Executive Licensing Panel - minutes

Centre 0100 (Bourn Hall Clinic)

Interim Inspection Report

Friday, 15 December 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Juliet Tizzard (Chair) Caylin Joski-Jethi Howard Ryan	Director of Strategy & Corporate Affairs Head of Intelligence Data Analyst
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 Bourn Hall Clinic is located on the outskirts of Cambridge and has held a treatment and storage licence with the HFEA since 1992. The centre provides a full range of fertility services.

1.2. The panel noted that, in the 12 months to 31 August 2017, the centre provided 1879 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels, this is a large centre.

1.3. The panel noted that the Person Responsible (PR) had submitted an application to vary their licence to include embryo testing. The report of this assessment will be considered by the panel at the same time as this interim inspection report.

1.4. The panel noted that the inspection took place on 10 October 2017.

1.5. The panel noted that at the time of the inspection, three major non-compliances concerning FET success rates, the Quality Management System (QMS) and the provision of information to the HFEA, were identified. There was also one 'other' area of non-compliance regarded infection control. The panel noted that since the inspection, the Person Responsible had given a commitment to implementing all the recommendations within the prescribed timescales.

1.6. The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence, particularly noting progress made by the centre in meeting the HFEA's multiple birth rate target.

2. Decision

2.1. The panel expressed concern regarding the centre's poor FET success rates, but noted the PR's engagement and acknowledged that planned actions seem to be having an effect. The panel urged the centre to address the outstanding non-compliances to improve the quality of service to patients.

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

Juliet Tizzard

Date

20 December 2017

Interim Licensing Report

Centre name: Bourn Hall Clinic
Centre number: 0100
Date licence issued: 1 April 2016
Licence expiry date: 31 March 2020
Additional conditions applied to this licence: None
Date of inspection: 10 October 2017
Inspectors: Karen Conyers (lead), Janet Kirkland
Date of Executive Licensing Panel: 15 December 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 (SLCs).

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. For 2015-2017 the foci of 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

The inspection team recommends the continuation of the centre's licence. In particular we note the progress made by the centre in meeting the HFEA multiple birth rate target.

The ELP is asked to note that the following recommendations for improvement are made in relation to three major and one 'other' area of non-compliance or poor practice:

Since the inspection visit the PR has given a commitment to implementing the following recommendations in the prescribed timescales:

Major areas of non-compliance:

- The centre's success rates for frozen embryo transfer (FET) in women under 40 years old are lower than the national average at a statistically significant level.
- The PR should ensure that the centre's quality management system (QMS) and auditing processes are effective in identifying and implementing appropriate corrective actions in response to audit findings.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

'Other' area of non-compliance:

- The PR should ensure infection control and prevention practices comply with statutory requirements and best practice guidance.

Information about the centre

Bourn Hall Clinic is located on the outskirts of Cambridge and has held a treatment and storage licence with the HFEA since 1992. The centre provides a full range of fertility services. Other licensed activities at the centre include storage of gametes and embryos. The current licence has not been varied.

The centre provided 1879 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2017. In relation to activity levels, this is a large centre.

The PR has submitted an application to vary their licence to include embryo testing. The executive reviewed this application in a desk based assessment of documents provided by the centre prior to the interim inspection visit. The report of this assessment is being considered by the ELP at the same time as this interim inspection report.

Details of Inspection findings

Quality of Service

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

Pregnancy outcomes[1]

HFEA held register data for the year ending 31 May 2017 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exception:

- clinical pregnancy rates following FET in patients aged less than 40 years are lower than average at a statistically significant level (recommendation 1).

In August 2017, the centre received a risk tool alert relating to this success rate. The centre's success rate in relation to FETs was discussed with the PR and centre staff during the renewal inspection in 2015. Since the renewal inspection the centre's inspector has been in regular contact with the PR who has continued to keep this area of practice under regular review, however the outcomes still remain lower than national average.

In 2016, the centre reported 20 cycles of partner insemination with three clinical pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

Multiple births[2]

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

HFEA held register data for the year ending 31 May 2017 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14.9%. This

[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%.

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 procedures with staff and to review witnessing documentation in patient records. These activities indicate 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, the centre's 'bring-forward' system was discussed with staff and reports of audits of stored gametes and embryos and the centre's storage logs 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 effective.

Staffing

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

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and confirmed that they 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, patient records, medicines management and infection control.

The centre's procedures for auditing and acting on the findings of audits are broadly compliant with requirements (recommendation 2). The centre's 'patient records audit' noted that a MT form had not been signed, and one couple had not had the welfare of the child assessment repeated prior to a subsequent treatment. However, the audit report did not document if there had been any immediate corrective actions to resolve these issues, or to consider how these omissions had been missed prior to treatment.

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

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 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 centre's process for administering and monitoring patients during intralipid infusion are undertaken in accordance with the Bourn Hall group's practices. These were reviewed and

considered to be compliant in a recent inspection of centre 0325 in November 2016 and were therefore not re-inspected in detail during 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 broadly compliant with guidance because one of the rooms used for phlebotomy does not have any handwashing facilities (recommendation 4).

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 during the inspection: culture medium, vitrification and warming medium, culture dishes, plastic ware. 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 one patient about their experiences at the centre. Centre staff provided their most recent analysis of patient feedback from August 2017, which had been collated from 44 questionnaires handed out at the first consultation and after egg collection. The inspection team noted several positive comments and centre staff confirmed that all feedback was discussed at monthly management meetings, and actions taken to address individual concerns raised.

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; and
- 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 compliant with HFEA requirements.

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 one critical, six major and six 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales. One area of non-compliance in relation to the QMS has been noted again on this inspection.

On-going monitoring of centre success rates

Since the last renewal inspection in September 2015 the centre has received four risk tool alerts related to multiple pregnancy rates, clinical pregnancy rates following IVF in patients aged less than 38 years, and clinical pregnancy rates following ICSI in patients aged less than 38 years. For each of these the PR responded appropriately, providing a commitment to keep success rates in this group of patients under review. Outcomes in these patient groups are now in line with national averages and the multiple pregnancy rate is meeting the HFEA target.

In addition, the centre received a risk tool alert relating to FET in patients aged less than 40 years which is discussed in the 'Pregnancy outcomes' section above.

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 partially compliant with requirements to submit information to the HFEA as there are a large number of data submission issues related to validation errors and late or missing information (recommendation 3). A copy of these reports has been provided to the centre to address.

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 three couples were affected by legal parenthood consent anomalies.

One couple sought a declaration through the courts in 2015 and the other two couples did not, and still do not, wish to pursue any further actions.

At the inspection on 22 September 2015, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA. Appropriate 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 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. Five sets of records where treatment with donor sperm had recently been provided, in circumstances where consent to legal parenthood was required, were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas of non-compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical 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	Executive review
None identified			

‘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	Executive review
FET success rates: 1. The centre’s success rates for FET in women under 40 years old are lower than the national average at a statistically significant level. The inspection team acknowledges the efforts taken so far by the PR and centre staff, and his commitment to addressing the success rate in the group of patients identified.	The PR should continue to address the pregnancy success rate for the patient group identified as currently being lower than national average. The PR should provide the centre’s inspector with a review of the centre’s success rate for FET in patients under 40 when responding to the report. Following this, the PR should provide quarterly updates on the actions taken to address the success rate for FET in patients less than 40, with a	We have reviewed the success rates for FET in women under 40 and have found no obvious cause for the lower rates earlier in 2017. We have now adopted the BHC Norwich drug FET preparation protocols at BHC Cambridge and have confidence that this drug regime works, since high FET rates have been achieved in our Norwich clinic. The results for this group have improved between May and September 2017 (Septembers clinical pregnancy rate for this group was 39.5%) and this	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The PR has provided all the requested information in relation to this area of practice. Further updates in January and April 2018 are awaited. **Further action is required**.

	goal of improving this success rate by 10 April 2018.	should be reflected in the HFEA clinic statistics over the coming months. We will monitor and provide quarterly updates on any actions taken to address the success rate for this group of patients.	
QMS 2. The centre's 'patient records audit' noted non-conformances but did not document if there had been any immediate corrective actions to resolve these issues, or to consider how these non- conformances had been missed prior to treatment. SLC T36. It is noted that the HFEA's assessment framework recommends classification as an 'other' non-compliance but, in consideration that a similar recommendation was made with regard to the QMS at the time of the renewal inspection, this	The PR should ensure that the centre's QMS and auditing processes are effective in identifying and implementing appropriate corrective actions in response to audit findings. The PR should review audit findings since the time of the last inspection in September 2015 to ensure that these are clearly documented and reviewed, and have led to the implementation of appropriate corrective actions. A summary report of the findings of these reviews including corrective actions, with timescales for implementation, should be provided to the centre's inspector by 10 January 2018.	A review of audit findings from September 2015 will be conducted. A report of the findings will be provided by 10 January 2018.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The findings of the review due by 10 January 2018 are awaited. **Further action is required**.

has been graded as a major non-compliance.			
Provision of information to the HFEA 3. There are a large number of data submission issues related to validation errors and late or missing information. General Direction 0005.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should ensure that the issues identified are addressed. A summary of the progress made in addressing these issues, and the timescales for completion should be provided to the centre's inspector with the PR's response to this report. The PR should review the systems and processes used for licensed treatment data submission to identify the reasons for this non-compliance. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 10 January 2018.	We run the error reports on a monthly basis and correct the errors at this point. We are reviewing the process of submitting data and propose implementing a revised group-wide process by the end of March 2018. We will then audit the process 3 months after this i.e. July 2018 and provide a summary report.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR and centre staff have provided a summary of the actions that have been taken, and the executive notes that these have been effective in clearing a number of the data issues noted. Given that the scale of the issues identified at this centre have not been seen at other centres across the group in their recent inspections, the executive considers that immediate and further actions would be expected to be taken by centre 0100 as a result of the review due to be completed by 10 January 2018. Therefore, it is expected that the audit of the effectiveness of changes to practice requested by 10 April

	The PR should audit the effectiveness of changes introduced in this area of practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 10 April 2018.		2018 should also be undertaken. Group-wide actions and audits planned by the PR would no doubt provide further assurance that licensed treatment activity is reported to the Authority accurately and in a timely manner across all centres within the group. The findings of the review due by 10 January 2018 and audit due by 10 April 2018 are awaited. **Further action is required**.

‘Other’ areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
Infection Control 4. One of the rooms used for phlebotomy does not have any handwashing facilities. SLC T17 and Health Building Note 00-09: Infection control in the built environment, 2013.	The PR should ensure infection control and prevention practices comply with statutory requirements and best practice guidance. The PR should review the usage of the room and its need for handwashing facilities. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre’s inspector with the PR’s response to this report. The PR should also review the centre’s infection control and prevention practices to include consideration of auditing compliance in this area of practice and suitability of the	Use of this room for phleotomy will be temporarily suspended until a sink is installed. It is anticipated this will be completed by January 2018. The use of this room has been reviewed previously by an Infection Control Specialist from Hinchingbrooke Hospital and no concerns were raised.	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The PR has provided confirmation of the review of the usage of the room, and actions taken with regard to this finding. The findings of the review due by 10 January 2018 are awaited. **Further action is required**.

	rooms used in clinical activities. A summary of the findings of the review should be provided to the centre's inspector by 10 January 2018.		

Additional information from the Person Responsible