Executive Licensing Panel - minutes

Centre 0314 (Leeds Fertility)

Interim Inspection Report

Friday, 28 July 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Hannah Verdin (Chair) Anna Coundley Anjeli Kara	Head of Regulatory Policy Information Access and Policy Manager Regulatory Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

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:

- 8th 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 Leeds Fertility has held a treatment and storage licence with the HFEA since 2010 and provides a full range of fertility services to NHS and privately funded patients.

1.2. The panel noted that in the 12 months prior to 28 February 2017, the centre had provided 2,057 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is a large centre.

1.3. The panel noted that the inspection took place on 23 May 2017.

1.4. The panel noted that at the time of the inspection on 23 May 2017, three major areas of non-compliance or poor practice were identified regarding the medical practitioner statement (MPS) statement, adverse incident reporting and consent. The panel noted that since the inspection, the Person Responsible (PR) had fully implemented the recommendations regarding adverse incident reporting and consent. The PR had provided a commitment to implement the recommendation concerning the MPS and an audit of the samples being stored will be submitted by November 2017.

1.5. The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence, noting the progress made by the centre in meeting the HFEA multiple birth rate target and the positive comments made by patients in relation to their experiences at the centre.

2. Decision

2.1. The panel expressed the importance of ensuring consent procedures, with regards to legal parenthood, are adhered to, encouraging the centre to continue to ensure staff understand the importance of recognising and documenting information in necessary cases.

2.2. The panel was satisfied the centre was fit to have its treatment and storage licence continued, provided that the MPS audit is submitted by November 2017.

3. Chair's signature

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

Signature

Name

Hannah Verdin

Date

4 August 2017

Interim Licensing Report

Centre name: Leeds Fertility
Centre number: 0314
Date licence issued: 25 January 2016
Licence expiry date: 24 January 2019
Additional conditions applied to this licence: None
Date of inspection: 23 May 2017
Inspectors: Susan Jolliffe (lead) Andrew Leonard
Date of Executive Licensing Panel: 28 July 2017

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 usually do this at the mid-point of the normal four year licence period, however because this centre was provided only a three year licence, the inspection was performed one year after the last renewal inspection.

For 2015-2017 the focus of an interim inspection is:

- **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 an 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

The inspection team recommends the continuation of the centre's licence. We note the progress made by the centre in meeting the HFEA multiple birth rate target and the positive comments made by patients in relation to their experiences at the centre.

The ELP is asked to note that recommendations for improvement were made in relation to three major areas of non compliance.

The PR has provided evidence that the following recommendations have been implemented:

'Major' areas of non compliance:

- The PR should ensure that all adverse incidents, including ovarian hyper stimulation syndrome (OHSS) cases that require a hospital admission and have a severity grading of severe or critical, are reported to the HFEA.
- The PR should ensure that the marital status of a woman to be treated with donor sperm is recognised, and that staff act upon the implications of her marital status regarding legal parenthood.

The PR has provided a commitment to implement the following recommendation:

'Major' areas of non compliance:

- The PR should ensure that medical practitioner statements are documented on the appropriate HFEA form for samples being stored under the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009.

Information about the centre

Leeds Fertility has held a treatment and storage licence with the HFEA since 2010 and provides a full range of fertility services to NHS and privately funded patients.

The centre provided 2057 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2017. In relation to activity levels this is a large centre.

A change of centre name was agreed by ELP on 21 April 2017, from The Leeds Centre for Reproductive Medicine to Leeds Fertility, and a change of PR was approved by an ELP in January 2017.

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]

For IVF and ICSI, HFEA held register data for the period 1 December 2015 to 30 November 2016 show the centre's success rates are in line with national averages.

In 2016, the centre reported 66 cycles of partner insemination with 10 pregnancies. This represents a clinical pregnancy rate of 15%, which is in line with the national average.

Multiple births[2]

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

Between 1 December 2015 and 30 November 2016, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 5%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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 activities were observed in the course of the inspection: egg collection; patient identification check; preparation for embryo transfer. All the procedures observed were witnessed using either manual or an electronic witnessing system in accordance 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, the 'bring-forward' system was discussed with staff and storage records were reviewed. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are generally effective. In some cases, however, samples are being stored for an extended storage period with appropriate patient consent and a medical practitioner's statement (MPS) of actual or likely premature infertility, but this statement is sometimes not clear as it is not routinely documented using the appropriate HFEA form (recommendation 1).

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: witnessing and consent to storage.

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:

- the use of CE marked medical devices
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding screening requirements and equipment failures

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 compliant with guidance.

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; egg collection tubes and sperm pots. The centre's audit of CE marking of materials was also reviewed. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience
During the inspection, we spoke to five patients who were available to speak with the inspectors about their experiences at the centre. Six patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive, nine of the eleven individuals providing feedback giving compliments about the care received.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions (with the exception of recommendation 3)
- maintains an effective system for responding to patient phone calls.

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 not reported any severe or critical ovarian hyper stimulation syndrome (OHSS) cases for the last two years. The centre's incident reporting log was reviewed at inspection and at least five cases had been reported internally and investigated, but not reported to the HFEA (recommendation 2).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2015, recommendations for improvement were made in relation to seven major and six 'other' areas of non compliance.

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

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

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.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies.

On this inspection, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA. Actions had been taken in response to the audit findings.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are

effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

To provide further assurance of the effectiveness of the centre's procedures the inspection team reviewed five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood and an offer of counselling prior to the consent being recorded, was seen to be in place before treatment in all cases.

One case reviewed showed that early in 2017 a woman had been provided with treatment with donor sperm. No consent to legal parenthood was required as the woman was treated without a partner. However, the patient's record showed that the centre's counsellor had discussed with the patient, the implications of receiving treatment with donor sperm as a single woman, albeit that she had been separated from her husband but not yet divorced. The legal position regarding parenthood in such circumstances is complex in that the patient's spouse, whilst still legally married, would in law be recognised as the parent of any child born.

Where a woman to be treated is still married or there is no evidence of legal separation, whilst being mindful of the patient's right to confidentiality, the centre should endeavor to determine whether the woman's spouse consents or withholds consent to her treatment. If this is not possible, the centre should document this. The patient should also be advised to record her lack of consent to her spouse being the legal parent by completing the HFEA 'Lack of Consent' (LC) form before treatment. There was no evidence of this in the patient's record.

Since the inspection, the PR has confirmed that this cycle of treatment was unsuccessful and therefore this represents a 'near miss'. The inspection team has concerns however that clinical staff were seemingly unaware of the patient's marital status and consequently the patient had not been provided with proper information or advised to complete an LC form and the situation was not identified by centre staff before treatment was provided (recommendation 3).

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be compliant with HFEA requirements. The inspection team had concerns regarding the adequacy of case review when considering the implications of treatment and providing information to patients (recommendation 3).

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 carried out.

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 area of non compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
None identified at this inspection		N/A	

‘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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. **MPS statement** Where gamete providers have consented to extended storage, the medical practitioner statement of actual or likely premature infertility is not always clear or documented on the appropriate HFEA form. (General Direction 0007).	The PR should ensure that medical practitioner statements are documented on the appropriate HFEA form when gametes or embryos are being stored under the provisions of the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009. The PR should conduct an audit of the records of sperm samples being stored under the 2009 regulations to determine the number requiring completion of HFEA MPS forms and the number for whom the present medical	The PR accepts that the medical practitioner statement was not completed in some cases where gamete providers had extended storage. Some of these patients were stored under the remit of old long term storage forms and reasons given in medical history or letter by clinician. The PR will conduct an audit of the samples being stored under the 2009 regulations to determine the number requiring completion of MPS forms and will submit the audit by November 2017.	The executive acknowledges the PR’s response and the commitment to fully implementing this recommendation. **Further action required**

	practitioners statement of actual or likely premature infertility is not clear or absent. A summary of this audit should be provided to the HFEA by 23 November 2017. In all cases where there has been a failure to comply with the 2009 storage regulations, the PR should seek independent legal advice on how to proceed, including whether affected patients ought to be informed. Proposed actions in response to this advice should be provided to the HFEA for review prior to any action being taken. The PR should investigate the barriers to ensuring medical practitioner's statements are in place using the correct documentation, and review processes accordingly. The PR should also ensure all relevant staff members understand the requirements of the 2009 storage	The PR questions whether MPS statements can be completed retrospectively in cases where there is a statement by the clinician of premature infertility, if not on the MPS form. The PR has reiterated to all clinical staff that for long term storage/extended storage that an MPS form must be completed. The administration team have had an amended summary of forms needed when preparing the notes for patients attending to extend storage. This was done on the 6th April (prior to the inspection date) Oncology patients who store sperm and who are likely to become infertile consent for 55 years but are reviewed at 10 years to confirm that they meet the criteria for ongoing storage and an MPS form would be completed at this stage.	

	regulations. The outcome of this investigation, including the centre's intended actions and the timescales for their implementation should be submitted to the HFEA by 23 August 2017. Given the need to seek a medical practitioner's statement occurs infrequently, the centre should conduct an audit within one year of the implementation of corrective actions, to assess the compliance of samples in storage beyond the statutory storage period. A summary report of the findings of the audit should be provided to the HFEA by 23 May 2018.	Staff were sent an email and links to the new consents released on 6th April this year. At this time they were asked to sign to understand that they understood the consent forms. It was reiterated at this time regarding the MPS forms. Staff were asked to sign to say they had read this email and the relevant links regarding the consent forms. The PR has requested that going forward, all notes of patients who have attended the clinic to extend storage beyond the statutory storage period are given to her to check that they comply with 2009 regulations. This will form part of the audit detailed below. The PR will conduct an audit of the long term storage patients following corrective actions and provide this data to the HFEA by May 2018	

2. **Adverse incident reporting** The centre has failed to report several relevant cases of OHSS to the HFEA. (SLCs T120 and T121)	The PR should ensure that the HFEA is notified of any relevant cases of OHSS in accordance with standard licence conditions. The PR should review all cases of OHSS since April 2015. Where cases meet the criteria for reporting to the HFEA as incidents, these should be submitted to the HFEA along with the outcome of any investigation and how any learning from these cases was acted upon. These reports should be submitted to the HFEA by 23 August 2017. The PR should investigate how this non-compliance has occurred, identifying the barriers to ensuring that all staff are aware of and act upon the requirements to report severe and critical cases of OHSS to the HFEA. The outcome of this investigation, including the	This non- compliance occurred due to a misunderstanding by the units previous lead nurse who believed that the HFEA no longer required notification and had informed staff that this was the case. This has now been rectified. A record of cases had been kept by the unit for the purpose of internal audit. A review has now been completed and 7 cases reported to HFEA on 14.6.17. A root cause analysis has been conducted with no clear theme emerging. The team at Leeds Fertility has been informed of the importance and process to report severe OHSS to the HFEA and also complete an internal datix report.This was implemented immediately following the inspection. Evidence of this can be seen by the reporting of an OHSS case on 23.6.17.	The PR has submitted all outstanding cases, and has completed a root cause analysis as requested. No further action required

	PRs intended actions and the timescales for their implementation should be provided to the centre's inspector by 23 August 2017.		
3. **Consent** One case reviewed showed that staff failed to adequately determine the marital status of a woman to be treated with donor sperm nor recognise and act upon the implications of her marital status regarding legal parenthood. (SLC T57; Interpretation of mandatory requirements 6b and Guidance Note 6.22)	The PR should ensure that the marital status of patients receiving donor treatment is known and that patients are provided with appropriate information and guidance accordingly. The PR should investigate the circumstances leading to this serious 'near miss' event to determine how it occurred and what measures need to be implemented to prevent a recurrence. A summary report of the findings and learning, together with the proposed corrective actions and evidence of their implementation, should be provided to the centre's inspector by 23 August 2017.	The PR confirms that documentation for all patients undergoing treatment now records marital status clearly. The patient in question had never previously attended with her husband, and always had sought treatment as a single woman. It was well documented by the consultant and counsellor that she was seeking to obtain treatment as a single lady and had started divorce proceeding s which she did not feel would be problematic.It was thought as her husband had never consented to any form of treatment that he would not be the legal father. The PR accepts this misinterpretation and has reiterated the process to staff members regarding the	The PR has investigated the circumstances that led to staff at the centre not determining the marital status of a woman being treated with donor sperm, and has introduced changes to ensure staff are aware of the importance of recognising and documenting the marital status in such cases. No further action required

		importance of legal parenthood. It is now clear that if a patient seeks treatment as a single person but is still currently married, then an LC form should be obtained from the patient before continuing furtur treatment and a WC form obtained from the partner if applicable (taking in to consideration the confidentiality of the patient). Since the inspection, the patient has been contacted regarding her current marital status and the divorce is not yet finalised. She attended on the 17th June 2017 and signed the LC form before any further treatment will commence.	

‘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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None identified at this inspection		N/A	

Additional information from the Person Responsible