Executive Licensing Panel - minutes

Centre 0170 (The Gateshead Fertility Unit)

Interim Inspection Report

Tuesday, 23 July 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Kathleen Sarsfield-Watson Howard Ryan	Director of Strategy and Corporate Affairs Communications Manager Data Analyst
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Moya Berry	Licensing Manager Committee Officer

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel noted that the Gateshead Fertility Unit is located within the Queen Elizabeth Hospital, part of Gateshead Health NHS Foundation Trust and has been licensed with the HFEA since 1996. The centre provides a full range of fertility services to NHS and self-funded patients, from a wide geographical area. Other licensed activities of the centre include storage of gametes and embryos.

1.2. The panel noted that, in the 12 months to 31 March 2019, the centre had provided 742 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre.

1.3. The panel noted that, for IVF and ICSI, HFEA register data, for the year ending 28 February 2019, show the centre's success rates are in line with the national averages.

1.4. The panel noted that, in 2018, the centre reported 8 cycles of partner insemination, with no pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.5. The panel noted that, HFEA register data, for the year ending 28 February 2018, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is likely to be statistically lower to the 10% multiple live birth rate target for this period.

1.6. The panel noted that an unannounced inspection took place on 15 May 2019.

1.7. The panel noted that at the time of inspection there was one major area of non-compliance concerning medicines management, and one 'other' area of non-compliance regarding submission of data. Since the inspection, the Person Responsible (PR) has committed to implement both recommendations made in the report, within the prescribed timescales.

1.8. The panel noted that the inspectorate recommended the continuation of the centre's treatment and storage licence, particularly noting the centre's low multiple pregnancy rate of 3% and the positive patient feedback.

2. Decision

2.1. The panel commended the centre on the positive patient feedback and low multiple birth rate, also noting the additional information, provided by the PR, in response to the interim inspection report.

2.2. The panel was satisfied the centre was fit to have its treatment and storage licence continued.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Clare Ettinghausen

Date

30 July 2019

Interim Licensing Report

Centre name: The Gateshead Fertility Unit
Centre number: 0170
Date licence issued: 1 January 2018
Licence expiry date: 31 December 2021
Additional conditions applied to this licence: None
Date of inspection: 15 May 2019
Inspectors: Lesley Brown (Lead), Nicola Lawrence
Date of Executive Licensing Panel: 23 July 2019

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. The current foci for an interim inspection are:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we note the centre's low multiple pregnancy rate of 3% and their positive patient feedback.

The ELP is asked to note that this report makes recommendations for improvement in relation to one major and one 'other' area of non compliance or poor practice.

Since the inspection visit, the PR has committed to implement the following recommendations within the required timescales:

Major area of non compliance:

- The PR should ensure that when staff are prescribing and administering controlled drugs the record keeping requirements are fully complied with.

'Other' areas of non compliance:

- The PR should ensure that annual IUI data returns are submitted to the HFEA within the relevant timescale.

Information about the centre

The Gateshead Fertility Unit is located within the Queen Elizabeth Hospital, part of Gateshead Health NHS Foundation Trust and has been licensed with the HFEA since 1996. The centre provides a full range of fertility services to NHS and self-funded patients from a wide geographical area.

The centre provided 742 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2019. In relation to activity levels this is a medium centre**.**

Other licensed activities of the centre include storage of gametes and embryos.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

HFEA held register data for the year ending 28 February 2019 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

In 2018, the centre reported eight cycles of partner insemination with no pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

HFEA held register data for the year ending 28 February 2019 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is likely to be significantly lower than the 10% multiple live birth rate target for this period.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activity was observed in the course of the inspection: egg collection. The procedure observed was witnessed using an electronic witnessing system in accordance with HFEA requirements. A witnessing audit was reviewed and witnessing was discussed with staff. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as

[1]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. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: medicines management; infection control; legal parenthood; witnessing; consent to storage, as well as the most recent review of the QMS.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- leadership
- patient support
- screening
- ovarian hyper stimulation syndrome reporting
- imports of gametes and embryos from outside the EU/EEA
- the use of the Single European Code
- the use of CE marked medical devices
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding: screening requirements, equipment failures, EU exit preparations and encouraging patients to provide feedback to the HFEA.

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be partially compliant with guidance because:

- The centre uses a controlled drugs register intended for use on a ward rather than for use in a theatre. As such the register only allows for recording a single patient identifier, rather than two patient identifiers. In addition, the ward register does not allow for the recording of any discard of unused controlled drugs as would be likely in a theatre setting. As a result, the centre cannot satisfy the requirements of regulations pertaining to the safe custody of controlled drugs as there is no record of the 'fate' of any unused portions. It should be noted, however that the standard of record keeping in the controlled drugs register at the centre was of a very high standard and the inspection team is confident that had the centre been using a controlled drugs register intended for use in theatre, these issues would not have occurred. See recommendation 1.

Prescription of intralipid 'off label'

Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, we reviewed infection control practices and found them to be compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of the following medical devices was reviewed in the course of the inspection: media, media supplements, vitrification kits; sperm preparation kits and plasticware. The centre's own CE marking audit was also reviewed. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Thirty patients have provided feedback in the last 12 months, giving an average five star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. All of the patients, who commented on this area, confirmed that they had paid what they expected to. Several

patients provided individual comments to the HFEA complimenting: helpful and friendly staff; the availability of private rooms while waiting and high quality information provision at the clinic.

The centre's own most recent patient survey responses was also reviewed. Feedback was comparable to that provided to the HFEA, with all categories surveyed being marked 'excellent' by more than 90% of respondents. In addition the results of the "friends and family" surveys from the first quarter of 2019 demonstrated that 100% of patients would recommend the centre.

No patients were available to speak to inspectors during this visit.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is non-compliant with the following HFEA requirement:

- The centre has failed to submit annual returns of intra uterine insemination (IUI) treatments for the following calendar years: 2016; 2017; 2018. This was discussed during the inspection, and the inspection team was assured that this was due to technical issues, that have since been resolved. See recommendation 2.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2017, recommendations for improvement were made in relation to five 'other' areas of non compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

Since the last renewal inspection in June 2017 the centre has not received any performance related risk tool alerts.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The clinic is compliant with requirements to submit information to the HFEA. There are currently no significant data submission issues at this clinic. This conclusion is based on a review of the clinic's register submissions conducted on 1 May 2019

Legal parenthood

Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the inspection in June 2017, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Six sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the inspection team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be made.

Critical areas of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical non compliance requires immediate action to be taken by the Person Responsible.

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
None			

‘Major’ area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- which can comprise a combination of several ‘other’ areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

A major area of non compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Medicines management The controlled drug register had only one patient identifier recorded for each entry and it did not have a section to record the supply, administration and discard of drugs for each patient. Only the administration of the drug was documented. NICE [NG46] 2016 ‘Controlled drugs: safe use and management’ sections 1.7.8 and 1.8.1 “Controlled Drugs in Peri-operative Care” (2018)	The PR should ensure that staff prescribing and administering controlled drugs are aware of the record keeping requirements for controlled drugs and maintain full compliance with controlled drugs regulations and practice guidance. The PR should ensure that the controlled drug register is appropriate for the location in which it is to be used. It is expected that a suitable register is in use by 15 August 2019. The PR should provide	We were surprised that this issue has been classified as a major non-compliance. We do not feel that our current practice reflects a major shortcoming from statutory requirements . The current controlled drugs register contains documented evidence of drugs that are 'wasted' and this is signed for by 2 qualified nurses as recommended in the NICE guidance (NG46) 1.7.8 that you have referenced. We feel that current practice is compliant with this.	The inspection team acknowledge the PR’s response. The inspection team considered that the centre’s practice deviated from the following requirement; “5. In keeping with the minimum requirements of Regulation 19 of the Misuse of Drugs Regulations 2001 and as recommended in the National Institute for Health and Care Excellence (NICE) guidance [5], recordkeeping for all Schedule 2 drugs in the

The Association of Anaesthetists of Great Britain & Ireland (AAGBI).	confirmation of this to the centre's inspector.	We have also audited this area of practice and can demonstrate complince with NICE guidance NG 46 1.8.1. There is also an audit by the Trust pharmacy of the controlled drugs book which has also revealed compliance with this guideline. We have attempted to access the AAGBI 2018 version of 'Controlled drugs in Peri-operative Care ' and this is not available even from the AAGBI website. We have consulted the 2006 version and feel we are are compliant with the summary of recommendations. Our last Renewal inspection in 2017 comments, and I quote directly from the insepction report under the section Medicines management (Guidance note 25), "The centre has arrangements in place for obtaining , recording, handling, using , keeping, dispensing, administering and disposing of medicines that are compliant with guidance"	controlled drugs register *must* be contemporaneous and include: • Patient's name, NHS or hospital number; • Date and time of administration of drug; • Amount of drug supplied; • Amount of drug administered; • Amount of drug disposed; • Signatures of person supplying and person administering the drug; • Signatures of person disposing of unused controlled drug and witness." "Controlled Drugs in Peri-operative Care" (2018) The Association of Anaesthetists of Great Britain & Ireland (AAGBI) A review of practice showed the centre failed to meet these minimum requirements by:

		We find it difficult to see how, in the absence of any change in practice or availbale guidance, we have gone from this to being advised that our practice is now a 'Major' area of non compliance. We do however agree to move to the recommended 'theatre style' controlled drug book within the required time frame.	• using a CD register that did not have space to record the patients NHS or hospital number • using a CD register which did not record the amount supplied and discarded • not witnessing the discard of unused drug The inspection team is assured that the PR has agreed to move to the recommended 'theatre style' controlled drug book by 15 August 2019. Further action required.

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate a departure from statutory requirements or good practice.

An ‘other’ area of non compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
2. **Submission of Data** The centre failed to submit annual returns of IUI treatments for the following calendar years: 2016; 2017; 2018. GD0005, paragraph 10.	The outstanding IUI annual returns have now been submitted. The PR should ensure that there is a process in place to ensure that IUI annual returns are submitted to the HFEA within the required timescales. No further action.	We apologise for this oversight which has now been rectified. We will endeavour to submit the IUI annual returns of at the appropriate time. As the number of IUI cycles is very small we feel that perhaps a reminder in the December or January Clinic Focus may assist clinics in timely reporting of IUI treatment cycles	The inspection team acknowledges the PR’s response, and commitment to submit annual IUI returns at the appropriate time. No further action required.

Additional information from the Person Responsible

In light of the comments related to medicines managemnt above, we do feel that this highlights a degree of inconsistency in the interpretation of compliance by different inspectors, although the issue of the controlled drugs book was discussed during the feedback we were not made aware that was would be considered a major non compliance.
From a personal perspective I find unannounced inspections very frustrating. The inspection occurred on a day when I had clinical commitments outside of the fertility unit which meant I could only have a fairly rushed meting with the insepctors at lunchtime and I was unable to attend for the feedack at the end of the inspection - I appreciate this is only my perspective but it is frustrating for the Person Responsible to play virtually no part in the on site inspection process.

Inspection team's response to the PR's statement

The inspection team would like to assure the PR that the executive has robust processes to prevent inconsistency in the interpretation of compliance by different inspectors. The grading of non-compliances are regularly reviewed, and revised where appropriate, and as such may differ over time.