Interim Inspection Report

Gateshead Fertility Unit
0170

Date of Inspection: 9 July 2009
Date of Executive Licensing Panel: 14 October 2009

Centre Details

Person Responsible	Mr Ian Aird
Nominal Licensee	Gateshead Health NHS Foundation Trust
Centre name	Gateshead Fertility Unit
Centre number	0170
Centre address	Queen Elizabeth Hospital Sheriff Hill Gateshead NE9 6SX
Type of inspection	Interim
Inspector(s)	Vicki Lamb
	Paul Knaggs
Fee paid	N/A
Licence expiry date	31 January 2013
NHS/ Private/ Both	Both

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About the Inspection:

This inspection visit was carried out on 9 July 2009 and lasted for 6 hours.

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 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.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

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 is part of the Gateshead Health NHS Foundation Trust and has provided licensed treatments since 1996. The unit offers self funded and NHS funded treatments to patients from the local geographical area. The unit is open from 8:30 to 17:00 on Monday to Friday.

The Person Responsible (PR) has been in post since 1998. He completed the Person Responsible Entry Programme (PREP) on 24 September 2007 and is experienced and suitably qualified. The PR is registered with the General Medical Council and is included on the specialist register of the Royal College of Obstetrics and Gynaecology.

In December 2008 the unit relocated within Queen Elizabeth Hospital to premises with significantly increased capacity.

Activities of the Centre[1] for the time period from 1 March 2008 – 28 February 2009

In vitro fertilisation (IVF)	114
Intracytoplasmic sperm injection (ICSI)	89
Frozen embryo transfer (FET)	58
Gamete intrafallopian transfer (GIFT)	0
Research	No
Storage gametes/embryos	Yes

Summary for Licence Committee

In considering overall compliance the PR is considered to have discharged their duties satisfactorily under S.17 of the HFE Act.

Premises and equipment were considered to be generally suitable.

The centres practices were considered to be generally suitable. Some improvements are recommended as follows:

- Average payment times exceed the 28 day limit
- Two third party agreements require renewing
- Some documents had not been reviewed in the last 12 months
- Competence assessments for all staff have not been performed
- Not all processes have been validated

The inspector considers that there is sufficient information on which to recommend the continuation of the licence. This is subject to compliance with recommendations within the prescribed timeframes.

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

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, Standard Licence Conditions or Code of Practice:
The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
The average payment time for treatment fees is 50 days. HFEA payment terms are 28 days and payment outside these terms is a breach of standard licence condition A.13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.	The PR should take steps to ensure that in future fees are paid within 28 days in compliance with A.13.3	By 1 January 2010
Third party agreements are in place for all suppliers and these agreements were provided to the inspection team. However, two of these agreements require renewing and are therefore not valid at present. This is a breach of standard licence condition A.5.1.	The PR should ensure that third party agreements are in place and up to date to ensure compliance with A.5.1.	By 1 November 2009

Some documents have not been reviewed in the last 12 months. This is a breach of S.5.2.5. The quality manager was aware of this and explained that the outstanding documents should be reviewed in the next few months with the help of one of the nurses.	The PR should ensure that all documents are reviewed at least every 12 months in compliance with S.5.2.5.	By the next inspection
Full competency assessments are not in place for all staff. This is a breach of S.6.2.2(c) and S.6.2.7(a).	Staff competence assessments should be performed to ensure compliance with S.6.2.2(c) and S.6.2.7(a).	By the next inspection
Validation has been started for a small number of procedures but it is not yet complete. This is a breach of S.7.8.3.	Validation of all processes should be performed to ensure compliance with S.7.8.3.	By the next inspection

Non-Compliance

Area for improvement	Action required	Time scale
None		

Recommendations

Area for improvement	Action required	Time scale
The counsellor is concerned that her current premises are not suitable for the infertility work that she does. Her counselling room is located within the obstetrics and gynaecology outpatients department.	It is recommended that the PR considers whether the current facilities comply with CoP S.6.3.5.	By 1 November 2009

Changes/ improvements since last inspection

Recommendations	Action Taken
The centre has taken an average 39 days to pay HFEA invoices in the year to 23 July 2008.	Payment of fees continues to be outside the HFEA's standard terms.

The centre's incident log contained several incidents that had occurred in the time since last inspection that had not been reported to the HFEA.	Incidents were seen to have been appropriately reported to the HFEA.
Sperm is being prepared in an area of the laboratory where the air quality is grade D, below the required grade C.	Sperm is now prepared in an area where the air quality meets the required standard.
The centre has not validated key equipment and processes.	Equipment was validated after being moved into the new premises.
On inspection several documents were found that had not been updated within a 12 month period.	Some documents have not been reviewed in the last 12 months. The quality manager was aware of this and explained that the outstanding documents should be reviewed in the next few months with the help of one of the nurses.
While the quality manager reports that effort has been made to obtain all of the required 33 third party agreements, 9 are still outstanding.	Third party agreements are in place for all suppliers and these agreements were provided to the inspection team. However, two of these agreements require renewing.
The welfare of the child form was appropriately signed in all 5 sets of notes examined at inspection, however, the final section confirming the centre's decision whether or not to proceed to treatment was not completed in 4 of the 5 examples.	This was seen to have been resolved.
While it is reported by the Quality Manger that the competence of all staff is regularly assessed and that staff take part in continuous education and professional development, in most cases, this is not documented.	Sedation competencies have been assessed for the nursing staff but full competency assessments are not in place for all staff.
Patient feedback questionnaire and counselling service user questionnaire results are not being analysed.	The patient feedback questionnaire has been analysed and improvements to the service made in response to comments from patients. The counselling questionnaire has also been analysed.
Success rates are displayed in the patient reception area, but they do not include national comparisons.	National statistics are now displayed alongside success rates for the centre.

The centre has a quality manual and dedicated 0.5 whole time equivalent (WTE quality manager (QM). However the QM reports that she is currently unable to allocate time to Quality Management due to clinical staff shortages.	The quality manager still does not have enough time to perform her role fully, but improvements to the quality management system have been made since the last inspection. More staff have been recruited and this should mean that the quality manager has more time to perform her role.

Additional licence conditions and actions taken by centre since last inspection

The licence was issued with no additional conditions.

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 the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Clinical governance
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
The HFEA licence was seen to be on display. An organisation chart for the centre was provided to the inspection team. This showed clear lines of accountability. Clinical incidents and complaints are discussed at unit meetings and files are kept for staff to access. Incidents were seen to have been appropriately reported to the HFEA. No complaints about the centre have been received by the HFEA. The centre has received two complaints since the last inspection and both these complaints have been resolved. The complaints log was reviewed during the course of the inspection and appropriate action was seen to have been taken in response to the complaints. HFEA alerts are available in the incidents file and this was seen by the inspection team. A contingency plan is in place and was provided to the inspection team. This includes a plan for the second consultant to take over responsibility for running the unit in the event of the PR being unexpectedly absent and an arrangement in place for counselling in the event that the counsellor is unexpectedly absent. Currently two of the embryologists are on maternity leave. Contingency arrangements in case of unexpected absence of the remaining embryologist were provided to the inspection team. Treatment cycles have also been reduced while there is only one embryologist working. Monthly meetings are held in the unit. Minutes of these are taken, emailed to individuals and

a hard copy is also kept. The minutes of these meetings were provided to the inspection team.

Areas for improvement

The average payment time for treatment fees is 50 days. HFEA payment terms are 28 days and payment outside these terms is a breach of standard licence condition A.13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee. At the last inspection the average payment time was 39 days.

Third party agreements are in place for all suppliers and these agreements were provided to the inspection team. However, two of these agreements require renewing and are therefore not valid at present. This is a breach of standard licence condition A.5.1.

Areas for consideration

None

Executive recommendations for Licence Committee

The PR should take steps to ensure that in future fees are paid within 28 days in compliance with A.13.3.

The PR should ensure that third party agreements are in place and up to date to ensure compliance with A.5.1.

Evaluation

Some improvement required

Areas not covered on this inspection

Resource management
Risk management

2. Quality of service

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

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
In the time period from the 1 January 2005 to 31 December 2007 the centre's outcomes for all treatments and all ages of patients were in line with the national average.
Areas of firm compliance
A quality manager has been appointed. The centre's quality policy was provided to the inspection team. A witnessing audit of five random sets of notes has been performed by the centre staff. No discrepancies were found. The centre staff informed the inspection team that now they have moved into the new premises they intend to undertake a patient satisfaction survey in September 2009. In the last survey the main complaint was that the phone was not being answered and calls were not returned quickly. In response to this a receptionist has been recruited to answer the phone and welcome patients. There is a suggestions and comments book for patients to complete if they wish. Documents provided to the inspection team were seen to be version controlled. Most, but not all, of these documents have been reviewed within the last 12 months. National statistics are now displayed alongside success rates for the centre. This was seen by the inspection team.
Areas for improvement
Some documents have not been reviewed in the last 12 months, but all documents had been reviewed in the last 18 months. This is a breach of S.5.2.5. The quality manager was aware of this and explained that the outstanding documents should be reviewed in the next few months with the help of one of the nurses.
Areas for consideration
The quality manager still does not have enough time to perform her role fully, but improvements to the quality management system have been made since the last inspection.

More staff have been recruited and this should mean that the quality manager has more time to perform her role.
Executive recommendations for Licence Committee
The PR should ensure that all documents are reviewed at least every 12 months in compliance with S.5.2.5.
Evaluation
Some improvement required
Areas not covered on this inspection
Quality objectives and plans Quality management review/evaluation

3. Premises and Equipment

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

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
There are proximity cards for access to the centre and to the theatre area. The proximity card readers record who has accessed the various areas. For safety reasons some security and engineering managers have access to the unit via proximity cards. They do not, however, have access to the rooms secured by keypad locks. Therefore they do not have access to stored material or patient records. Visitors have to use the video intercom to request access. The theatre and recovery areas appeared to be suitably equipped. The men's room is discreetly located with little noise or disturbances. Keypad locks were seen to be in place on all doors where records, gametes or embryos are kept. Air quality is tested every six months by an external specialist contractor. The last air quality testing was performed on 19 January 2009 and the results were seen to meet the requirements. There is an oxygen depletion alarm outside the laboratory door. Equipment monitoring in the laboratory is performed via a data logging system. New equipment is validated before use and the records for this were seen by the inspection team. CE products are used were possible. The storage facilities were seen to be appropriate and the dewars were all seen to be locked. Staff facilities include basic kitchen facilities, toilets, seating and dining area and a television. Treatment records are kept in a room locked with a digital keypad lock.

Counselling records are kept securely in the counsellor's office.
Areas for improvement
None
Areas for consideration
The counsellor is concerned that her current premises are not suitable for the infertility work that she does. Her counselling room is located within the obstetrics and gynaecology outpatients department and obstetric scans are performed in a neighbouring room. During the new premises inspection in December 2008, the inspection team were informed that counselling sessions would take place in one of the two consultation rooms on the fertility unit. It is recommended that the PR considers whether the current counselling facilities comply with CoP S.6.3.5.
Executive recommendations for Licence Committee
It is recommended that the PR considers whether the current counselling facilities comply with CoP S.6.3.5.
Evaluation
No improvement required
Areas not covered on this inspection
None

4. Information

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

Summary of the findings from the inspection of the following areas of practice:

- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Audit of records
Five patient records were checked for consents and welfare of the child assessments. No discrepancies were noted. Five patient records were checked for witnessing documentation. No discrepancies were noted.
Areas of firm compliance
Patient information was reviewed by the inspection team at the last renewal inspection and was not reviewed at this inspection. Patients' passports are copied and the copies placed in the notes for identification purposes. These were seen by the inspection team. The inspection team were informed that the centre intend to start running patient information evenings for new patients. There are no problems with data submission to the HFEA.
Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Evaluation
No improvement required
Areas not covered on this inspection
Information for service users

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	0.8
NMC registered nurses	2.5
Non NMC registered clinical staff	0.84
HPC registered scientists	2.2
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	1.5
Counsellors	0.45

Summary of laboratory audit
Summaries of embryo and sperm audits were provided to the inspection team. There were four discrepancies noted on the stored embryo audit. These were all incidences of broken plugs. However, in all cases the correct number of straws were present in the correct locations. In the sperm audit, there was one discrepancy noted. This was one ampoule of donor sperm that was not found. The patient has been lost to follow up and therefore no action has been taken.
Summary of spot check of stored material
Two samples were spot checked. No discrepancies were noted and all paperwork was seen to be correctly completed.
Areas of firm compliance
The training log for the newest nurse was seen by the inspection team. It demonstrated that she had received appropriate training for the tasks that she performs. She also has the

opportunity to undertake CPD.

Sedation competencies have been assessed for the nursing staff and will be reviewed annually.

Staff confirmed that appropriate screening is performed on donors and this was confirmed at the inspection in September 2008.

There have been four instances of three embryos being transferred to a patient since the last inspection. In all cases the patients were aged 40 or over. This was confirmed by the inspection team.

The centre has a multiple births minimisation strategy and were seen to have complied with the requirements of Direction D.2008/5.

Laboratory staff participate in NEQAS semen assessment and the results for this were provided to the inspectorate.

The embryologists participate in the ACE CPD scheme.

Batch records for all consumables are kept and were seen by the inspection team.

A formal on-call system is in place for laboratory staff to respond to emergencies.

There is no limit to the number of counselling sessions a patient can have and all sessions are free of charge.

The counsellor receives supervision which is paid for by the Trust and is working towards BICA accreditation.

Areas for improvement

Full competency assessments are not in place for all staff. This is a breach of S.6.2.2(c) and S.6.2.7(a). The centre staff are aware that more work is needed on competence assessments in order to meet the requirements of the Code of Practice.

Validation has been started for a small number of procedures but it is not yet complete. This is a breach of S.7.8.3.

Areas for consideration

None

Executive recommendations for Licence Committee

Staff competence assessments should be performed to ensure compliance with S.6.2.2(c) and S.6.2.7(a).

Validation of all processes should be performed to ensure compliance with S.7.8.3.

Evaluation
Some improvement required
Areas not covered on this inspection
None

Report compiled by:

Name:……Vicki Lamb…….

Designation:….Inspector…….

Date:……..22 July 2009……..……

Appendix A: Centre staff interviewed

The PR and four members of staff were interviewed

Appendix B: Licence history for previous 3 years

Licence	Status	Type	Active From	Expiry Date
L0170/10/a	Active	Treatment with Storage	14/01/2009	31/12/2013
L0170/9/a	Replaced by new version	Treatment with Storage	05/07/2007	31/01/2009
L0170/8/b	Replaced by new version	Treatment with Storage	01/01/2007	31/01/2009
L0170/8/a	Replaced by new version	Treatment with Storage	01/02/2006	31/01/2009

Appendix C: Response of Person Responsible to the inspection report

Centre Number……170…….

Name of PR……..……Mr Ian Aird…….

Date of Inspection…….9th July 2009. ……..

Date of Response……27th August 2009……

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

Signed…….by email……

Name……..Mr Ian Aird…….

Date……27th August 2009……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

We have reviewed the report fully and can find only one factual inaccuracy in Section 5 page18. The on-call system for laboratory staff is an informal system.

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

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

Breaches of the act, Standard Licence Conditions or Code of practice

Breach	Action taken / planned	Time Scale
The average payment time for treatment fees is 50 days. HFEA payment terms are 28 days and payment outside these terms is a breach of standard licence condition A.13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this license as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section16(6) of the Act, within 28 days of the date of the notice of such additional fee.	The process for payment of HFEA fees is currently under review. Discussions are ongoing with the Trust Finance Department to improve the to ensure payment within 28 days	By 1 January 2010
Third party agreements are in place for all suppliers and these agreements were provided to the inspection team. However, two of these agreements require renewing and are therefore not valid at present. This is a breech of standard licence condition A.%.1	The two third party agreements outstanding have now been renewed ensuring that all third party agreements are now up to date	Completed
Full competency assessments are not in place for all staff. This is a breach of S.6.2.2 (c) and S.6.2.7(a)	Competency assessments for nursing staff are now appropriate. Assessments for laboratory staff are currently on going	By the next inspection
Validation has been started for a small number of procedures but it is not yet complete. This is a breach of S.7.8.3.	Work is continuing on validation of all processes and procedures	By the next inspection

Recommendations

Area for improvement	Action planned / taken	Time Scale
The counsellor is concerned that her current premises are not suitable for the infertility work that she does. Her counselling room is located within the obstetrics and gynaecology outpatients department.	The counsellor has been offered the use of the counselling rooms within the IVF unit for the purpose of her infertility work. She is employed by the Trust to provide counselling services for the Womens Health Division hence the location of her existing office. Any change in the location of her office would need to sanctioned and organised by the Trust and is beyond the remit of the Fertility Unit	No time scale – Counsellor already has access to counselling rooms within the fertility unit