Licence Renewal Inspection Report for Treatment and Storage Centres

Leicester Fertility Centre
0068

Date of Inspection: 22nd March 2007
Date of Licence Committee: 7th June 2007

TRIM: 06/3144

CENTRE DETAILS

Centre Address	Leicester Fertility Centre Women's Hospital Leicester Royal Infirmary Leicester LE1 5WW
Telephone Number	0116-258-5922
Type of Inspection	Renewal
Person Responsible	Mrs Janine Elson
Nominal Licensee	Mr Alan Davidson
Licence Number	L0068-12-c
Inspector(s)	Tony Knox Sarah Hopper Tahir Hussain
Fee Paid - date	Not due at the time of writing this report.
Licence expiry date	30th September 2007

Index

Page

Centre details 2

Index 3

About the Inspection 4

Brief Description, Activities Summary & Risk Assessment 5

Evaluation & Judgement 6

Breaches, Non-compliance Records, Proposed Licence 7

Changes/Improvements, Additional Licence Committees 8

Organisation 10

Quality of Service 12

Premises and Equipment 15

Information 17

Laboratory and Clinical Practice 19

Appendix A 21

Appendix B 22

Appendix C 23

About the Inspection:
This inspection visit was carried out on 22nd March 2007 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between April 2006 and March 2007.

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

This small to medium sized centre was first licensed in 1992 and provides both private and NHS funded treatments to patients primarily from the local area. Since the last inspection, an application has been received to change PR and to vary the centres licence to include egg freezing. Both were approved by Licence Committee with no additional conditions. The centre has a good history of Regulatory compliance.

In the Leicester's Pathway Project, provision has been made to move the fertility unit to a new location within the Leicester General Hospital. This provision allows for a purpose built Assisted Conception Unit which would be two to three times the size of the current centre. Due to Trust funding difficulties, this plan has been placed on hold however, but the Trust have sanctioned the provision of some additional space linking onto the existing centre which is currently being developed. Plans for these additional rooms have been drafted and will provide additional space for consultation, scanning and an additional laboratory for sperm preparation. A tour of the additional space was provided by centre staff at the inspection.

Private patients are still primarily consulted at the BUPA Hospital in Leicester prior to being referred onto the Leicester Fertility Unit for treatment. The Person Responsible (PR) envisages that in the future, some of the private patients will also be consulted at the Leicester Fertility Unit.

The centre is open from Monday to Friday with occasional weekend work for which a rota is provided for staff to work to.

Activities of the Centre

Licensed treatment cycles	IVF ICSI Egg Sharing Egg Donor	171 114 2 5
Donor Insemination		42
Unlicensed treatments	IUI GIFT Ovulation Induction Tubal Surgery	
Research		None
Storage		Yes

Summary for Licence Committee

The centre has seen a change in PR since the last inspection who is focusing on modernizing the service provided at the centre. There is a good history at the centre of Regulatory compliance. The Executive would recommend the renewal of the centres licence for a period of five years, with an additional inspection prior to the centre moving into the expanded facilities.

Risk Assessment

Prior to the inspection, the centre had been allocated a risk score of 16%. Following the inspection, the risk score was re-calculated and shows a current risk rating of 21%**.** This increase has primarily been the result of the change in PR since the last inspection.

The centre follows the Trust Clinical Governance and Risk policies and procedures. Risk assessments have been carried out on gamete and embryo handling and liquid nitrogen procedures and handling since the last inspection. A Quality Manager is in post and the centre is ISO accredited.

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
It was observed during the tour of the premises that samples were removed from a storage dewar without being witnessed.	Witnessing must be performed in accordance with the Witnessing Directions D2004/4.	Immediate
During the laboratory audit, embryos for one patient were found remaining in storage where consent had expired and was therefore no longer valid. Centre staff informed the inspectorate that attempts to contact the patient had been made on numerous occasions but the patient had refused to respond. The patient was again contacted (successfully) during the course of the inspection and resolution to this breach was rectified.	Stored samples must only remain in storage where there is valid storage consent.	Immediate

Non-Compliance

Area for improvement	Action required	Time scale
Emergency trolley located within the operating theatre provided no evidence that the equipment had been regularly checked.	Emergency equipment to be regularly checked and records maintained to provide evidence of those checks.	Immediate
Cryostore was seen to be open when no staff member was working within the area.	Means of ensuring the cryostore door closes when not in use must be found.	Immediate
There is currently no system in place for the verification of patients attending the unit for treatment.	Policy and procedure to be implemented to verify the identity of patients attending for treatment.	Three months
No formal documented contingency plan was in place in the event of a disaster scenario.	PR to formalise a contingency plan for disaster situations.	Six months

Recommendations	Time scale
Laboratory audit provided pre-inspection provided detail of anomalies found during the audit but not the corrective actions that were taken to correct them. This information should also be provided on the audit report.	Immediate
Some patient information provided for patients being treated using donated gametes also contained information pre-dating the SEED Regulations. The PR noted that all patient information was currently being reviewed and updated and that this information would be amended to remove any possible confusion.	Six months

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
Cryostore door should be kept closed unless staff were working within the area. Appropriate health and safety warning signs should be obtained and fixed to the door to indicate the presence of liquid nitrogen within the room.	Staff were reminded that this door should remain closed when not in use however, during the course of the inspection, it was noted that the door was not properly closed on a couple of occasions when staff were not present. Appropriate safety signs were in place.
Egg donor information needed to be amended to indicate that it was not compulsory for the egg donor to know if a live birth had resulted from her donation.	Information had been amended.
Counselling protocol for oncology patients under the age of 16 to be amended to indicate that 'Parents cannot consent on behalf of their children to any licensed procedures, including the storage of mature gametes'.	Protocol amended.
Extract ventilation within the cryostore was positioned too high on the external wall to provide any real benefit and additional ventilation should be provided.	A second ventilation unit had been installed at an appropriate height.

Additional licence conditions and actions taken by centre since last inspection

C	None
A	**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:

- 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 centre was seen by the inspectorate to be well organised. Staff interviewed were supportive of the new PR and of the changes being made for the improvements of the services provided. All staff commented on the high level of support they received from each other and management and on the cohesiveness of the team overall. Staff were seen to employed in sufficient numbers with appropriate qualifications to discharge their duties. Risk management and clinical governance strategies are employed following the Trust policies and procedures and in accordance with their ISO certification/accreditation requirements. The centres next ISO assessment has been scheduled for 22/5/2007. Provision of a business plan for the modification of the centre premises was provided showing expected timelines for completion. There is a robust incident reporting procedure in place which conforms to the requirements of the HFEA and which is known to all staff. No incidents have been reported since the last inspection.
Areas for improvement
The HFEA Finance Department noted that there was an invoice in dispute with the centre which was being examined at the time of the inspection. It has since been reported that some treatment cycles have been registered more than once during the implementation of the HFEA EDI system and is now in the process of being resolved.
Executive recommendations for Licence Committee
None

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

Live Birth Rates

Data obtained from the HFEA shows that for the period 31/3/02 to 1/4/05, IVF/ICSI and FET success rates in the age group below 35 were below the national average. Donor Insemination rates for this same age group show to be well above the national average. The same data shows an OHSS rate of 3.74%. This was discussed with the PR. It was explained that even suspected cases of OHSS are reported regardless of whether the patient was experiencing any of the symptoms. She stated that this policy was currently being reviewed.

Success rates provided by the centre for the year ending 31/12/05 show the following success rates obtained: -

	Below 38	All Ages
IVF/ ICSI (Treatment cycles started)	30.2%	29.8%
IVF (Per embryo transfer_	40.0%	43.1%
ICSI (per embryo transfer)	43.9%	40.5%
FET (per embryo transfer)	32.6%	33.3%
DI	16.3%	13.6%

Areas of firm compliance

Evidence was found in patient notes to indicate that a suitable Welfare of the Child assessment had been conducted with the exception of one set of notes as seen in section 4 of this report..

There is confidentiality policy in place which is communicated to all staff during either induction or ongoing training, and all notes are stored securely within the reception area of the centre, which is staffed at all times during opening hours. The unit itself is fully alarmed and secured by digital keypad locks and motion detectors.

Patients are provided with both verbal and written information regarding the treatment options available to them. All staff interviewed noted the importance placed upon the requirement of providing dignity and privacy to patients at all times.

There is a robust complaints policy in place which conforms to the requirements of both the HFEA and the Trust. Since the last inspection, 14 complaints had been received and investigated, of which 11 had been resolved and three were ongoing. The PR noted that the majority of complaints received related to funding which was made available to them for treatment through their PCTs. As a consequence to this, the staff have produced a further information booklet for patients detailing the steps required to appeal for funding. All complaints are discussed at the monthly management meeting. These meetings are minuted and evidence was provided during the inspection.

The centre utilises a suggestion box within the waiting room to obtain comments from patients using the service. Responses are analysed regularly and a patient satisfaction survey is produced (evidenced during the inspection), and communicated to all staff. From the last survey, an action plan was produced and provided for inspection, detailing areas of patient concern and actions to be taken by centre staff to improve the service to the patients.

Counselling facilities remain unchanged since the last inspection and remain fit for purpose. Counselling is well promoted within the unit and provided free of charge. It is approximated that there is currently a 20% take-up rate for counselling. The counsellor is also the Head of Nursing. During interview, the inspector was satisfied that despite holding this dual role within the unit, counselling provided remained independent of any treatment provided to the patients. As a result of the increase in numbers of counselling sessions required, a second counsellor has been appointed for the centre, who is expected to provide an additional 26 hours cover for the unit and is due to commence her post in April.

Donor selection criteria were considered fit for purpose and detailed all relevant screening requirements.

The centre operates an egg sharing scheme. It was noted that the protocols and patient information provided pre-inspection were considered fit for purpose.

The Head of Nursing/Counsellor sees all patients under the age of 18 years to explain what is required of them whilst at the centre and to go through their consents with them.

Areas for improvement
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered.

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:

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

Areas of firm compliance
There have been no changes to the premises since the last inspection and they remain fit for purpose. Plans to extend the centre have been provided to the HFEA and work is to commence in June 2007 to provide the centre with additional consulting and scanning space along with an additional laboratory, next to the main treatment room, where sperm preparation will be performed. This will provide additional space within the embryology laboratory. Provision for the extension of the security system has also been considered. All storage dewars are alarmed and there is a low oxygen alarm in place. The door to the cryostore now displays safety notices indicating that liquid nitrogen is stored within the room. Additional extract ventilation has been fitted within the room at an appropriate height to provide additional protection within the area. There is a backup generator in place to provide electricity to the unit in the event of a power failure. This covers all critical equipment. The PR stated that this equipment is tested monthly (at a weekend when service to the centre will not be disrupted) by the main hospital maintenance department. There is a documented system for monitoring equipment and performance which details whose responsibility it is to arrange for the servicing. This was evidenced during the inspection. It was also evidenced that portable appliance testing (PAT) had been performed since the last inspection. There is a robust policy in place for reporting incidents which conforms to the requirements of both the HFEA and the Trust. No incidents have been reported since the last inspection.
Areas for improvement
On two occasions during the course of the inspection, it was noted that the door to the cryostore was slightly open although no staff were working within the area at the time. This was raised with the PR and senior embryologist as being a point of concern from the last inspection. The inspectors were assured that this matter had been raised with all staff following the last inspection but would be re-emphasised to ensure all staff leaving the area ensure that the door is firmly closed upon leaving. The emergency trolley located within the main treatment room provided no evidence of regular checks being performed on the content or equipment held on it. Whilst staff provided assurance that in the case of an emergency, another emergency trolley would be brought to

the unit from the Gynaecology unit, staff were requested to commence regular checks on their trolley and to provide recorded evidence that the checks had been performed. This was agreed by the PR.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered.

Evaluation
Some improvement required.

4. Information

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

Summary of findings from inspection:

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

Outcome of audit of records
The last HFEA operational audit was performed in 2004 and was reported on during the last inspection. Nineteen sets of patient notes were reviewed for treatments including egg donation, egg recipients, IVF, ICSI, DI and FET. One error was noted where a "Welfare of the Child" consent had not been obtained for the partner of a patient undergoing treatment. A form had been forwarded to the GP containing both patient names however, the form was returned to state that the male patient was not registered at the GP practice. This had been overlooked.
Areas of firm compliance
All patient and donor information is currently in the process of being reviewed along with all protocols for the centre. This is in accordance with the requirements of their Quality Management System, the impending implementation of the EU Tissue and Cells Directive changes and ISO standard requirements. All relevant consent forms were found in the notes. The notes were found to be organised well and details required for the purposes of the audit were easily found. All protocols provided pre-inspection, plus additional information requested during the inspection were considered suitable and fit for purpose by the inspectorate. The HFEA Registry Department reported regular updates from the centre.
Areas for improvement
Whilst all of the information provided pre-inspection contained current information, some information provided for patients having treatment using donor gametes also included information relating to requirements before the SEED Regulations were passed. It was recommended that to prevent possible confusion, pre-SEED information should be removed to show the current status of the Regulations only.
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	5
NMC registered nurses	5
HPC registered scientists	3 + 1 Andrologist
Scientists working towards registration	1
Support staff (receptionists, record managers, quality and risk managers etc)	8 staff – 1 x senior administrator, 1 x administrative officer, 2 x clerical officers, 3 x team support workers and 1 x unit domestic.

Summary of laboratory audit
A report was provided pre-inspection showing an audit conducted between 25/4/06 and 5/5/06 on 17 liquid nitrogen dewars. Nine errors were recorded on the audit and had been resolved with the exception of one case (listed under Breaches in this report) where a sample remained in storage past its' consented time period.
Summary of spot check of stored material
Two patients' embryos were traced from records to dewars and two patients' embryos were traced from dewars to records. No discrepancies were found. Evidence of splitting patient embryos between dewars was also observed for oncology patients. Two patients' sperm samples were tracked from dewars to records and two patients' sperm samples were tracked from records to dewars. No discrepancies were found.
Areas of firm compliance
Assessment of patients and donors is completed in accordance with written protocols taking into account information obtained from patient history, eligibility of funding requirements, referral letter and discussions at consultation. Protocols and procedures are in place to ensure the safe handling of samples within the laboratory which were considered fit for purpose by the inspectorate. With the exception of the isolated incident (summarised under Breaches), all witnessing steps were evidenced as

being performed according to Directions D2004/4. All steps were evidenced in the patient notes as being completed.

The centre does have a policy for the treatment of viral positive patients. Where this is performed, the treatment only is provided but patients are advised that freezing of spare embryos will not be performed at the centre. Patients requiring this service are referred to a licensed treatment centre in Coventry.

Screening of samples is performed as per their screening protocols. It was noted by the PR that syphilis screening is also conducted routinely on patients. This action has been considered necessary due to an increased number of patients presenting with this condition at the Leicester General Hospital genito-urinary medicine clinics.

It was evidenced that there were sufficient number of suitably qualified members of staff working within the centre. Training folders were maintained by each member of staff which contained evidence of CPD training attended, mandatory training completed and, where required, evidence that assessment of competence had been completed and signed off by a suitably qualified member of staff.

All staff interviewed stated that they were well supported in their CPD requirements despite limited funds being available through the Trust.

Three, three embryo transfers were conducted since the last inspection all of which were conducted in women over the age of 40 with reasons documented.

Areas for improvement
As noted in the 'Breaches' section of this report, an isolated Breach in witnessing samples being removed from storage was observed during the course of the inspection. All staff must be reminded of witnessing requirements and the stages where witnessing must be performed. This was agreed with the PR and senior embryologist.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
PGD/PGS are not performed at this centre.

Evaluation
Some improvement required.

Report compiled by:

Name Tony Knox

Designation Inspector

Date 4th April 2007

Appendix A: Centre Staff interviewed

Janine Elson – Person Responsible
Six other members of staff.

Appendix B: Licence history for previous 3 years

2007

Licence Committee 21 March 2007

Application to vary the centres licence presented to include egg freezing. This was approved.

2006

Licence Committee 18 December 2006

Application taken to Licence Committee to change the PR. This was granted.

2005

Licence Committee 31 October 2005

Condition removed from Centre's licence.

Licence Committee 9 June 2005

Licence continued with one condition and no recommendations.

2004

Licence Committee 23 June 2004

Licence continued with one additional condition

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number 0068

Name of PR Miss Janine Elson

Date of Inspection 22/03/07

Date of Response 23/04/07

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

Comments copied from returned response received 26/04/07.
All actions requiring immediate response have been dealt with.
A camera to verify patients' identity has been ordered, and a policy formulated.
Enquiries have been made to other units regarding the disaster contingency plan – this will be formalised within the sex months if another unit can be found who agrees to such an arrangement.
Rewriting of patient information continues and should be complete within the next six months.
The refurbishment is continuing in line with the time scales provided to the inspectors.

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).

Comments copied from PR response received 26/04/07
Page 15: The generators are not tested at the weekend, but during the week so we know that the back up system works.
Page 19: We have 1+1 Andrologist HPC registered scientists and 3 scientists working towards registration.
Page 19: We don't have any embryos stored for oncology patients but do have sperm form oncology patients split across dewars.
Page 20: GUM clinics are at LRI, not LGH

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