Licence Renewal Inspection Report for Treatment and Storage Centres

Lanarkshire Acute Hospital NHS Trust
0098

Date of Inspection: 20th December 2006
Date of Licence Committee: 16th April 2007

TRIM: 06/3144

CENTRE DETAILS

Centre Address	Infertility Department Monklands Hospital Monkscourt avenue Airdrie Lanarkshire ML6 0JS
Telephone Number	01236 748748
Type of Inspection	Renewal
Person Responsible	Mr. Ian Smith
Nominal Licensee	John Browning
Licence Number	L0098/12/a
Inspector(s)	Dr. Neelam Sood
	Mr. Wil Lenton
Fee Paid - date	08/01/2007
Licence expiry date	30/06/2007

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About the Inspection:
This inspection visit was carried out on 20th December and lasted for 6 hours. The report covers the pre-inspection analysis, the visit and information received between October 2005 and November 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 Lanarkshire NHS Trust Infertility Department is a small centre that provides NHS funded donor insemination treatments to patients from the local area. The centre has been licensed since 1992. The centre has a low volume of activity and provided only 54 licensed treatments in the last year.

The centre is part of the Lanarkshire Acute Hospitals NHS Trust and is based in the Monklands Hospital in Airdrie. The premise is an adequate, clean and seems to be having privacy for patients.

Sufficient numbers of appropriately qualified and competent staff are employed at the centre. The person responsible is appropriately qualified and was found to be familiar with nursing, laboratory, administrative and managerial aspects of the service. He is well supported by staff and an established management team.

Activities of the Centre

Licensed treatment cycles	54
Donor Insemination	
Unlicensed treatments	IUI
Research	
Storage	Yes

Summary for Licence Committee

The centre had two breaches during previous inspection:-

- Not all cryostorage vessels fitted with low nitrogen level alarms and /or auto-dial facilities.

- 50% of the oncology patients cryopreserved semen samples had not been split into separate storage vessels.

The above two breaches have been rectified.

The inspection team recommend the renewal of the centres' licence for five years.

Risk Assessment

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
None		

Non-Compliance

Area for improvement	Action required	Time scale
None		

Recommendations	Time scale
To maintain a log book of departmental meetings	As soon as possible
To publish the annual successful live birth rates in the patient information leaflets	As soon as possible
Installation of outstanding cryostorage vessel low nitrogen alarms	As soon as possible
Purchase/installation of Class II laminar-flow cabinet for the processing of gametes	As soon as possible
Revision of laboratory witnessing procedure	As soon as possible

Proposed licence variations

None

Changes/ improvements since last inspection

The PR informed the inspection team that the NHS Trust has funded the unit to purchase an extra cryostorage tank, which would facilitate the splitting of stored semen samples together with the fitting of low nitrogen level monitors to all vessels.

The copy of purchase orders has been submitted to the inspection team. The PR is expecting the equipment to be installed by early February 2007.

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
The Person Responsible and a number of staff members commented that the organisational structure and operational procedures of the centre are appropriate for the licensed activities provided. The organisational structure is well documented and displayed in the waiting area. It includes responsibilities, accountability and reporting relationships. The PR is appropriately qualified as documented in his CV and demonstrated at interview to meet the specified PR responsibilities. The PR is familiar with Chair's letters and stated that HFEA alerts are circulated to all staff via email or in meetings. Members of the team are in daily contact with each other and issues in relation to the provision of DI treatments are addressed as required. A memo system seen on data base ensured that all staff members are well informed of any developments or issues and meetings as required. The staff stated that departmental meetings occur almost everyday. The staff finds this arrangement more suited to the relatively small size and nature of the infertility unit. The counsellor and other staff members confirmed that updates on changes affecting all staff at the centre are emailed and circulated to all members of staff. The adverse incident log book was examined by the inspection team. There were no incidents reported to the HFEA last year. The Inspection team was informed by the PR that there are contingency arrangements in place in the event of an emergency. In discussion the PR explained that there is a risk management and a clinical governance team in the main hospital for every new procedure. Evidence of risk assessments being carried out at the unit was made available for the inspection team. Information from HFEA finance department showed that there were no issues with the centre over the payment of treatment fees.
Areas for improvement
The minutes of departmental meetings to be recorded and made available to staff.

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

Evaluation
One 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
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates
The DI success rates do not differ significantly from the national average.
Areas of firm compliance
During a tour of the premises it was seen that patient records are stored in a locked room, in locked cabinets. The complaint log book was reviewed on the day of inspection and no complaints were found. Welfare of the Child issues are discussed during the meetings when appropriate. Responses to the HFEA patient questionnaire revealed that patients at this centre are more satisfied than average with all aspects of the centre and their treatment. The centre has separate rooms for patients to have their privacy during ultrasound and other clinical procedures. An audit of counselling services was provided to the inspection team. The counsellor stated that patients can be seen the next day. The counselling facilities were found to be fit for purpose and an arrangement is in place for patients to contact the counsellor. The patients' counselling notes are kept by the counsellor and no one else has access to them. The counsellor does not attend departmental meetings but PR informs her through email or by telephone. The counsellor commented that she very much feels part of the team and is updated on changes within the centre.
Areas for improvement
The feedback from patients was obvious in the form of thank you and greeting cards. The inspection team advised the staff to have their own feedback questionnaires and the success rates should be written in the information leaflets.

Executive recommendations for Licence Committee
Areas not covered on this inspection
All areas covered.

Evaluation
One 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 premises for the licensed treatments were found to be private, quiet, clean, comfortable and patient friendly during the tour of the premises. In the event of power failure, there is an access to the hospital's back up generator. The centre has a dedicated storage room inside the andrology laboratory. The scientific inspector found the cryopreserved samples are securely stored within the laboratory and access to tanks is via both a mortice lock and keypad. The evidence of servicing, maintenance contracts for major equipments were seen in the course of the inspection. A log book for daily measurement/recording of heated-block temperatures, liquid nitrogen levels in cryostorage vessels was seen by an inspector and found to be satisfactory. Arrangements were seen to be in place in the event of the oxygen monitor alarm system being activated. The report of risk assessment for large scale liquid nitrogen spill in liaison with the local fire brigade was found to be satisfactory.
Areas for improvement
Two dewars did not have a low nitrogen level alarm and were not connected to autodial facilities. The PR confirmed that funds have been issued for the purchase of a new dewar and alarms. Purchase orders have been submitted to the HFEA. The PR is expecting to have new equipment by the beginning of February 2007. In order to comply with the forthcoming EUTD air-quality requirements, the PR was advised to install a class II laminar-flow cabinet for the processing of gametes. The PR confirmed that this was one of the items identified as a requirement by the NHS Trust and was in the project-plan.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

Evaluation
Some improvements required.

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
Five patients' records were reviewed at the time of inspection. These were found to be in good order with evidence of 'Welfare of Child' assessment and HFEA consents to use and storage.
Areas of firm compliance
The HFEA licence was seen displayed in the reception area. Registry at HFEA reported no issues of late reporting. The fees always have been paid on time. A folder containing version controlled laboratory protocols was seen in the laboratory, and document control system was found to be in place. There are written standard operating procedures for filling vessels and protocols describe how the cryostore is secured which were checked at the inspection. The information for patients and protocols that were provided to the inspection team was considered to be adequate. All information on outcomes of treatment is recorded on the centre's database and a member of the nursing team monitors outcomes on a monthly basis. Patients' notes were seen on the day of the inspection with evidence of witnessing within them.
Areas for improvement
The witnessing procedure within the laboratory did not include any double witnessing when the sample is removed from the incubator and placed into the first labelled patient tube.
Executive recommendations for Licence Committee
Witnessing procedure to be modified.
Areas not covered on this inspection
All areas covered.

Evaluation
One 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 (PR to confirm and please fill it up)

GMC registered doctors	one
NMC registered nurses	One Part time/ one full time
HPC registered scientists	Six
Scientists working towards registration	None
Support staff (receptionists, record managers, quality and risk managers etc)	Three
Counsellor	one

Summary of laboratory audit
A rolling audit of stored samples is performed during the course of each year and a summary of the 2005 audit was provided prior to the inspection. No discrepancies were reported.
Summary of spot check of stored material
An audit of cryopreserved samples stored on site was found to be in place, both from the cryostorage vessel to the notes and vice versa.
Areas of firm compliance
The PR and other scientists are registered with the Health Professions Council (HPC). The NL is registered with GMC. The two members of the nursing team are registered with Nursing and Midwifery Council (NMC). The infertility unit is recognised by the BFS and RCOG for the special skills and the counsellor is a member of BICA. The PR confirmed that doctors, nurses, andrologist have their respective registrations and the respective documents were seen on inspection. The personal development plans of all the members of the staff showed evidence of training and CPD in the last year. The counsellor showed the plan for the next year's training. All staff interviewed stated that they had opportunities for CPD, in the form of both internal and external activities; the unit has funds for the staff which was seen on inspection. Evidence of their professional achievements was found updated. All patients are screened for HIV, Hepatitis B and C prior to treatment. Evidence of

communication between the clinical and laboratory staff was observed on the day of the inspection. All staff are recruited via the Human Recourses department at Monklands Hospital. Evidence of their professional achievements was found updated. The PR is responsible for staff recruitment
Areas for improvement
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
PGD/PGS – not provided at this centre.

Evaluation
No improvements required.

Report compiled by:

Name: Dr. Neelam Sood

Designation: Inspector

Date 20/12/2006

Appendix A: Centre Staff interviewed

Person Responsible and three other members of the team.

Appendix B: Licence history for previous 3 years

Centre: **Lanarkshire Acute Hospitals NHS Trust**

Centre no: **0098**

Licensed for: **DI and the Storage of Patient and Donor Sperm.**

Person Responsible: **Mr Ian Smith**

First licensed: ***1992***

2006

Interim Inspection 27th April 2006

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

2004

Interim inspection 26 October 2004

Licence Committee 26 February 2004
The committee agreed to renew the licence for 3 years with no additional conditions and five recommendations.

2003

Renewal Inspection visit on 9th December

Licence Committee 23rd February
The Committee agreed to continue the Centre's licence which expires 30th June, 2004. The Committee made two additional recommendations.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number…0098

Name of PR……Mr. Ian Smith

Date of Inspection……20th December 2006

Date of Response……5th March

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

AREAS FOR IMPROVEMENT

1. ORGANISATION

The minutes of the departmental meetings to be recorded and made available to staff

RESOLUTION

The unit has decided to trial the expansion of the laboratory team meeting, which are already documented to include all other staff.

2. QUALITY OF SERVICE

Creation of a feedback questionnaire and advising success rates on information sheets.

RESOLUTION

One of the laboratory staff has been tasked with the creation of a suitable questionnaire relevant to our unit. This is in progress.

The success rates are being added to the information sheets by the nursing staff.

3. PREMISES AND EQUIPEMENT

- Two dewars were not connected to low level alarms and were not connected to autodiallers.

- Compliance with forthcoming EUTD air quality regulations.

RESOLUTION

We have now finally received the new cryogenic bank and the upgrades of old banks with alarms and autodiallers has been completed in the past few days. There had been a problem of availability of an engineer although we had been in receipt of all the items.

All banks are now fully compliant with low level alarms and autodial facility

The EUTD air quality requirements are still in progress. This has involved discussions with the estates department by the companies involved .There are still some issues and costing detail outstanding.

4. INFORMATION

The witnessing procedure within the laboratory did not include any double witnessing when the sample is removed from the first labelled patient tube.

At present we have one biomedical scientist allocated for the Andrology lab on a daily basis from the pathology department. At present we are still investigating ways to achieve compliance as this is obviously a staffing resource problem.

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

TRIM: 06/3144

Licence Committee Meeting

16 April 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

Lanarkshire Acute Hospital NHS Trust (0098)
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 (33 pages)
- no papers were tabled.

1. The papers for this item were presented by Neelam Sood, HFEA Inspector. Dr Sood informed the Committee that this is a small centre offering only donor insemination treatment to NHS funded local patients. Fifty-four such treatments were carried out last year. The centre has a low risk score of 5%. Since the centre was previously inspected, all samples cryopreserved on behalf of oncology patients have been split into separate storage vessels and some dewars are now alarmed with auto-dial equipment. However, two dewars remained un-alarmed at the time of the inspection, although the PR has since reported that this has now been rectified.

2. The Committee noted that the missing dewar alarms noted at the inspection constitute a breach of Chair's letter CH(04)03. The Committee further noted that the witnessing procedure did not include double witnessing at the step where the

sample is removed from the incubator (as reported at page 14 of the report). The Committee noted that this is a breach of Directions on witnessing: D2004/4.

3. The Committee noted that all of the recommendations by the inspection team have been now implemented by the Person Responsible (PR), as shown by the PR's response to the report at appendix C.

4. The Committee decided to renew the centre's licence for a period of five years, with no additional conditions.

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