Licence Renewal Inspection Report for Treatment and Storage Centres

Hartlepool General Hospital
0031

Date of Inspection: 12 September 2006
Date of Licence Committee: 18 December 2006

CENTRE DETAILS

Centre Address	The Cameron Unit University Hospital of Hartlepool Holdforth Road Hartlepool TS24 9AH
Telephone Number	01429 522409
Type of Inspection	Renewal Treatment and Storage
Person Responsible	Mr M Menabawey
Nominal Licensee	Sue Blowers
Licence Number	L0031-11-a
Inspector(s)	Parvez Qureshi (Lead inspector)
	Neelam Sood
	Sarah Hopper
	Christopher Haines (Observer) Stephen Yau (Observer)
Fee Paid - date	No (to be invoiced)
Licence expiry date	28 February 2007

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About the Inspection:
This inspection visit was carried out on 12th September 2006 and lasted for six hours. The report covers the pre-inspection analysis, the visit and information received between January and September 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 Hartlepool General Hospital has been licensed since 1992 and has a good history of compliance with no previous conditions on its licence. A range of licensed treatments are offered to both private and NHS funded patients, most of the referrals being from Hartlepool and the surrounding areas.

Currently around 130 treatments per year are carried at the centre. Since the last inspection no major changes have been made to the premises.

Some progress towards the proposed merger between University Hospital of Hartlepool and North Tees and Stockton Hospital has taken place. On completion, this will result in the relocation of the centre into a new fertility unit.

The centre is open Monday to Friday from 9am to 5pm, outside of these hours support is provided by staff from the main hospital. There is an organisational structure in place which defines role of each member of staff.

The Person Responsible is appropriately qualified to discharge his duties as outlined in section 17 of the HF&E Act.

Activities of the Centre

Licensed treatment cycles (IVF/ICSI and FET)	124
Donor Insemination	7
Unlicensed treatments	GIFT, IUI, Ovulation induction, Husband ovulation, Epididymal sperm aspiration, Testicular sperm aspiration and Testicular biopsy.
Research	No
Storage	Yes

Summary for Licence Committee

A breach of the Code of Practice relating to three embryo transfer for a patient under the age of 40 years was noted during the inspection.

Some improvements have been made at the centre since the last inspection. However, additional improvements are required in all parts of the service provided.

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

Risk Assessment

The current risk matrix score for centre is 16%.

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
Three embryo transfer for a patient under the age of 40 years.	PR to review the policy on three embryo transfer.	Immediately.

Non-Compliance

Area for improvement	Action required	Time scale
Reviewing of laboratory protocols.	Amending of protocols.	Within a month from report being presented to the Licence Committee.

Recommendations	Time scale
Review of current staffing level.	Immediately.
Review of extra space for the centre.	Within 6 months from report being presented to the Licence Committee.
Development of a patient feedback questionnaire.	Within three months from report being presented to the Licence Committee.
Review of CPD for staff	Immediately.
Amendments to 3ET protocol	Immediately.

Proposed licence variations

None

Changes/ improvements since last inspection

Splitting of oncology samples has been carried out.
Updating of protocols and patient information.
The centre has acquired a new database.
Additional training notes have been developed for the nursing staff.
Senior embryologist becoming an ICSI practitioner

Additional licence conditions and actions taken by centre since last inspection

C	Not applicable
	Not applicable

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
Documentation supplied for the inspection included an organisational chart showing main functions and lines of accountability within the unit. Key members of the staff have an extensive experience of working in the fertility field and also have been at the centre for a considerable time. Minutes of multi-disciplinary team meetings held at the centre to discuss practice related issues were reviewed by the inspection team. Complaints and incidents logs are in place. Evidence of risk assessments being carried out at the unit was made available for the inspection. The centre has access to an ethics committee. However, since the last inspection no referrals have been made to it. The inspection team was informed by the PR that there are contingency arrangements in place in the event of an emergency. The PR stated that the centre uses the Trust's clinical governance policies. Information from the HFEA finance department showed that there were no issues with the centre over the payment of treatment fees.
Areas for improvement
Since the last inspection, there has been an increase in the workload at the centre. Discussions held with the centre's staff indicated that they are working under pressure and require both additional staff and expansion of the premises.

All staff need to be made aware of the HFEA alerts, complaints procedure and reporting of incidents to the HFEA. Currently there is no Quality Manager in place at the centre. However the PR stated that this new post will require funding from the Trust.

Any staff meetings held at the unit need to be documented and made available to the appropriate staff. On many occasions staff are unable to attend meetings due to workload.

Executive recommendations for Licence Committee

The PR to ensure that both staffing level and space issues are addressed before there is a further increase in the workload.

Areas not covered on this inspection

All areas covered.

Evaluation

Some improvements required.

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection:

- 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 information from the HFEA Success Rate Assessment can be summarised as follows: The IVF/ICSI for all age groups is lower than national average. The FET for the age group 40-42 higher than national average and for age band below 35 is lower than national average. The DI for all age groups is lower than national average.
Areas of firm compliance
Patients attending for treatment are made aware of the centre's success rates via the patient information leaflets. Documentation submitted for the inspection together with discussions held with the staff and the review of the patient notes showed that 'Welfare of Child' assessments are being conducted at the centre. All patients' medical records are stored in secure areas with only members of the staff having access to them. Consultations with the patients are held in private rooms and any treatment offered to them is documented in their notes. Two patients were interviewed during the inspection, their responses were positive about the quality of service they had received. However, both patients commented on the lack of privacy in the waiting area. Three patient questionnaires were returned to the HFEA. Overall the responses were positive and these were discussed with the centre's staff.

The counsellor attends patients support group meetings. She stated that this enables her to make patients aware of counselling service at an early stage of their treatment. The counsellor is a member of British Infertility Counselling Association (BICA). Her CPD is up to date and evidence of this was provided during the inspection. The counsellor stated that no separate charge is made for counselling.

All counselling sessions take place in a dedicated room located within the centre and the notes are kept in a secure place. The counsellor stated that the uptake rate for counselling was high and she attributed this to her attending the patients support group meetings. She receives regular supervision from a mentor and attends the centre's multi-disciplinary meetings.

The counselling audit supplied to the inspection team confirmed that there were a total of 89 referrals from January 2006 to August 2006. Referral data show that therapeutic counselling being the most frequent.

Areas for improvement

Since the last inspection no complaints have been received. However, the centre's complaints are handled by the hospital's complaints officer and not by a member of the centre's staff. In the event of a complaint, the hospital's complaints officer would inform the PR. The PR stated that the current arrangement was adequate.

Currently there is no patient feedback procedure in place at the centre. Therefore the staff need to develop a method by which to seek patients' views as a continuous improvement measure.

Executive recommendations for Licence Committee

None.

Areas not covered on this inspection

Donor selection, egg sharing and Protection of children arrangements (for patients under 18yrs).

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
Currently the premises are set in a number of locations within the hospital. However, since the last inspection some progress towards the proposed merger between University Hospital of Hartlepool and North Tees and Stockton Hospital has taken place. On completion, this will result in the premises being relocated into a new fertility unit. The inspection team were shown drawings for the proposed fertility unit. All areas seen during the inspection were found to be clean and well presented. In the event of a power failure, there is an access to the hospital's back up generator. The access to the laboratory, which houses the cryostorage facilities, is restricted to authorised staff only This was seen during the inspection. Dewars are locked and alarmed. They are topped up on a weekly basis and a record is made of this. There is a low oxygen monitoring system in place but it was currently out of action and awaiting service. Daily checks are performed on the temperature in the incubator and these are recorded, evidence of this was seen during the inspection. The senior embryologist stated that all oncology samples have now been split, evidence of this was provided during the inspection. The current cryostore facilities are adequate for the volume of work being carried out. Evidence of witnessing in the laboratory is documented in the patients' records and this was checked by the inspection team. Maintenance contracts are in place for key pieces of equipment and these were seen during the inspection.
Areas for improvement
Checking and recording of carbon dioxide levels in incubators. Air quality in the laboratory is not currently monitored.
Executive recommendations for Licence Committee
None.

Areas not covered on this inspection
All areas covered.

Evaluation
Some 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

A total of ten patient records were reviewed during the inspection. These records also included two for patients who had three embryo transfers (3ET), one of them being under 40 years of age. Overall the notes were found to be well organised with all the relevant documents being in place including the reasons for the 3ET. However, some errors were identified in the HFEA (00)6 and (00)7 forms and these were discussed with the centre's staff.

The HFEA operational audit was conducted on 6th September 2006, with the following summary:

- The review found adequate manual systems in place for the recording and reporting of data for the HFEA's statutory register.
- Sample testing found reporting to be complete and accurate and generally timely.
- Review of patient files found signed consents for treatment, use and storage of gametes in addition to evidence of consideration of issues relating to the welfare of the child.

Areas of firm compliance

The centre's information management was considered to be satisfactory by the inspection team.

In comparison to the last inspection, an improvement was noticed in the patient information submitted for the inspection. Two patients who were interviewed on the day of the visit made positive comments on the quality of centre's patient information.

The following information was seen by the inspection team on the day of the visit:
Centre's treatment licence and complaint procedure.
HFEA printed material.
Counselling services and centre's information booklet.

No issues were raised by the HFEA Registry regarding return of treatment forms.

Areas for improvement
The laboratory protocols for keeping of embryos past expiry date and the criteria used for three embryo transfer need to be amended.
Executive recommendations for Licence Committee
The PR needs to review the 3ET policy for patients under 40 years of age. A number of laboratory protocols need to be updated.
Areas not covered on this inspection
All area covered.

Evaluation
Some improvements required.

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

- 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	2
NMC registered nurses	3
HPC registered scientists	2 (1 providing locum cover)
Scientists working towards registration	--
Support staff (receptionists, record managers, quality and risk managers etc)	2

Summary of laboratory audit
The inspection team was provided with information of a recent laboratory audit of stored samples. No discrepancies were found.
Summary of spot check of stored material
An audit of 2 embryos and 2 sperm samples was carried out. No discrepancies were found.
Areas of firm compliance
There are policies in place for assessment of patients seeking treatments and for screening of patients. A thorough witnessing procedure is carried out at the centre, evidence of this was seen in the patients' notes. Overall some of the key protocols reviewed by the inspection team do reflect the quality of service being offered at the centre. The PR stated that recruitment of staff and their suitability to work within the unit is the responsibility of the Trust's HR department.

Areas for improvement
Due to the current workload not all staff are able to attend multi-disciplinary team meetings, indicating inadequate staffing level at the centre. This was evident from the discussions held with the staff. Currently CPD for staff is not fully supported by the centre's management. The reason for this being the availability of funds. However, some of staff are self funding their own CPD.
Executive recommendations for Licence Committee
CPD for all staff needs to be addressed by the centre's management. The workload to staff ratio requires addressing.
Areas not covered on this inspection
PGD/PGS.

Evaluation
Some improvements required.

Report compiled by:

Name……Parvez Qureshi…….

Designation…..Inspector…….

Date……9 October 2006……

Appendix A: Centre Staff interviewed

PR and six other members of the staff

Appendix B: Licence history for previous 3 years

2006

Licence Committee 24th May 2006
The Licence Committee agreed to the continuation of the centre's licence with no additional conditions.

Interim inspection: 27th January 2006

2005

Licence Committee 19th December 2005
The Licence Committee agreed to the postponement of the Interim Inspection on 17th November 2005.

2004

Licence Committee 25th October 2004
The Licence Committee made three recommendations.

Interim Inspection due: Week of 29th August 2004

2003

License Committee: 6th November 2003
The License Committee noted that additional Laboratory space was desperately needed, however they\did extend the license for 3 years to expire on the 31st of February 2007.

- No additional conditions were placed on the license.
- 5 recommendations are presently on the license.

Interim inspection: 29th August 2003 – Completed

Interim inspection 20th February 2003 – postponed

Licence Committee 29th January 2003
The Licence Committee agreed to vary the centre's licence to include ICSI, with one condition.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……

Name of PR……..

Date of Inspection……..

Date of Response……

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

Response received from PR and is available on request.

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