Licence Renewal Inspection Report for Treatment and Storage Centres

The Lister Fertility Clinic
0006

Date of Inspection: 25 July 2006
Date of Licence Committee: 22 November 2006

TRIM: 06/3144

CENTRE DETAILS

Centre Address	The Lister Hospital Chelsea Bridge Road London SW1W 8RH
Telephone Number	020 7730 3417
Type of Inspection	Renewal
Person Responsible	Hossam Abdalla
Nominal Licensee	Mary Power
Licence Number	L0006/11/b
Inspector(s)	Dr Vicki Lamb
	Mr Tony Knox
	Mr Parvez Qureshi
Fee Paid - date	Not yet billed
Licence expiry date	28 February 2006

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About the Inspection:
This inspection visit was carried out on 25 July 2006 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between October 2005 and July 2006.

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 centre has been licensed since 1993 and offers a comprehensive range of treatments including pre-implantation genetic screening (PGS). It is a large centre which carried out in excess of 1400 treatment cycles in the last year. Sufficient numbers of appropriately qualified and competent staff are employed at the centre. There is an organisational structure in place which defines accountability, responsibility and reporting relationships. The person responsible is appropriately qualified to discharge his duties as outlined in section 17 of the HF&E Act. The centre is ISO 9001 accredited. The majority of the centre's patients are private with a small minority of NHS patients. The centre has a reasonable history of regulatory compliance and generally has worked constructively with the HFEA to alter practice that is not compliant with regulatory requirements.

Activities of the Centre

Licensed treatment cycles	IVF ICSI Egg donation Egg recipient	941 883 109 109
Donor Insemination		70
Unlicensed treatments	IUI GIFT Ovulation induction	
Research	No	
Storage	Yes	

Summary for Licence Committee

Two breaches of the Code of Practice and one case of non-compliance with Directions were noted during the inspection. The team also made several recommendations to the PR and centre staff. Overall, the centre required some improvements.

Improvements to the premises have been made since the last inspection and morale at the centre appeared to be good.

The inspection team recommend renewal of the centre's licence for a period of 3 years.

Risk Assessment

The centre has a risk score of 21%.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement 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
Appropriate storage measures are not in place for all patient records; some are currently being stored openly in an office. This constitutes a breach of section 11.14 of the Code of Practice.	Secure storage should be found for the notes that are currently held in the administration office.	Since the inspection the PR has confirmed that all notes have been removed from the office and are now stored in a secure locked area.
A 'paper only' audit of stored material has been performed; the tanks were not checked. This is a breach of section 9.11(i) of the Code of Practice.	The storage tanks should be checked to reconcile the centre's records with the genetic material stored.	Since the inspection it has been reported that a physical audit of all stored embryos will be carried out by the end of the year, and an audit of stored sperm will be carried out in the first half of 2007.

Non-Compliance

Area for improvement	Action required	Time scale
The centre should arrange that witnessing is always performed contemporaneously. This is non-compliance with Directions 2004/4.	Develop a protocol to ensure the Directions are complied with.	Since the inspection it has been arranged for hospital resident medical officers (RMOs) to perform witnessing in the laboratory on weekends to overcome this problem. These staff members have been added to the centre's licence.

Recommendations	Time scale
Formal contingency arrangements should be put in place.	3 months
The centre should consider having a separate theatre log for the procedures they perform to retain confidentiality.	
An alternative location should be found for the emergency trolley.	This has been arranged since the inspection
All medical staff should attend an annual update of BLS.	By next inspection
A written emergency protocol for responding to damaged storage vessels should be developed.	The PR reports that this has been addressed since the inspection.
A protocol needs to be developed to cover what happens if a donor withdraws their consent for embryos in storage to be used in treatment.	Since the inspection the PR reports that this has been done.
Records should be kept of CPD completed by the lab staff.	Since the inspection the PR confirms that this has been done.

Proposed licence variations

None

Changes/ improvements since last inspection

The ownership of the HCA group of hospitals, which includes The Lister Hospital, has recently changed. The PR reported that no changes to the functioning of the Fertility Clinic are expected as a result of this.
An arrangement with an additional satellite centre has been reported to the HFEA.
Two additional consulting rooms have been obtained.
Much of the flooring within the centre has been replaced since the last inspection.

Additional licence conditions and actions taken by centre since last inspection

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
An organisation chart indicating lines of reporting was provided to the inspection team. The key staff members have extensive, appropriate experience as evidenced by interviews. Adequate space, equipment and staffing are available to cover the treatments offered. The complaints log and incident log were reviewed during the inspection. All complaints had been responded to appropriately. Two were still unresolved. All appropriate incidents had been reported to the HFEA. The centre report that changes have been made to protocols and working practices in response to these incidents. In discussion, the team were informed that all HFEA alerts are stored on a computer drive that is accessible to all staff. Risk assessments are carried out according to the alert. The centre achieved ISO 9001 accreditation in August 2005. The document management is in accordance with ISO 9001 and protocols provided to the inspection team were seen to be version-controlled, with effective from and review dates. The clinical governance log was reviewed by the team. This log contained protocols on clinical audit, clinical governance strategy, audits of cycles performed within the unit, infection control policies for the hospital and audit of patient feedback from the hospital. In documentation provided to the team prior to the inspection the clinic reported that HCA, who own The Lister Hospital, has a clinical governance structure with representatives from the Fertility Clinic. There is a risk manager in place and five risk assessments were reported as having being performed in the last year. Minutes of management, unit, nurses and lab meetings were seen. The centre usually pays invoices within the required timescale.
Areas for improvement
In discussion with the PR, the team was informed that there are no formal contingency arrangements in place should the centre have to unexpectedly cease providing treatment, but The Lister Hospital is part of the HCA group and support would therefore be available from other hospitals within that group.

Executive recommendations for Licence Committee
Formal contingency arrangements should be put in place within 3 months.
Areas not covered on this inspection
All areas covered.

Evaluation
Some improvement 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

Live Birth Rates
The IVF/ICSI and FET success rates for all age groups are higher than the national average. The DI success for all age groups are significantly lower than the national average.
Areas of firm compliance
The counsellor confirmed that she is involved in welfare of the child assessments and some cases are discussed at multidisciplinary meetings with the consent of the patients concerned. Patients are allocated a private room for recovery after egg collection. These were seen and considered to be satisfactory. Centre-specific patient feedback was seen to have been collected, collated and analysed. Patient feedback received by the HFEA showed that the main cause of dissatisfaction was lack of information, however, three patients who were interviewed were all very happy with the service they had received, stating that treatments were explained to them in a lay-friendly manner. The counselling room was seen. This room was pleasantly decorated and comfortably equipped. An audit of counselling services was provided to the inspection team. A total of 660 clients were seen between June 2005 and May 2006. No charge is made for counselling. The counselling notes are kept separately from the main patient notes. Evidence of this was seen during the inspection. The counsellor informed the team that counselling can be offered at short notice if required, and also by telephone or email. The counsellor reported that she attends multi-disciplinary team meetings. The team were informed that a second counsellor is being recruited to provide cover for the existing counsellor. The inspection team observed that there were three waiting areas for patients; two within the centre and one nearby. It was explained that this gives patients choice as to the environment they prefer to wait in. It was reported that there are two dedicated semen production rooms at the centre. They are located adjacent to the laboratory. The production rooms were not seen during the course of the inspection as they were in use. The centre report that photographic identification is used for all patients, and the GP is always contacted if the patient is a donor.

There is an emergency mobile telephone number for patients to call if they have clinical issues.

Areas for improvement
It was noted during the inspection that numerous sets of patients' notes were stored openly within the administration office. It was explained that there was a temporary lack of space within the records room. It was explained that archiving of notes within the records room had been arranged and once completed the notes currently stored within the administration office would be transferred back. It was also noted that along with the other future plans, consideration is being given to moving all of the hospital notes and the IVF units notes into the one main records store. The PR was reminded of the requirement for all notes to be in secure storage. Since the inspection the PR has confirmed that all notes have been removed from the office and are now stored in a secure locked area. Patients undergoing an operating theatre procedure have their details added into the theatre log. It was suggested that the centre should consider having a separate theatre log for the procedures they perform to retain confidentiality. It was noted that this could be held in a secure location within the theatre department for inspection purposes by other bodies such as the Healthcare Commission.

Executive recommendations for Licence Committee
Secure storage should be found for the notes that are currently held in the administration office. The current arrangements constitute a breach of section 11.14 of the Code of Practice. This has been addressed since the inspection.

Areas not covered on this inspection
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
The centre is located within a private hospital which is part of a large group of hospitals. The hospital and unit receptions were well-presented and the staff helpful. The inspection team were required to sign in on arrival at the centre for security reasons. All areas of the unit that were inspected were seen to be adequate. Much of the flooring within the centre has been replaced since the last inspection. Two extra consulting rooms have been obtained since the previous inspection. Centre staff informed the team of the proposed expansion that should occur in the next couple of years. Although the current premises are adequate, the expansion will provide the centre with extra floor space which will improve the environment for both patients and staff. Storage facilities within the laboratory were adequate. All dewars, except one, were seen to be alarmed. The dewar which is not alarmed is unsuitable for alarming according to the manufacturer. There is a low oxygen monitor situated within the cryostore and it was reported that if the unalarmed dewar failed this alarm would be triggered. This alarm was seen to be working as it was activated during the spot check of stored material. The team was informed that there is a protocol for the security men to respond to the dewar alarms. Evidence of servicing and regular maintenance of equipment was seen in the laboratory. The work station cleaning record was also seen. The storage tank topping up record was seen. Topping up is performed weekly. Embryo culture is perfomed in mini-incubators. One of the advantages of this is that there is minimal chance of cross-infection between patients' samples, as the centre treats some viral positive patients. An emergency trolley was seen within one of the treatment rooms on the unit. This room was fitted with a keypad lock. It was noted that the log for the trolley had been signed daily indicating that it had been checked. There is 1 intermediate life support (ILS) trained member of staff working within the unit. It was noted that basic life support (BLS) training is provided to nursing staff but not to the medical staff regularly.
Areas for improvement
The cryostore would benefit from more space being allocated to it. This should be addressed when the centre expands its premises. The storage dewars are not locked. The Laboratory Director explained that due to the amount of activity it is not practical to lock the tanks. They are stored in a locked room with restricted access which is fitted with a motion detector for out of hours use. During the feedback session following the inspection, it was suggested that an alternative location be found for the emergency trolley, as in an emergency access to the trolley could be

restricted. This has been addressed since the inspection. It was recommended to the PR that all medical staff attend an annual update of BLS.
Executive recommendations for Licence Committee
All medical staff should attend an annual update of BLS.
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
23 patient records were reviewed at the inspection. Four had uncompleted or missing welfare of child assessments, one had an unsigned (00)6 form, one had incompatible wishes after death on the (00)7 form and three had both copies of the (00)6 and (00)7 forms in the records. The centre is working to address these issues.
Areas of firm compliance
The centre produces extensive patient information. The information and protocols that were provided to the inspection team was considered to be satisfactory. The information on multiple pregnancies was considered by the inspection team to be particularly informative. Within the main waiting area the following were clearly displayed: - HFEA poster, ISO certificate, counselling notice, HFEA booklets, how to contact staff in an emergency out of normal working hours, patients charter and complaints notice. The centres licence was displayed on the wall in the main corridor of the reception area, which also had displayed another copy of the ISO certificate and the Lister Fertility Clinic Quality Policy. The Healthcare Commission licence was displayed on the 1st floor of the Hospital by the lift access site. Registry at HFEA reported no issues of late reporting of treatment cycles. The main storage location of patient records was seen during the inspection and considered to be adequate, although it was full and some records were being stored in an office.
Areas for improvement
Some errors were identified during the audit of patient records. The centre has improved its record keeping since the last inspection but further improvement is required.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered.

Evaluation
Some improvement 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	7
NMC registered nurses	9
HPC registered scientists	8
Scientists working towards registration	
Support staff (receptionists, record managers, quality and risk managers etc)	13

Summary of laboratory audit
The centre reported that an audit of stored samples has occurred in the last 12 months. This was a paper audit and the contents of the tanks were not checked.
Summary of spot check of stored material
A spot check of stored material was conducted during the course of the inspection. Two embryo samples were checked from the records to their place within the dewars, and one embryo sample was checked from the dewars to the records. No errors were found. Two sperm samples were checked from the records to the dewar location, and one sperm samples was checked from the dewars to the records. All samples were located correctly.
Areas of firm compliance
Witnessing was observed in practice within the laboratory. The scientific inspector observed witnessing of sperm samples being processed, processing of sperm, and eggs arriving into the laboratory. Good communication between staff members was observed. Only one pot containing unprocessed sperm was in the processing area at one time, although processed sperm samples remain in the processing area. The Lab Director reported that there is a budget for CPD and she feels that the funding is adequate. It was reported that all staff who are eligible are registered with the Health Professions Council (HPC). The newest member of the laboratory team stated that she had undertaken a hospital induction programme.

The centre reported that documentary evidence is obtained and kept in personnel files to ensure that all staff are registered with the appropriate professional bodies.
The training log for one of the consultants was seen. This showed attendance at courses, but some mandatory training had not been attended.
The staff interviewed felt they were supported in terms of their CPD.
Extra staff are being recruited now in anticipation of the proposed expansion. The extra staff being recruited are a nurse, an embryologist and an ultrasonographer. A counsellor is also required to support the existing counsellor.
Critical areas within the centre are accessed by swipe cards. This was seen during the inspection.
At the last inspection it was noted that some patients were refusing to undergo screening. The team were informed that all patients are now being screened for HIV, Hepatitis B and C.
The PR was keen to demonstrate the greatly increased number of single embryo transfers being performed, with good pregnancy rates, compared to last year.

Areas for improvement

A physical audit of the storage tanks has not been performed in the last year. Since the inspection it has been reported that a physical audit of all stored embryos will be carried out by the end of the year and stored sperm will be audited at the beginning of 2007.
There is no documented emergency protocol for responding to damaged storage vessels. Since the inspection the PR reports that this has been addressed.
No evidence of lab CPD was available on the day of the inspection. Records of CPD should be kept. Since the inspection the PR has confirmed that records of lab CPD will be kept.
An additional counsellor is required for the centre to cover the periods of time when the existing counsellor cannot be in attendance.
Witnessing at the weekends should be addressed to ensure that all witnessing is conducted contemporaneously with the procedure, and not retrospectively on the Monday morning.
Directions 2004/4 cover the requirement for witnessing and state that 'a contemporaneous record must be made….'. Since the inspection it has been arranged for hospital RMOs to perform witnessing in the laboratory on weekends.
A protocol needs to be developed to cover what happens if a donor withdraws their consent for embryos in storage to be used in treatment. Since the inspection the PR reports that this has been done.
During the course of the inspection it was confirmed that in two cases in the last year three embryos had been transferred into women under the age of 40. One woman was 39 and on her seventh attempt, the other was 38 and undergoing her eighth attempt at treatment.

Executive recommendations for Licence Committee

The storage tanks should be checked to reconcile the centre's records with the genetic material stored.
A written emergency protocol for responding to damaged storage vessels should be developed within 3 months. This has been rectified since the inspection.
A protocol needs to be developed to cover what happens if a donor withdraws their consent for embryos in storage to be used in treatment. This is now in place.
The centre should arrange that witnessing is always performed contemporaneously. This has been addressed since the inspection.

Areas not covered on this inspection
All areas covered.

Evaluation
Some improvement required.

Report compiled by:

Name: Dr Vicki Lamb

Designation: Inspector

Date: 14 August 2006

Appendix A: Centre Staff interviewed

Person Responsible: Hossam Abdalla

Seven other clinic staff

Appendix B: Licence history for previous 3 years

2006

Licence Committee 7 June 2006
Sperm import requests approved.

Licence Committee 22 March 2006
Licence continued and additional condition removed.

2005

Licence Committee 28 February 2005
Representations against licence condition – LC agreed to vary the condition set by the previous licence committee to the following**.**

- That the centre carries out an audit of all of its records of material placed into storage from 1 January to 30 September 2004, noting any inconsistencies in consents. This audit should be carried out within 6 months and the results reported back to the Committee.

2004

Licence Committee 13 December 2004
The Committee noted with serious concern that a high number of discrepancies and omissions were found in patient consent forms during the audit of notes at the inspection. They agreed to make a proposal to vary the centre's licence to impose the following condition:

- That the centre carries out an audit of all of its records over the past 12 months, noting any inconsistencies in consents. This audit should be carried out within 3 months and the results reported back to the Committee.

Licence Committee 13 May 2004
The Committee considered an incident at the centre and was satisfied that it should take no further action.

Licence Committee 22 April 2004
The Committee agreed to vary the licence to include laser and chemical assisted hatching. The Committee agreed that Charlotte Knight should be recognised as an embryo biopsy practitioner.

Licence Committee 5 April 2004
The Committee approved the centre's application to vary their licence concerning PGS protocol

Licence Committee 28 January 2004
The Committee deferred the decision to vary the centre's licence concerning their PGS protocol until the matter had been discussed with SCAG.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number: 0006

Name of PR: Mr Hossam Abdalla

Date of Inspection: 25 July 2006

Date of Response: 31 October 2006

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

- Notes from office are now stored in a secure locked area
- Embryo audit - by end of 2006
- Sperm audit – by end of June 2007
- Hospital RMO's (Resident Medical Officers) to perform witnessing in the lab during weekends. CV's of new RMO's were sent to HFEA.
- Contingency Plan – to be finalised within next 3 months.
- Emergency trolley relocated.
- Emergency Protocol for damaged vessels completed.
- All Medical staff to attend Basic Life Support by next inspection.
- Protocol for donor withdrawing consent completed
- Records of CPD for Laboratory staff now kept on-site

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

Name: Mr Hossam Abdalla

Date: 31/10/2006

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).