Executive Licensing Panel - minutes

Centre 0008 (CARE Fertility Tamworth)

Interim Inspection Report

Tuesday, 11 February 2020

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Yvonne Akinmodun Helen Crutcher	Director of Strategy and Corporate Affairs Head of Human Resources Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

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 CARE Fertility Tamworth is located in Tamworth and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services

1.2. The panel noted that, following the renewal inspection in March 2017, the Executive Licensing Panel (ELP) had some concerns about non-compliances relating to donor screening, consent and reporting of treatment data to the HFEA. The panel agreed to the inspectorate's recommendation to issue a four-year licence, with no conditions, but requested that the inspectorate conduct a targeted interim inspection within 12 months of the licence coming into force.

1.3. The report of the targeted interim inspection was considered by ELP in December 2018 and included two critical areas of non-compliance concerning consent to storage and medicines management. There were also three major areas of non-compliance regarding infection control, process validation and equipment. The panel allowed the continuation of the centre's licence, requesting that a further interim inspection be conducted within the next 12 months; the panel were now being presented with this further interim inspection report.

1.4. The panel noted that, in the 12 months to 31 October 2019, the centre had provided 459 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a small sized centre.

1.5. The panel noted that, for IVF and ICSI, HFEA register data, for the period 1 August 2018 to 31 July 2019, show the centre's success rates are in line with the national averages.

1.6. The panel noted that, in 2018, the centre reported 12 cycles of partner insemination, with no pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

1.7. The panel noted that, HFEA register data, for the period between 1 August 2018 and 31 July 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 5%. This represents performance that is likely to be significantly lower from the 10% multiple live birth rate target for this period.

1.8. The panel noted that an unannounced inspection took place on 16 December 2019.

1.9. The panel noted that, at the time of inspection, two major areas of non-compliance were identified concerning the storage of gametes and embryos and legal parenthood. Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement both recommendations made in the report.

1.10. The panel noted that the centre is well led and provides a good level of patient support.

1.11. The panel noted that the inspectorate recommended the continuation of the centre's treatment and storage licence.

2. Decision

2.1. The panel noted that only 34 patients had provided feedback on their experience of the centre, in the last 12 months, through the 'Choose a Fertility Clinic' facility available on the HFEA website, giving the clinic an average five star rating and positive, complimentary comments regarding its staff and homely atmosphere; the panel suggested that the centre should actively encourage patients to use this mechanism to provide feedback.

2.2. The panel was satisfied the centre was fit to have its treatment and storage licence continued, acknowledging the centre's improvement in non-compliances identified at this inspection, hoping continued improvement will be evident at the renewal inspection.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

13 February 2020

Interim Licensing Report

Centre name: CARE Fertility Tamworth
Centre number: 0008
Date licence issued: 1 August 2017
Licence expiry date: 31 July 2021
Additional conditions applied to this licence: None
Date of inspection: 16 December 2019
Inspectors: Lesley Brown (Lead), Susan Jolliffe.
Date of Executive Licensing Panel: 11 February 2020

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: HFEA held register data for the year ending 31 July 2019 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 5%. This represents performance that is likely to be significantly lower than the 10% multiple live birth rate target for this period.

The centre is well led and provides a good level of patient support.

The ELP is asked to note that this report makes recommendations for improvement in relation to two major areas of non compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations:

Major areas of non compliance:

- The PR should ensure that the legal parenthood consenting process is appropriate.
- The PR should ensure that gametes are only held in storage if effective consent to storage is in place.

Information about the centre

CARE Fertility Tamworth is located in Tamworth and has held a licence with the HFEA since 1992.

The centre has changed ownership and PR twice since the last renewal inspection in March 2017. At the time of the renewal inspection the centre was operating under the name Midland Fertility Services. In June 2017, the name of the centre was changed to IVI Midland and the Person Responsible (PR) was changed. In May 2019 a further change of PR was approved to re-appoint the original PR. In July 2019 the centre name was again varied, to CARE Fertility Tamworth, to reflect that the centre is now part of the CARE group.

The centre provides a full range of fertility services.

The centre provided 459 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2019. In relation to activity levels this is a small centre.

Following the renewal inspection in March 2017 the ELP had some concerns about non-compliances relating to donor screening, consent and reporting of treatment data to the HFEA. The panel agreed to the inspectorate's recommendation to issue a four-year licence with no conditions but requested that the inspectorate conduct a targeted interim inspection within 12 months of the licence coming into force.

The report of the targeted interim inspection was considered by ELP in December 2018 and noted that it included two critical areas of non-compliance, concerning consent to storage and medicines management, and three major areas, concerning infection control, process validation and equipment. The panel allowed the continuation of the centre's licence but required that a further interim inspection be conducted within the next 12 months. This is a report of that further interim 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 period 1 August 2018 to 31 July 2019 show the centre's success rates are in line with national averages.

In 2018 the centre reported 12 cycles of partner insemination with no clinical pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

[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 $p \leq 0.002$.

Multiple births[2]

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

Between 1 August 2018 and 31 July 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 5%. 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 inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and review the centre's own witnessing audit. 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, 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 not effective because:

- One sample of sperm remained in storage even though the statutory storage period ended on 2 November 2019. The patient had confirmed in September 2019 that they wished to allow their gametes to perish.
- One set of eggs remained in storage even though the statutory storage period ended on 17 November 2019. The patient has expressed a desire to extend storage, due to premature infertility, but has failed to return completed storage consent forms.

See 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 and staff in the laboratory were able to carry out their activities without distraction.

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

[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%.

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 and consent to storage.

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

We also consider 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
- extension of storage consent
- 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 content of the centre's website
- the centre's audit of legal parenthood

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: media, media supplements, vitrification kits; sperm prep kits and laboratory plasticware. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support

New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

Patient feedback

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. 34 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. The majority of patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting friendly, caring, professional staff and the homely atmosphere at the clinic.

During the inspection the inspectors spoke to one patient couple who also provided positive feedback on their experiences.

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 fully compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the targeted interim inspection in 2018, recommendations for improvement were made in relation to two critical, three major and one 'other' areas of non-compliances or poor practice.

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 targeted interim inspection in September 2018, 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 15 November 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 that inspection in September 2018, 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. Eight sets of

records where treatment with donor sperm has 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 are partially compliant with HFEA requirements. This is because the centre's most recent legal parenthood audit, completed between October and November 2019 identified several non-compliances. In one case, involving patients returning for treatment, the intended legal parent completed a new PP form with errors which may have undermined the quality of the consent. The centre sought legal advice regarding this audit finding, prior to the inspection, and have resolved the concerns identified. The audit also reported one case in which an offer of counselling could not be identified, several where inappropriate consent forms were used to capture consent to posthumous birth registration (e.g. PP form instead of PBR form), and one in which a PBR form was not present.

See recommendation 2.

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

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	Executive review
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	Executive review
1. **Storage of gametes and embryos** On the day of the inspection the centre did not have written effective consent for the storage of cryopreserved gametes for two sets of patients. Schedule 3, 8(1) HF&E Act 1990 (as amended), SLC T57	The PR should ensure that written effective consent is in place for all gametes and embryos in store. The PR should resolve both cases where gametes are being stored without written effective storage, providing confirmation when responding to this report. The PR should perform a root cause analysis of each case to discover why gametes were being held in storage without appropriate written consent. A report of the findings should be	In one case the discard has been accomplished. In the other , the necessary form for extended storage has been received	The Executive acknowledges the PR’s response and assurance that the both cases have been resolved. The PR has committed, via email, to provide the root cause analysis within the required timeframe. Further action required.

	submitted to the centre's inspector by 16 March 2020.		
2. Legal Parenthood The centre's audit of legal parenthood consent identified the following non-compliances; • One case in which a new PP form had been completed with errors when patients returned for treatment. • Inappropriate use of the PP form instead of the PBR form, and a missing PBR form. • One case where the auditor was unable to identify an offer of counselling. Schedule 3, 8(1) HF&E Act 1990 (as amended), SLC T58, SLC T61.	The PR should ensure that appropriate legal parenthood consent forms are correctly completed. The PR should ensure that counselling is offered prior to taking consent, and that the offer is appropriately documented in patient records. In the one case where this was unclear, the PR should complete a full review of the patient record, for evidence an offer of counselling was made. A report of this review should be provided when responding to this report. When responding to this report, the PR should provide a copy of the root cause analysis, due to be completed as part of the corrective actions identified in the audit report.	The offer of counselling was recorded on the donor sperm order sheet. The counselling had beeen undertaken at Birmingham Women's Hospital but the couple had transferred here. Version 5 of the pp form had been completed correctly on 7/3/19. Version 6 was completed on 29/03/19 but the final declaration was not signed. Legal opinion confirmed that the intention was clear. THe PBR case involves an ongoing pregnancy and there are no further embryos in storage from this treatment.	The Executive acknowledges the PR's response and assurance that an offer of counselling was present in the relevant patient record. The PR has provided the root cause analysis as requested. No further action required.

	Further actions may be recommended once the PR has responded to this report.		

‘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	Executive review
None			

Additional information from the Person Responsible