Executive Licensing Panel - minutes

Centre 0325 (Bourn Hall) Interim Inspection Report

Friday, 10 February 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Juliet Tizzard (Chair) Howard Ryan Jessica Watkin	Director of Strategy & Corporate Affairs Report Developer 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 Bourn Hall (Norwich) Limited has held a licence with the HFEA since May 2013 and provides a full range of fertility services. Bourn Hall (Norwich) is part of the Bourn Hall group and operates a satellite service at Bourn Hall Clinic in King's Lynn.

1.2. The panel noted that the inspection took place on 15 November 2016.

1.3. The panel noted that in the 12 months to 30 September 2016, the centre provided 471 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

1.4. The panel noted that at the time of the interim inspection, two major and two 'other' areas of non-compliance were identified. The panel noted that the PR had given a commitment to fully implementing the recommendations of the inspectorate within the prescribed timescale.

1.5. The panel noted that the inspectorate recommends the continuation of the centre's Treatment and Storage licence.

2. Decision

2.1. The panel was satisfied that 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

21 February 2017

Interim Licensing Report

Centre name: Bourn Hall (Norwich) Limited
Centre number: 0325
Date licence issued: 1 May 2015
Licence expiry date: 30 April 2019
Additional conditions applied to this licence: None
Date of inspection: 15 November 2016
Inspectors: Karen Conyers, Susan Jolliffe
Date of Executive Licensing Panel: 10 February 2017

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2015-2017 the foci of interim inspections 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, 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.

The ELP is asked to note that there are four recommendations for improvement in relation to two major areas of non-compliance and two 'other' areas of practice.

In responding to the report the PR has given a commitment to fully implementing the following recommendations in the prescribed timescales.

Major area of non-compliance:

- The PR should ensure compliance with medicines management regulations and best practice guidance.
- The PR should ensure that CE marked medical devices are used wherever possible.

'Other' areas of practice that require improvement:

- The PR should ensure that audits of witnessing include a review of electronic witnessing system alerts.
- The PR should ensure fees payable to the HFEA are made within the required timeframe.

Information about the centre

Bourn Hall (Norwich) Limited has held a treatment and storage licence with the HFEA since May 2013 and provides a full range of fertility services. Bourn Hall (Norwich) is part of the Bourn Hall group and operates a satellite service at Bourn Hall Clinic in King's Lynn.

The centre provided 471 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2016. In relation to activity levels this is a small centre.

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 30 June 2016 show the centre's success rates are in line with national averages.

For the year 2015 the centre reported five cycles of partner insemination with no clinical pregnancies. This represents a clinical pregnancy rate which is comparable to 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 30 June 2016 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The 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

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, the centre's 'bring-forward' system was discussed with staff and reports of audits of stored gametes and embryos, the centre's storage logs, and consent to 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 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 centre's audits of documentation of witnessing, consent to storage, legal parenthood and medicines' management (controlled drugs) were reviewed during the inspection.

The inspection team considered that the centre's audit practices are broadly compliant with requirements. The centre's audit of witnessing did not include an evaluation of electronic witnessing system alerts issued, for example, when a patient's details on the system do not match those on a tube or dish introduced into the workspace (see recommendation 3).

Inspectors 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 as listed above,
- 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,
- the HFEA reports of adverse incidents from 2010 to 2015 and
- the HFEA Clinic Focus articles regarding: legal parenthood consent, screening requirements, incident reporting and medicines management.

Overall, the inspection team considers that 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 partially compliant with guidance because:

- The resuscitation trolley located outside the procedure room downstairs contained four anaphylactic drugs (adrenaline, hydrocortisone, salbutamol, chlorphenamine) past their expiry date despite being checked daily by staff (see recommendation 1). It was noted that there was also a set of in-date anaphylaxis drugs in this resuscitation trolley.
- The inspection team also noted that the resuscitation trolley upstairs had four intravenous (IV) saline solutions past their expiry date, also despite being checked daily by staff (see recommendation 1).

The expired items were immediately removed from both trolleys by the Lead Nurse.

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 processes for administering and monitoring patients during intralipid infusion were reviewed and considered to be suitable. Written information provided to patients being offered intralipid therapy is 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, the inspection team 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: culture medium, vitrification and warming medium, culture dishes, plasticware. The centre is using a non-CE marked product as a medical device which is a plastic Pasteur pipette for measuring the volume of semen samples (see recommendation 2). A CE marked alternative is being sought for use in all the laboratories within the Bourn Hall group.

Patient experience

During the inspection no patients were available to speak with the inspectors about their experiences at the centre. One patient provided feedback directly to the HFEA in the time since the last inspection. The centre staff provided their most recent patient satisfaction survey where feedback was generally positive, all comments are shared with staff and any themes or trends are noted, and action is 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;
- 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 there are no further areas of practice that require improvement.

Since the time of the last renewal inspection the centre has been issued with two risk tool alerts related to the late payments of HFEA invoices, which is non-compliant with the requirements of the Authority (see recommendation 4).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2014, recommendations for improvement were made in relation to five major and three 'other' areas of non-compliance.

The PR subsequently provided information and evidence that all the recommendations were fully implemented within the required timescales. However, one area of non-compliance was also found on this inspection: the use of a non-CE marked medical device (see 'Equipment and Materials' section above).

On-going monitoring of centre success rates

Since the last renewal inspection the centre has received one risk tool alerts related to multiple pregnancy rate to which the PR has responded appropriately providing a commitment to monitor outcomes and success rates in this group of patients.

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 and there are currently no significant data submission issues.

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 provided a report of the audit to the HFEA within the required timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies. At the renewal inspection in December 2014, 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 provide their assurance of the robustness of the 2014 audit, 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	Executive review
None identified during this inspection.			

‘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
Medicines management 1. The resuscitation trolley located outside the procedure room downstairs contained four anaphylactic drugs past their expiry date despite being checked daily by staff. The inspection team noted that the resuscitation trolley upstairs had four IV saline solutions past their expiry date, also despite being checked daily by staff. The expired items were immediately removed from both trolleys during the	The PR should ensure compliance with medicines management regulations and best practice guidance. The PR should undertake a review to identify the factors that have led to 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 15 December 2016. Within three months of the review, the centre should carry	I have undertaken a review of the factors that relate to the findings of out of date medication and IV solutions on the resuscitation trolley. The Head of Pharmacy introduced a medicine box which included all drugs required. This resulted in a anaphalaxis box to be redundant. As this was still in date she added it to the new box. The new box was sealed and dated. The trolley check was undertaken and as the date on the box was current the nurses did not open the box and therefore did not	The executive acknowledges the PR’s response and her commitment to fully implementing this recommendation. The PR has provided the requested review and a summary of the corrective actions implemented. The executive awaits the report of the audit due by 15 March 2017. Further action is required.

inspection. SLC T2 and Clinic Focus July 2015: ‘Management of medicines’.	out an audit of this area of practice to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre’s inspector by 15 March 2017.	appreciate that the 'old' anaphalaxis box was inside and out of date. This item has been removed and appropriately discarded. The out of date anaphylaxis kits have been removed, and the nurses and doctors have been made aware that all anaphylaxis medicines are now in the emergency drugs box. SOP PH040 and associated forms (Date checking matrix, as amended for Norwich, and Drugs due to expire form) has been highlighted to Norwich clinic. The Head of Pharmacy and Lead Nurse will agree who is to be responsible for the maintenance of these forms. This error occurred when introducing a new drug box and is unlikely to occur again. The IV fluids were 500ml bags. When the nurse checked these and were out of date there were no 500ml bags to replace. The nurse added a 1l bag (in date) however did not	

		remove the 500ml bags. The nursing staff have had this issue raised with them, and aware of the importance of checking and removing out of date stock. Actions put in place include an extra resuscitation trolley check by a Senior Nurse on a monthly basis. An audit will be undertaken and sent through to you by 15th March 2017	
Equipment and materials 2. The centre is using a non-CE marked product as a medical device: a plastic Pasteur pipette for measuring the volume of semen samples. SLC T30. In consideration that the use of non-CE marked medical devices was an issue at the renewal inspection and similar recommendations have been made across the Bourn Hall group, this has been graded as a major non-compliance.	The PR should ensure that CE marked medical devices are used wherever possible. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. However, in view of the assurances that the centre is already sourcing an alternative product it is expected that this action will be addressed by 15 February 2017. It is also expected that all centres within the group will address this issue, if applicable to that centre, by 15 February 2017.	As was explained to the inspector during the visit.This product was CE marked as an IVD, and was validated in-house to ensure it's safety and efficacy. (before any class II products were available). The last stock we took delivery of was noticed not to bear any CE. MB immediately queried this with the manufacturer (01/11/2016 email evidence available), who responded that the removal of CE was in direct response to 2014 EU guidance making it illegal to CE mark certain products. When asked why customers had not been made aware of this the	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The executive acknowledges the actions being taken across the group and awaits confirmation that this has been addressed by 15 February 2017. The executive notes that a plastic Pasteur pipette that is CE marked as a medical device has been available for some time.

		manufacturer apologiesd and copied the letter sent out in March last year (copy available), this letter also states that the product is identical in every way to that which was CE'd, hence an immediate change to an un-tested product was not considered appropriate. We would like to point out that at the time of the inspection the removal of CE marking had been noticed by the laboratory staff and an alternative Class II CE marked product (Repromed, 113421) was already undergoing evaluation and acceptance testing. Furthermore the unnanounced removal of the CE mark by a long term supplier was outsiden of the control of Bourn Hall Ltd. and should not in any way be interpreted as a failure to comply with previous HFEA recommendations. We believe that our vigilence in spotting the removal of CE marking, in the absence of notification from the manufacturer along with our	The PR is reminded of the HFEA guidance issued in a Clinic Focus article in September 2016 that when a product is being used as a medical device it is expected that the CE marking is appropriate for that use, i.e. as a medical device rather than as an in vitro diagnostic device (IVD). Further action is required.

		immediate action to source an appropriate alternative demonstrates the robustness of our systems and that this finding should not be classed as major. Assuming the Repromed product passes our validation and acceptance testing it will be in place before the February 2017 deadline.	

‘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
Quality Management System 3. The centre’s audit of witnessing practice did not include an evaluation of electronic witnessing system alerts. SLC T36.	The PR should ensure that audits of witnessing include a review of electronic witnessing system alerts. The PR should conduct an audit of the centre’s electronic witnessing system alerts since the time of the last inspection to assess whether any alerts may have resulted in an actual mismatch of gametes or embryos, or any identification errors. The PR should review the centre’s processes to ensure that electronic witnessing system alerts are assessed regularly and update staff training and competency in using the electronic witnessing	Future audits of witnessing will incoroporate a review of witnessing system alerts. An audit of electronic witnessing alerts since the last inspection will be conducted in the timeframe specified. The Lead Embryologist will review the electronic witnessing system alerts monthly, and update relevant staff training where necessary. This process will be included in SOP EM003-WI48 by February 2017.	The executive acknowledges the PR’s response and her commitment to fully implementing this recommendation. The executive awaits the reports of the audit and review of the centre’s processes by 15 February 2017. Further action is required.

	system in relation to actions to be taken when an alert has been issued. A summary report of the audit and review including corrective actions, and the timescales for their implementation, should be provided to the centre's inspector by 15 February 2017.		
Person Responsible 4. Fees payable to the HFEA have not always been paid within the required timeframe. SLC T9d and CH (10)02.	The PR should ensure fees payable to HFEA are made within the required timeframe. The PR should take appropriate action to ensure that all HFEA invoices are paid within the timescales specified by the Authority, and advise the centre's inspector of these actions by 15 February 2017.	I have requested a review of payments by the Finance Director and will advise the inspector of actions by 15th Feb as requested..	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The executive awaits an update on actions taken in relation to this area of practice by 15 February 2017. Further action is required.

Additional information from the Person Responsible