Executive Licensing Panel - minutes

Centre 0070 The Bridge Centre London

Interim Inspection Report

Wednesday, 1 August 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Niamh Marren Kathleen Sarsfield Watson	Director of Strategy and Corporate Affairs Regulatory Policy Manager Communications Manager
Members of the Executive	Richard Chamberlain Bernice Ash	Temporary Committee Clerk Committee Officer
Observers	Catherine Burwood	Senior Governance 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:

- 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 Bridge Centre is located in London and has held a licence with the HFEA since 1992. Until January 2015 the centre provided a full range of fertility services including embryo testing. The centre had also provided a UK based egg sharing programme, offering treatment using donated eggs, and was the primary centre for a large network of satellite and transport centres. The centre was inspected on 10 April 2018.

1.2. In 2016 the PR informed the HFEA that treatments offered at the centre were limited to partner insemination treatment. The centre had been extensively refurbished, and the embryology laboratory decommissioned, albeit retaining embryo cryostorage facilities. Patients requiring treatment involving the creation of embryos or the use of donor sperm were to be treated at the London Women's Clinic, centre 0105, under a satellite agreement.

1.3. On 9 September 2016 the Executive Licensing Panel agreed to the renewal of the centre's treatment and storage licence but applied an additional condition to the licence issued, i.e. removing the licensing of activities involving the creation of embryos. It permitted storage and distribution - to allow embryo cryostorage and transport to centre 0105 for use in treatment to continue.

1.4. The panel noted that the centre provides partner insemination treatments only. Eight cycles of treatment with no pregnancies were provided in 2017. There were no multiple pregnancies resulting from the insemination treatments in 2017.

1.5. At this inspection the PR confirmed no change to licensed activities at the centre, and that it undertakes the following activities:

- Sperm donor recruitment and selection
- Donor sperm procurement, processing, cryostorage and distribution
- Partner insemination
- Egg donor recruitment and selection
- Satellite service with centre 0105 as the primary centre, for all aspects of fertility treatment and egg donation.

1.6. The PR outlined a plan to re-introduce insemination treatment using donor sperm at the Bridge Centre. The inspection team considered this plan and noted that its implementation would not require an application to amend the centre's licence.

1.7. The panel noted that the centre has not performed reportable treatments apart from partner insemination and two donor insemination cycles therefore no risk tool alerts have been generated.

1.8. The panel noted that there were no critical areas of non-compliance, nor major areas of non-compliance. 'Other' areas of non-compliance related to audits of legal parenthood which the PR was due to supply to the lead inspector by 10 September 2018; and the use of medical devices not marked with the appropriate CE marking that was to be rectified by 10 November 2018.

1.9. The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence. In particular the inspectorate noted both levels of performance have been maintained since the last inspection in 2016, and noted the enthusiasm and engagement of the team with regards to the PR's vision for the future of the centre.

2. Decision

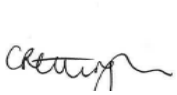
2.1. The panel were pleased to hear that the PR had confirmed that he had complied with both recommendations made in the inspection report.

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

28 August 2018

Interim Licensing Report

Centre name: The Bridge Centre
Centre number: 0070
Date licence issued: 1 October 2016
Licence expiry date: 30 September 2020
Date of inspection: 10 April 2018
Inspectors: Janet Kirkland and Andrew Leonard
Dare of Executive Licensing Panel: 1 August 2018

Additional conditions applied to this licence: Following a variation of the licence at the PR's request in 2016, an additional condition was added to the licence:

a) The centre is not permitted to carry out the following activities:
- creation of embryos in vitro
- procuring embryos
- keeping embryos
- processing embryos
- placing any permitted embryo in a woman
- using embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques.

The Person Responsible is also the Licence Holder (LH) for the centre. He has, since the inspection, informed the centre's inspector of his intention to apply to vary the licence and has identified a suitable individual for the position of Licence Holder.

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 a short notice 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 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 both that levels of performance have been maintained since the last inspection in 2016, and the enthusiasm and engagement of the team with regards to the PR's vision for the future of the centre.

The ELP is asked to note that this report makes recommendations for improvement in relation to two 'other' areas of non compliance or poor practice as follows:

'Other' areas of practice that require improvement:

- The PR should ensure that the audit methodology used to review the practice of patients providing consent to establish legal parenthood, includes consideration of evidence that an offer of counselling is made prior to the completion of consent forms;
- The PR should ensure that appropriately CE marked medical devices are used where possible.

Since the inspection the PR has confirmed that he has complied with both of these recommendations.

Information about the centre

The Bridge Centre is located in London and has held a licence with the HFEA since 1992.

Until January 2015 the centre provided a full range of fertility services including embryo testing. The centre also provided a UK based egg sharing programme, offering treatment using donated eggs, and was the primary centre for a large network of satellite and transport centres.

In 2016 the PR informed the HFEA that treatments offered at the centre were limited to partner insemination treatment. The centre had been extensively refurbished and the embryology laboratory decommissioned, albeit retaining embryo cryostorage facilities. Patients requiring treatment involving the creation of embryos or the use of donor sperm were to be treated at the London Women's Clinic, centre 0105, under a satellite agreement.

On 9 September 2016 the executive licensing panel agreed to the renewal of the centre's treatment and storage licence but applied an additional condition to the licence issued, removing the licensing of activities involving the creation of embryos. It permitted storage and distribution - to allow embryo cryostorage and transport to centre 0105 for use in treatment to continue.

At this inspection the PR confirmed no change to licensed activities at the centre, and that it undertakes the following activities:

- Sperm donor recruitment and selection
- Donor sperm procurement, processing, cryostorage and distribution
- Partner insemination
- Egg donor recruitment and selection
- Satellite service with centre 0105 as the primary centre, for all aspects of fertility treatment and egg donation.

The PR outlined a plan to re-introduce insemination treatment using donor sperm at the Bridge Centre. The inspection team considered this plan and noted that its implementation would not require an application to amend the centre's licence.

The PR also explained that the refurbishment of the centre went well but further work to the top floor of the premises, involving moving the cryostore, is being considered. The PR acknowledged this will require an application to vary the premises, and committed to keeping the centre's inspector informed.

The PR described some restructuring of the centre team. He is confident that the changes made will improve the services offered to patients and increase patient satisfaction, in addition to ensuring that the centre and its team continue to progress and maintain compliance.

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

The centre team provides partner insemination treatments only. Eight cycles of treatment with no pregnancies were provided in 2017.

Multiple births

The single biggest risk of fertility treatment is a multiple pregnancy. There were no multiple pregnancies resulting from the insemination treatments in 2017.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of sperm and eggs (gametes) or embryos and that identification errors do not occur.

There were no activities being performed in the laboratory on the day of the inspection. The Scientific Inspector was able to discuss the witnessing procedures with centre staff and to review records that were present in the laboratory. The inspection team concluded that witnessing practices and documentation are compliant.

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 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.

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients 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 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 legal parenthood.

The centre's procedures for auditing and acting on the findings of audits are broadly compliant with requirements as the audit methodology used for auditing effective consent to legal parenthood did not appear to review whether evidence was available that counselling had been offered to patients, prior to them signing legal parenthood consent forms (recommendation 1).

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 generally effective in ensuring compliance with guidance issued by the HFEA, with the exception of the use of two medical devices which were CE marked but not at the appropriate level, as discussed below.

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 medical devices in use in the laboratory was reviewed. We found the centre to be broadly compliant with HFEA requirements to use CE marked medical devices wherever possible because the following two medical devices were CE marked, but not at the appropriate level:

- Cryovials
- Semen collection pots

(recommendation 2).

Patient experience

On the day of the inspection there were no patients 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.

We discussed the feedback mechanism with the quality manager: she informed us that the centre has three opportunities for patients and donors to provide feedback: by email, by an internet based system (‘survey monkey’) and by paper questionnaires.

The centre’s most recent audit of feedback was discussed on the inspection. We were informed that the scope of the audit was from January 1 – December 31 2017 and included 3000 individuals contacted – current patients, potential patients who have made enquiries and patients who have completed treatment. The centre team had not finalised the audit findings however one action point was that they propose to redesign information provided by the centre to patients. From the basic analysis and from discussion and observations made on the inspection visit it was assessed 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, indicate that the centre is compliant with HFEA requirements, with the exception of the issues identified in the body of the report.

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 one critical, three major and four '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

The centre has not performed reportable treatments apart from partner insemination and two donor insemination cycles therefore no risk tool alerts have been generated.

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.

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 April 2016 legal parenthood consenting processes were found to be robust.

Treatments with donor gametes are generally not performed at The Bridge Centre, although one patient did receive insemination treatment there earlier this year, at her request because she had previously received such treatment at the centre before the activities provided changed in 2016. Patients are normally treated with donor sperm under a satellite agreement with London Women's Clinic (0105). Responsibility for auditing consent to legal parenthood within the satellite activities, ultimately lies with London Women's Clinic, although audits are performed at The Bridge Centre.

The team at The Bridge Centre consult with satellite patients, providing information and ensuring that effective consent to legal parenthood is in place. The Bridge Centre team have audited this aspect of their activities and the inspection team reviewed the legal parenthood audits from October 2017 to March 2018; the audits reported no non-conformances. The audit methodology did not however include a review of evidence whether the patients had been offered counselling (recommendation 1).

The Quality Manager repeated the audit after the inspection to include evidence of the offer of counselling and it was found to have been offered in all cases.

The inspection team also saw evidence of the most recent audit of the satellite centre by the primary centre London Women's Clinic, performed on 30 January 2018. The consenting processes used at The Bridge Centre were reported by this satellite audit to be compliant with requirements related to consent to legal parenthood.

The centre's inspector will inform the PR of London Women's Clinic of the non-compliance with CH14(01).

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
None			

‘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
1. Audits of legal parenthood consenting were not performed as described in Chief Executive’s letter 14(01) because they did not include a review of evidence that counselling had been offered prior to legal parenthood consents being signed. SLC T36	The PR should ensure, with immediate effect, that the audit methodology for legal parenthood includes a review of evidence of the offer of counselling prior to the completion of legal parenthood consent forms. The PR should, in responding to the report provide the HFEA with assurance that all patients attending for treatment with donor gametes are offered counselling prior to consenting to treatment.	The audit methodology for compliance with pp/wp legal requirements has now been amended to ensure clear analysis of the accuracy of the pp/wp HFEA forms and to evidence the offer of counselling. This framework has also been applied to the audit of PBR form use. These audits will be completed on a 3 monthly basis. The counselling checklist has also been amended to make direct reference to discussions surrounding the importance of these forms in particular within	The PR’s response is acknowledged. The PR should ensure that an audit is performed three months after the corrective actions have been implemented and provide the lead inspector with a summary of the audit results. By 10 September 2018.

		the framework of ensuring informed consent. The counselling audit schedule has been increased to 3 monthly to ensure compliance to the new checklist.	
2. The following medical devices used by the centre are not CE marked at an appropriate level: • Cryovials • Semen collection pots SLC T30	We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that the centre provides to patients. In consideration of this, the PR should inform the HFEA in his response to the report, either of the anticipated time by which appropriate CE marking is expected to be obtained for the two devices at issue, or of the action that will be taken to ensure compliance within the next six months. The PR should also include information regarding any action taken to mitigate any risks resulting from the use of inappropriately CE marked products. This information should be provided at the time of responding to this report	With guidance from our HFEA inspector, efforts were made to replace the non CE marked products in the laboratory. Semen collecting pots: Although apparently CE marked at the time of inspection, on closer scrutiny it was noted that the product number was not appropriately associated. Following discussion with the manufacturer, they confirmed that the marking was a 'self-certification'. Immediate action was taken to identify a suitable alternative. A number of samples were provided	The PR's response is acknowledged. The lead inspector must be informed when a suitable alternative to the cryovials has been identified. By 10 November 2018.

		for evaluation. A suitable alternative was identified and use was commenced on the 19th April 2018. Prior to commencement other licensed laboratories were contacted to confirm effectiveness of the product. The change in product and batch was carefully logged on the RI witness system traceability module to provide transparent evidence at a later date if required. Cryovials: it was noted that the cryovials in use at the time of inspection were CE marked but with no number specification. It was then confirmed by the manufacturer (Thermo Scientific) that the product was IVD suitable only. This was following the discontinuation of the manufacturers IVF line	

		and the replacement line being provided. Research being undertaken to find a CE marked (IVF appropriate) alternative has so far been fruitless. Therefore we continue to use the same cryovial whilst research continues. This is under the understanding that the product must be replaced with 6 months of the inspection. In parallel to this work, the consumable 6 monthly audit has been amended to include reference to the confirmation of CE marking on products used in the laboratory and clinical areas.	

Additional information from the Person Responsible