Executive Licensing Panel - minutes

Centre 0321 (Newlife Fertility Centre)

Interim/Additional Inspection Report

Friday, 6 October 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Juliet Tizzard (Chair) Ian Peacock Anna Quinn	Director of Strategy and Corporate Affairs Systems Manager Scientific 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 the Newlife Fertility Centre is located in Epsom and has held a treatment (including embryo testing) and storage licence with the HFEA since 2011. The centre provides a full range of fertility services, including embryo testing.

1.2. The panel noted that in the 12 months to May 2017, the centre had provided 268 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is a small centre.

1.3. The panel noted that for the year ending February 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 15%: this represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

1.4. The panel noted that a renewal inspection, performed in 2016, identified a significant number of non-compliances including two critical, ten major and five 'other' areas of practice that required improvement. The Executive Licensing Panel renewed the centre's licence for a period of three years rather than the usual four, recommending that an interim inspection to assess the ongoing effectiveness of recommendations implemented should be conducted within one year of the licence coming in to force.

1.5. The panel noted that the inspection took place on 18 July 2017.

1.6. The panel noted that at the time of the inspection on 18 July 2017, five major areas of non-compliance or poor practice were identified concerning screening and testing of patients, medical gas cylinders, oxygen on the emergency trolley, CE marked devices in the laboratory and annual data returns. The panel noted that since the inspection, the Person Responsible (PR) has complied with all the recommendations apart from that concerning CE marked devices, but had agreed to comply with this, with an update due to be provided by 18 October 2017.

1.7. The panel noted that the inspectorate recommends the continuation of the centre's treatment (including embryo testing) and storage licence, noting the progress made by the centre in reducing their multiple birth rate.

2. Decision

2.1. The panel noted the non-compliances and the steps taken by the PR to address them, urging the centre to continue to improve its practice.

2.2. The panel was satisfied the centre was fit to have its centre's treatment (including embryo testing) and storage licence continued.

3. Chair's signature

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

Signature

Name Juliet

Tizzard

Date

18 October 2017

Interim Licensing Report

Purpose of the report

Centre name: Newlife Fertility Centre
Centre number: 0321
Date licence issued: 03 August 2016
Licence expiry date: 02 August 2019
Additional conditions applied to this licence: None
Date of inspection: 18 July 2017
Inspectors: Janet Kirkland MacHattie, Lesley Brown
Date of Executive Licensing Panel: 6 October 2017

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 announced 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. 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 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

The inspection team recommends the continuation of the centre's licence. In particular we note the progress made by the centre in reducing their multiple birth rates.

The Executive Licensing Panel is asked to note that there are recommendations for improvement in relation to five major areas of non-compliance.

Since the inspection, the PR has confirmed that he has complied with the following recommendations:

Major areas of non-compliance:

- the PR should ensure that screening tests are performed in accordance with licence conditions and professional body guidelines;
- the PR should ensure that gas cylinders stored at the centre are secure and not at risk of falling over;
- the PR should ensure that checks performed of emergency equipment include the expiry date of the oxygen cylinders;
- the PR should ensure that annual data returns for intrauterine insemination treatments with partner sperm are submitted to the HFEA as per Directions.

The PR has agreed to comply with the following major non-compliance.

- the PR should ensure that appropriately CE marked devices are used where available.

Information about the centre

The Newlife Fertilty Centre is located in Epsom and has held a licence with the HFEA since 2011.

The centre provides a full range of fertility services including embryo testing.

The centre provided 268 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to May 2017. In relation to activity levels this is a small centre.

A renewal inspection performed at the centre in 2016 identified a significant number of non-compliances including two critical, ten major and five 'other' areas of practice that required improvement. The ELP renewed the centres licence for a period of three years rather than the usual four, recommending that an interim inspection to assess the ongoing effectiveness of recommendations implemented should be conducted within one year of the licence coming in to force. This is a report of that inspection.

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 year ending February 2017 show the centre's success rates are in line with national average.

The PR has not submitted the annual data return for insemination treatments using partner sperm for 2016.

Multiple births[2]

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

HFEA held register data for the year ending February 2017 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 15%. This represents performance that is not likely to be significantly different to 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 inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff, to review the centres audit and relevant standard operating procedure (SOP) and

[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%.

to review two cases on the RI witness system. 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 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 and the atmosphere in the clinic appeared calm at all times. There were no activities in the laboratory on the day of the inspection however laboratory staff confirmed that they are able to carry out their activities without distraction and are 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, consent to storage and patient feedback.

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 centre's audits of legal parenthood
- the centre's rolling audit system which includes consent and welfare of the child
- the use of CE marked medical devices
- the content of the centre's website
- HFEA Clinic Focus articles regarding: Zika and Ebola virus.

- knowledge of chief executive letter CE(16)02 regarding the change in legal interpretation of storage expiry dates.

The centre is broadly effective in implementing learning from their audits and or guidance from the HFEA (see recommendation three) because the PR has not ensured compliance with Licence Condition T30 and guidance from the HFEA Clinic focus September 2016 in relation to the use of CE marked medical devices.

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 a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed at the inspection in 2016 and considered to be suitable.

Written information provided to patients offered intralipid therapy was reviewed following the previous inspection and was compliant with guidance.

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, flush solution, vitrification kits, sperm preparation kits and laboratory plasticware. We found the centre to be partially compliant with HFEA requirements to use CE marked medical devices wherever possible because the following medical devices are not appropriately CE marked: 5 ml round bottom tubes, 14 ml round bottom tubes and sperm pot.

Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. Two patients provided feedback directly to the HFEA in the time since the last inspection. This feedback was predominantly positive as was the centre's own feedback reviewed on inspection.

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;

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, indicated the following non compliances:

- A sperm donor's initial tests for HIV and hepatitis B and C were performed using nuclei acid testing (NAT) alone and not standard serological testing. The samples were then stored for later use in donation without further tests being performed. The other donor screening tests required by SLC T52 were performed in a compliant manner.
- The oxygen cylinder on the emergency trolley was passed the expiry date on the label;

- Gas cylinders stored in a cage outside of the premises were not fully chained to secure them and were therefore at risk of falling over.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2016 recommendations for improvement were made in relation to two critical, ten major and 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.

This inspection visit provided an opportunity to evidence that recommendations made relevant to these areas of non-compliance had been implemented and fully imbedded in practice. The inspection team were able to conclude that compliance has been maintained in all but two of the areas of concern, these being:

- Some of the medical gas cylinders stored in a cage outside of the building were not secure and at risk of falling over;
- Not all consumables used in the laboratory are appropriately CE marked;

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 broadly complaint with requirements to submit information to the HFEA as the PR had not at the time of the inspection submitted the annual data return for treatments of insemination with partner sperm performed at the centre (see recommendation four).

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.

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 four 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 the offer of counselling was seen to be in place prior to consent and treatment in all cases.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be 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 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			

‘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. A sperm donor’s initial tests for HIV and hepatitis B and C were performed using NAT testing alone and not standard serological testing. The samples were stored for later use in donation without further tests being performed. SLC T52; CoP guidance 11.22 and 11.23. The donor was screened using standard serological testing after treatment had been provided to a recipient and was found to be negative.	The PR should ensure that donors are screened in accordance with standard licence conditions and professional body guidelines. The PR should ensure that the centres SOP’s reflect this requirement. The PR should perform an audit of all cycles where sperm from donors recruited at the centre has been used to ensure that the testing has been performed in a compliant manner. This should also include sperm used in surrogacy treatment cycles.	The issue has been addressed. Donors will all be screened in line with standard licence conditions and HFEA guidelines. All SOP's reflect the screening process that donors must go through prior to any donation. An audit has been carried out of all donor treatments to date that include the use of sperm in any donation cycle including surrogacy and the audit report is attached.	The PR’s response is acknowledged and the audit has been received. The audit result as reported by the centre indicated that screening of all other sperm donors recruited at the centre had been performed in compliant manner. No further action.

	The PR should provide the centres inspector of the results of this audit when responding to the inspection report.		
2. Some of the medical gas cylinders stored in a cage outside of the building were not secure and were at risk of falling over. This was an issue on the previous inspection however the cylinders at that time were situated within the building. SLC T17	The PR should ensure that medical gas cylinders are properly stored and provide confirmation of this to the centre's inspector when responding to this report.	This issue has been addressed. A chain has been ordered. The spare medical gas cylinder will be chained up at all times like the others.	The PR's response is acknowledged. The centre's inspector has been informed by email that the cylinders have now all been secured. No further action.
3. The oxygen on the centres emergency trolley had passed the expiry date stated on the cylinder. This was replaced immediately on the day of the inspection. SLC T17	The PR should ensure that daily checks of the emergency equipment include a check that the oxygen cylinder is within its expiry date and is suitable to use. Three months after the implementation of corrective actions, the PR should audit the records of the daily critical equipment checks, to ensure that a check that the oxygen cylinder is within its expiry date	This issue has been addressed. The oxygen cylinder was immediately changed. The crash trolley checklist (ND&F17), has been updated to include an aid memoir to check the oxygen cylinder expiry date and all other expiry dates.	The PR's response is acknowledged. Audit to be received by 18 October 2017.

	has been consistently performed. The PR should inform the centre's inspector of the result of the audit by 18 October 2017.		
4. The following consumables used in the laboratory are not appropriately CE marked: 5 ml round bottom tubes, 14 ml round bottom tubes and sperm pot This was identified as an area for improvement at the previous inspection. Recurrence of this non-compliance could indicate a lack of learning from previous recommendations and guidance from the HFEA. This has been elevated to a major non-compliance SLC T30 Clinic Focus September 2016	The PR should ensure that appropriately CE marked medical devices are used where available. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. In consideration of this the PR should identify suitable CE marked alternative products by 18 October 2017 and confirmation, along with a timeline for introduction, provided to the centre's inspector. The PR should aim to be fully compliant, no later than 18 January 2018.	Replacement consumables that are CE marked for all items mentioned have been identified and will be ordered over the next 2-3 weeks. The CE marked consumables will be introduced over the next few months as the stocks of non-CE marked consumables become depleted i.e. phased approach. This will allow us to monitor any impact on the quality of treatment.	The PR's response is acknowledged. The centre's inspector to receive an update on progress towards compliance with this recommendation by 18 October 2017.

5. The PR has not submitted the annual data return for insemination treatments using partner sperm for 2016. General Directions 0005	The PR should ensure that the annual data is submitted no later than 28 February in each calendar year.	This issue has been addressed. The annual IUI data submission for 2016 has been completed and submitted to the HFEA. A reminder has been set for this event.	The PR's response is acknowledged. No further action.

Additional information from the Person Responsible