality has been monitored by an external company on behalf of the laboratory and was shown to be compliant to the standards. This was monitored quarterly and they tested the lab background and the air quality in processing areas. It was seen that all cryo-storage dewars were locked and liquid nitrogen alarms were in place for all dewars and an auto-dialler was in place for out-of-hours monitoring with a written protocol in place for actions required if the alarm sounds. In the event of a power failure the centre is covered by a back up generator.
Areas for improvement
None.
Areas for consideration

It was seen that although the low oxygen monitor was in place, there was no external audio or visual alarm.
Executive recommendations for Licence Committee
It is recommended that the centre have a new premises inspection before the move to the new unit takes place to ensure that all the HFEA requirements have been put into place. The centre should seek the advice of local health and safety representatives in relation to the safety of the cryostorage facilities (specifically in relation to procedures for responding to a low oxygen level alarm) in compliance with S 4.2.3.
Areas not covered on this inspection
Counselling facilities Staff facilities Control of records Risk assessments

Evaluation
No improvements required.

4. Information

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

Summary of findings from inspection:

1. General Information
2. Meetings and communication
3. HFEA Alerts
4. Confidentiality and access to health records
5. Traceability and coding
6. Coding/ identification of samples
7. Information for service users/consents
8. Donor information
9. Donor registration
10. Surrogacy
11. Procurement and distribution of receipt of gametes and embryos
12. Home procurement report documentation
13. Packaging &distribution
14. Labelling of packages containing procured gametes
15. Transportation, labelling of shipping container and recall
16. Receipt of gametes

Areas of firm compliance
Information for patients was reviewed by the inspectorate and its content was found to be appropriate. This was reviewed more comprehensively at the previous renewal inspection and was seen to be sufficient and has had no major updates since. Meeting minutes were reviewed by the inspectors. Minutes document discussion of the centre's activities, HFEA related business and alerts. Minutes were evidenced on file. Patient records were appropriately stored in either a locked cabinet for current patients, the rack for patients being treated on the day or in the locked notes store in locked filing cabinets for all other patients. Records are tracked by the use of an Excel spreadsheet for the ACU patients. All staff are asked to sign a confidentiality statement when they commence employment at the centre. Traceability of consumables is ensured by the maintenance of a batch log which details batch numbers and the start/end dates of batch usage. Media batch numbers are also entered into the patient records with the laboratory notes. Patient samples are identified with patient name, date of birth and hospital number. The centre has documented guidelines for the management of ovarian hyperstimulation syndrome.
Areas for improvement
Almost all sperm samples for treatment are produced at home. This is potentially non compliant with guidelines at G 2.3.1 of the Code of Practice. This issue is under review and on site sperm production facilities will be included in the new premises.

Areas for consideration
None.

Executive recommendations for Licence Committee
The PR should ensure that a formal procedure is in place for the home procurement process.

Areas not covered on this inspection
Packaging &distribution. Labelling of packages containing procured gametes. Transportation, labelling of shipping container and recall. Receipt of gametes. Donor information. Donor registration. Surrogacy.

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:

1. Laboratory processes
2. Selection and Validation of laboratory procedures
3. Laboratory's documented procedures
4. Storage of gametes and embryos
5. Counselling
6. Witnessing

Full time equivalent staff

GMC registered doctors	5
NMC registered nurses	4
HPC registered scientists	1
Scientists working towards registration	1
Support staff (receptionists, record managers, quality and risk managers etc)	7
Counsellors	1

Summary of laboratory audit / Audit of records
There was a breach identified in the centres own sperm/embryo audit where there were four instances of embryos, and two of sperm identified where stored material was kept after consent to store had expired. Some samples have subsequently been discarded and the rest will be disposed of as part of the ongoing plan formulised by the laboratory manager. Five records in total were examined for witnessing, two for IVF, one for IUI, one for sperm freeze and one for embryo freeze. All records were complete and evidence of witnessing was seen for all the required steps. These same records were examined for consents, WoC and completeness and were found to contain no errors. It was noted that the centre staff and the counsellor were aware of their duties for the Welfare of the Child and the consent forms used by the centre were considered appropriate. Evidence was seen that the WoC forms were used to ensure as part of the patient assessment.
Summary of spot check of stored material
Sperm: two samples from tank to records and two from the records to tank were checked. Embryos: two samples from tank to records and two from the records to tank were checked. There were no discrepancies noted on the day of inspection.
Areas of firm compliance
There was an operational procedure and process for the induction of new staff and this was fully documented in the QMS. Training logs were evidenced for all disciplines and a back-up

copy was kept on the QMS. The Trust checks the qualifications of new employees prior to the offer of employment.

It was evidenced that the incubator temperature and carbon dioxide levels were monitored daily with the substantiating paperwork available on the day of inspection. The traceability of lab consumables e.g. media, plastic-ware and ET/IUI catheters were also kept electronically.

The counselling service at Homerton is provided to all patients free of charge and they can have as many sessions as required to ensure that the patient feels satisfied. The counsellor is a member of British Infertility Counselling Association (BICA) and has many years experience. The service is well used and is well promoted by the staff as seen by the counselling audit.

Areas for improvement
The PR should review the procedures for disposing of cryopreserved material for which there is no valid consent to storage as a matter of urgency. Any changes in procedure implemented as a result of the review should be communicated to the relevant staff and protocols should be amended as required. Witnessing at the time of transfer of cryopreserved material should be implemented. The laboratory does not have any internal or external quality assurance (QA) processes in place
Areas for consideration
None.
Executive recommendations for Licence Committee
The Licence Committee is asked to endorse the recommendations made in relation to the areas for improvement cited above.
Areas not covered on this inspection
Validation

Evaluation
Some improvement required.

Report compiled by:

Name: Tahir Hussain

Designation: Regulatory Inspector

Date: 21 April 2008

Appendix A: Centre Staff interviewed

Person Responsible
Nominal Licensee
4 other members of staff

Appendix B: Licence history for previous 3 years

Change of PR on 5th December 2007
The Licence Committee approved the application

Application in pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 on 2nd May 07

The Committee agreed to vary the centre's licence

Renewal Inspection on 30th January 2007
Licence Renewed for three years with no additional conditions

Renewal Inspection on 18th May 2006
Licence Renewed for one year with no additional conditions

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number:

Name of PR:

Date of Inspection:

Date of Response:

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

Signed:

Name:

Date:

1. 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).

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

1) We have revisited the extension of storage of embryos and the consent.
2) A new protocol will be written and implemented by the end of June for the storage of embryos and their extension. This entire practice will be reviewed by our new consultant embryologist and should be ready by September 2008.
3) The witnessing of transfer of cryo preserved material will be immediately started.
4) The internal and external quality assurances will be addressed by December 2008.The new consultant embryologist will take this as a priority.
5) We will design a robust method of verifying the home procurement of sperm.. This will be in place by July 2008.
6) In the interim plans are made to obtain a room in the hospital premises to be able to produce semen. We hope to have it by July 2008.
7) A report detailing risk management and work to be done in the old unit will be done by the end of June 2008.

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

25 June 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 5

Homerton University Hospital (0153)
Interim Inspection

Members of the Committee:	In Attendance:
Anna Carragher, Lay Member – Chair	Debra Bloor, Head of Inspection
Emily Jackson, Lay Member	Claudia Lally, Committee Secretary
Richard Harries, Lay Member	
Present via conference telephone:	Providing Legal Advice to the
Rebekah Dundas, Lay Member	Committee:
	Nusrat Zar, Herbert Smith

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 (29 pages)
- no papers were tabled.

1. The papers for this item were presented by Debra Bloor, Head of Inspection. Dr Bloor informed the Committee that this centre provides IVF and DI treatments to NHS funded and self funding patients. The centre provided approximately 400 treatment cycles in 2007 and is currently preparing to relocate to new premises.

2. Dr Bloor reported that the inspection team considered the unit to have effective organisation, however there were concerns over imminent staff changes with one of the two embryologists expected to leave the unit. The team recommended that the Person Responsible undertake an assessment of how many cycles can safely be accommodated. In response to this recommendation the Person Responsible has confirmed that the unit proposes to reduce workload by 40% in consideration of staff changes and the forthcoming move to new premises.

3. Dr Bloor further reported that the quality of service and premises were considered to be in need of no improvement. However, there was a concern that the low oxygen level alarm was not connected to any visual or audio monitor and

the Person Responsible was advised to seek the guidance of local health and safety representatives to ensure procedures for responding to an alarm are safe.

4. Dr Bloor drew the Committee's attention to the fact that information reviewed in the course of the inspection was considered appropriate. The inspection team had noted that sperm production occurs off site and this is potentially non compliant with guidelines. It was recommended that a formal procedure be implemented for home procurement and the inspection team had noted that the new premises will have on-site sperm production facilities.

5. Dr Bloor reported that scientific practice was considered largely compliant, however, recommendations were made in relation to witnessing at the time of transfer of cryopreserved material, disposal of embryos reaching the end of their consented storage period and quality assurance procedures in the laboratory. She informed the Committee that feedback from the Person Responsible received after compilation of the Committee papers confirms that witnessing practices have been revised as recommended; new protocols for the review of storage of cryopreserved material will be implemented by the end of June 2008 with a further review of procedures in September; the centre expects to have a robust procedure for home procurement by July and also expects to have premises for on site sperm production by July.

6. Dr Bloor concluded with a statement that the Person Responsible has been responsive to the recommendations of the inspection team and the Executive recommend that the licence should continue.

The Committee's Decision

7. The Committee noted the breaches identified in the inspection report, particularly the storage of cryopreserved material without written consent, which is a breach of the Human Fertilisation and Embryology Act 1990.

8. The Committee noted the Person Responsible's response to the findings of the report. It requested that the Executive monitors the resolution of these issues and that the issues are considered as part of the forthcoming new premises inspection.

9. The Committee agreed that the centre's licence should continue with no additional conditions.

Signed…….. … Date……..
Anna Carragher (Chair)