Licence Renewal Inspection Report for Treatment and Storage Centres

Cheltenham General Hospital
0151

Date of Inspection: 25.05.06
Date of Licence Committee: 27.07.2006

TRIM: 06/3144

CENTRE DETAILS

Centre Address	Department of Microbiology Cheltenham General Hospital Sandford Road, Cheltenham Gloucestershire GL53 7AN
Telephone Number	01242274067
Type of Inspection	Renewal – Inspection of storage centre
Person Responsible	Alan Lees
Nominal Licensee	Dr. Sean Elyan
Licence Number	L0151-8-a
Inspector(s)	Dr. Neelam Sood
	Mr. Tony Knox
Fee Paid - date	
Licence expiry date	31-10-2006

Index

About the Inspection:
This inspection visit was carried out on 25th May 2006 and lasted for 5 hours. The report covers the pre-inspection analysis, the visit and information received between July 2005 and May 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 makes 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 was first licensed in 1995 for storage of sperm for NHS patients undergoing oncology treatment. The patients are referred to the oncology centre from the counties of Gloucestershire, Herefordshire and Worcester. Approximately fifteen patients cryopreserve semen samples annually.

The centre does not charge patients for storage of sperm and stores samples until the patient's 55th birthday. It has a good history of compliance and the current licence has no additional conditions.

Activities of the Centre

Licensed treatment cycles	No	
Donor Insemination	No	
Unlicensed treatments	N0	
Research	No	
Storage	Yes	

Summary for Licence Committee

The inspection team recommends the renewal of the centre's licence for five years.

Risk Assessment

The current risk assessment for the centre based on the risk matrix is 0%.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvements Required	Significant Improvement required
	X	

Evaluations from the inspection

Topic	No Improvements required	Some Improvements 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 (Marion the following is a new addition not included in the previous draft report as I had forgotten may be the tension of my exams. Apologies.)

Breach	Action required	Time scale
The centre's Licence had Guy Routh as Nominal Licensee but the application form submitted for the inspection showed Sean Elyan as a Nominal Licensee. The PR was not sure whether this change had been approved by the Licence committee.	Approval of Nominal Licensee by Licence Committee.	ASAP

Non-Compliance

Area for improvement	Action required	Time scale
N/A		

Recommendations	Time scale
To develop an ownership consent form for the patients producing samples at home.	1 month
To produce a procedure to respond to an emergencies occurring in the semen production room.	2 weeks
Address and contact details for the HFEA should added to the current complaints procedure in the event that a patient wished to contact HFEA directly rather than go through the Trust, PALS system or the Healthcare Commission as stated in the current policy.	One Month
New consent forms must be forwarded to the patients immediately rather than wait until the annual contact letter is due again.	With immediate effect

Proposed licence variations

N/A

Changes/ improvements since last inspection

Recommendation	Action taken

N/A	

Additional licence conditions and actions taken by centre since last inspection

C	**The Centre had not complied with the requirements set out in Chair's letter CH(04) 03 to split samples of oncology patients between two dewars.**
A	**All samples have now been split in accordance with the Chair's letter.**
C	**To install low nitrogen alarm linked to an auto-dialler.**
A	**All dewars in use are now connected to autodiallers.**

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
The unit was assessed as being well organised. The Scientist and Nurse co-coordinator have been working in the centre since the centre has been established. There are annual meetings held by all staff and minutes of the meetings were seen on inspection. Because the centre is so small many of other communications between the staff are carried out informally or through emails on a daily basis. The staff were aware of the last alerts issued by HFEA. The PR stated that all relevant alerts are issued to the Trust and to the other departments where the alerts are considered relevant within the Hospital, such as the last alert concerning power shortages. The risk assessments and Clinical Governance are handled through the hospital's main Clinical Governance Department. It was noted that a Quality Management system is in the process of development in line with the requirements of the EUTD and a Quality Manger has been appointed recently by the Trust. An ethics committee is available through the main hospital. The PR reported that the services of this committee have never been needed.
Areas for improvement
None
Executive recommendations for Licence Committee
None

Areas not covered on this inspection

Payment of treatment fees (N/A)

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
NA (Storage for Oncology Patients sperm only)
Areas of firm compliance
The patients have access to the hospital's patient and advice liaison service (PALS) to feedback comments or complaints about their treatment or the services offered. The advertisement of this service was observed throughout the hospital. The staff confirmed that systems are in practice. The nurse reported that he is in the process of devising questionnaires for use for oncology patients only. The patient's records are held within the Pathology Building within a two drawer filing cabinet which was seen to be locked. Access to the pathology laboratory is restricted by a swipe card system. The Counsellor is a qualified radiographer, has a diploma in counselling and currently at the dissertation stage of completing her MSc in counselling services. She has been counselling for seven years at the oncology unit and for three years working with patients using the storage facility. She stated that she is included in the discussions developments of the service provision offered to oncology patients.
Areas for improvement
During interview the policy for protection of children under 18yrs of age was discussed and it was found that the staff had not covered this aspect of services. The PR informed the inspection team so far they never had a child under 18yrs of age. It was recommended to include the hospital's child protection policy in the guidelines in case a patient under the age is referred to the centre.

It was suggested that the address and contact details for the HFEA should be added to the current complaints procedure in the event that a patient wished to contact the HFEA directly rather that go through the Trust, PALS system or the Healthcare Commission as stated in the current policy. This was agreed by the PR.

Executive recommendations for Licence Committee

A Child Protection Policy to be included in the guidelines.

To add HFEA details in the current complaints procedure as good practice.

Areas not covered on this inspection

Donor selection

Egg sharing and surrogacy

Evaluation

Some improvements required

3. Premises and Equipment

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

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
The centre is a part of the Oncology Unit and comprises Pathology Laboratory, and a secure cryostore room at the back of Pathology building. The centre has a large waiting area and facilities for disabled patients. There are four rooms on the second floor of the building which have been made available to the patients for producing their samples. The rooms were found fit for the purpose. They have a bed, comfortable chairs and en suite bathroom. All have emergency call bells. The semen samples are processed and cryopreserved in the pathology laboratory. The laboratory is situated on the first floor of the Pathology/Microbiology building which is controlled by swipe cards. The laboratory does not have Laminar flow hood for processing of samples. The PR reported the laminar flow hood has been requested, but no agreement has been given by the Trust currently because of the financial status. The cryostore is located at the back of the Pathology building in a secure area. There are five dewars within the storage room in addition to three storage tanks of liquid nitrogen. Two of these tanks are directly attached to the vapour phase tanks which automatically fill these vessels as and when required. The other dewars are manually fitted from the other storage tank. All dewars are alarmed and linked to an autodialler, and a low oxygen alarm is installed which is connected to an audible klaxon alarm just outside the storage area. The cryostore facilities were found to be adequate by the inspection team. The maintenance records of all the equipment were found up-to-date. A counselling room is provided on the ground floor of the Oncology Department within the Radiotherapy Department. This appeared to be comfortable and fit for the purpose. Plans for the new premises were presented to the inspectors regarding the possible location of the storage facility at the Gloucester Hospital. The PR explained that these plans are preliminary ideas which have been put forward to the Trust. However, this may not happen due to the current financial status of the Trust. The PR is aware that prior to moving to the new premises, the HFEA would need to be informed and involved with checking the new premises.
Areas for improvement
None

Executive recommendations for Licence Committee
None
Areas not covered on this inspection
N/A

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:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
Ten sets of notes were reviewed during inspection. • 2 sets of notes did not have disclosure consents from the patient and their partner. • One set of notes showed that the patient had been in communication with the centre to inform them that he no longer had a partner and wished to change his consent. No further action had been taken. • One set of notes did not have disclosure consent. The centre has recently revised the consent forms and these should be forwarded to the patients immediately rather than waiting until the annual contact letter was due. This is in the event that the patient dies and the incorrect consents remain on the file. This was agreed by the PR.
Areas of firm compliance
All protocols and consent forms were provided with the renewal application and were found to be appropriate. The nurse coordinator informed the inspection team that the oncology unit provides patients with complete information regarding semen storage for those undergoing radiotherapy or chemotherapy. The inspection team found the information leaflets thorough with counselling services in detail on the notice board near the front desk. Patients are given information about counselling services treatment and implications The inspection team noted the thorough and complete patient notes that contained all relevant consent forms and witnessing sheets. Semen samples are not to be discarded in the event at that patients could not be contacted. It was noted during the course of inspection that annual letters will continue to be sent. Checks are also made on all available databases with in the hospital to check whether a patient has died and for the last contactable addresses. The discarding policy also makes reference to having this process witnessed.
Areas for improvement

None

Executive recommendations for Licence Committee

None

Areas not covered on this inspection

N/A

Evaluation

No 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	Dr. Alan Lees
NMC registered nurses	Mr. Ian Ingledew (Nurse Co-ordinator)
HPC registered scientists	Mr. Stephen Parsons (senior MLSO) two other biomedical scientists
Scientists working towards registration	NA
Support staff (receptionists, record managers, quality and risk managers etc)	Niki Adkins

Summary of laboratory audit
A full audit of all the dewars, patient records and consent form is carried out yearly as evidenced by log books.
Summary of spot check of stored material
Two semen samples from books to dewars and two from dewars to books were checked, no discrepancies were found. No problems were identified.
Areas of firm compliance
Patients are first seen by an oncologist and then are referred to the nurse co-coordinator. The nurse assists patients in the completion of HFEA forms as well as the centre's own consent forms. Nurse takes the semen samples from the oncology unit to the pathology laboratory for processing. All samples are received by the scientist. All staff at the centre receive funding for continuing professional development. They are registered with their appropriate professional bodies and their registration was found satisfactory. The nurse coordinator is undertaking a prescribing course and has attended a fertility oncology symposium last year. The scientist attends conferences relating to infertility. The courses attended are certified and evidence was seen on site in their folders. The staffing structure in the unit was found stable and all key members of the staff have been in post for a number of years.

The alarmed dewars were found connected to an autodial facility. In the event that the auto dialler is triggered, the on call scientist will attend the site to check the dewars, rectify the problems and re-set the system. Protocols were found in place for these emergency procedures.

Areas for improvement
It was noted by inspection team that some patients produce samples at home. No process was in place at the time of inspection for ensuring the ownership of the semen sample on arrival at the hospital. A form had been previously created by the scientist but not implemented. • It was suggested that this should be adopted as soon as possible and this was agreed.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
PGD/ PGS

Evaluation
Some improvements required

Report compiled by:

Name…Dr Neelam Sood …….

Designation…Inspector……..

Date……05.06.2006……

Appendix A: Centre Staff interviewed

The inspection team interviewed the PR Dr. Alan Lees and three other members of the staff.

Appendix B: Licence history for previous 3 years

Licensing History

Centre 0151 Cheltenham General Hospital

Person Responsible: Dr Alan Lees

2005
Inspection 22 July 2004

Licence Committee 28 April 2005
The licence committee agreed to recognise Dr Alan Lees as the person responsible

2004
Inspection 14th July 2004

Licence Committee 13 October 2004
The committee added no additional conditions and one recommendation

2003
Inspection 9th May 2003

Licence Committee 11th July 2003
The committee added no additional conditions and two recommendations.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre
Number…0151……

Name of PR…Dr Alan Lees

Date of Inspection 25/5/06

Date of Response 28/6/06

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

Ownership consent form written and for implementation within next month
Complaints procedure to be added to checklist, HFEA contact details to be included within patient information leaflet
Outstanding consent forms will be sent to patients as soon as possible

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

Signed…. 

Name…Dr Alan Lees

Date……28/6/06

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).

New Nominal Licensee is Dr Sean Elyan, page 7box marked breach
Please change oncology nurse to biomedical scientist, page 17 staff section

Include Niki Adkins as support staff, p 17 staff section

Please could you clarify statement on page 15, areas of firm compliance. “Semen samples are not to be discarded in the event that patients could not be contacted.” We were led to believe verbally at the inspection that such samples could be discarded after we have failed to contact the patient despite best efforts.

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