Executive Licensing Panel - minutes

Centre 0295 (Bristol Centre for Reproductive Medicine)

Interim Inspection Report

Friday, 9 September 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) David Moysen Jessica Watkin	Head of Business Planning Head of IT Policy Manager
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
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 Bristol Centre for Reproductive Medicine is located in Southmead Hospital, Bristol and has held a treatment and storage licence with the HFEA since 2007. The centre provides a full range of fertility services.

1.2. The panel noted that the centre's licence is due to expire on 18 December 2018.

1.3. The panel noted that the inspection took place on 14 June 2016.

1.4. The panel noted that in the 12 months to 31 May 2016, the centre provided 980 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

1.5. The panel noted that for the period 1 March 2015 to 28 February 2016, HFEA-held register data for IVF and ICSI, showed the centre's success rates were in line with national averages with the following exception:

- the clinical pregnancy rate following IVF in women aged 38 years and over is significantly higher than the national average.

1.6. The panel noted that in 2015, the centre reported 169 cycles of partner insemination with 25 pregnancies. This represents a clinical pregnancy rate of 15% which is likely to be in line with the national average.

1.7. Between 1 March 2015 and 28 February 2016, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 15%. This means that the centre's multiple live birth rate is likely to meet the 10% maximum multiple live birth rate target for this period.

1.8. The panel noted that at the time of the renewal inspection on 14 June 2016, one major and four other areas of non-compliance were identified. The panel noted that the Person Responsible (PR) has committed to implementing all of the recommendations.

1.9. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices.

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

2. Decision

2.1. The panel had regard to its decision tree.

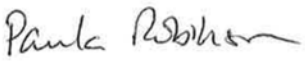
2.2. The panel was satisfied that the centre was fit to have its treatment and storage licence continued.

2.3. The panel noted that there are recommendations with timescales for implementation set shortly after this Executive Licensing Panel meeting and agreed that the inspectorate should provide the panel with an update, at the next available meeting, confirming whether the outstanding recommendations were implemented within the prescribed timescales.

3. Chair's signature

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

Signature



Name

Paula Robinson

Date

16 September 2016

Interim Licensing Report

Centre name: Bristol Centre for Reproductive Medicine
Centre number: 0295
Date licence issued: 19 December 2014
Licence expiry date: 18 December 2018
Additional conditions applied to this licence: None
Date of inspection: 14 June 2016
Inspectors: Grace Lyndon (Lead), Andrew Leonard
Date of Executive Licensing Panel: 9 September 2016

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 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 the inspection team note the IVF pregnancy rate results for patients aged 38 and over which is significantly above the national average.

The ELP is asked to note that there are recommendations for improvement in relation to one major and four 'other' areas of non compliance or poor practice as follows:

Major areas of non compliance:

- The controlled drugs cupboard should be attached to an outside or solid wall, and a review of the controlled drugs register showed that:
  - the PR should ensure that any alterations made in the controlled drugs register are made by using a margin note or footnote.
  - the PR should ensure that the amount of drug administered, the time the drug is administered and the amount of drug discarded is always documented; and
  - the PR should ensure that each entry is not consistently signed off by two staff members.

'Other' areas of practice:

- The PR should conduct a review of infection prevention and control practices to ensure that the clinical environment adheres to regulations and best practice guidance.
- The PR should complete required audits and review the audit programme to ensure it is compliant in the range of activities audited.
- The PR should review the information provided on the centre's website and should ensure it is compliant with the requirements.
- The PR should ensure that the cylinders are chained for safe storage.

The PR has committed to implementing all recommendations.

Information about the centre

The Bristol Centre for Reproductive Medicine is located in Southmead Hospital, Bristol and has held a treatment and storage licence with the HFEA since 2007. The centre provides a full range of fertility services.

The centre provided 980 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2016. In relation to activity levels this is a medium 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 period 1 March 2015 to 28 February 2016 show the centre's success rates are in line with national averages with the following exception:

- the clinical pregnancy rate following IVF in women aged 38 years and over is significantly higher than the national average.

In 2015, the centre reported 169 cycles of partner insemination with 25 pregnancies. This represents a clinical pregnancy rate of 15%. Although data for this period has not yet been analysed, this represents a clinical pregnancy rate that is likely to be in line with the national average.

Multiple births[2]

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

Between 1 March 2015 and 28 February 2016, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 15%. This means that the centre's multiple live birth rate is likely to meet the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: egg collection; removal of embryos from storage; sperm preparation; and discard of embryos. All of the procedures observed were witnessed using an electronic witnessing system, with additional manual witnessing where required, in accordance 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 inspection team discussed the 'bring-forward' system with staff and reviewed the electronic storage database and the most recent audits of stored gametes and embryos. These activities indicated that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

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[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%.

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 were 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 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 prescribed standard operating procedures (SOPs) and that the centre's processes meet 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; quality management system; legal parenthood; satellite centres; infection control; consent to storage and the patient feedback survey.

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

- the centre has not undertaken a medicines management audit (recommendation 3);
- two of its four satellite centres have not been audited for compliance, albeit their websites and the records of patients processed by these satellite have been audited (recommendation 3); and
- the centre's own infection control audit did not identify the non wipe seats used within the treatment rooms (recommendation 2).

The inspection team 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 use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood
- the timescales used for taking bloods for patient screening tests
- the management of samples in storage
- advice and information concerning Zika virus

The centre has an effective learning culture in place and has ensured compliance with guidance issued by the HFEA, notwithstanding some of the website success rate data being out of date, 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 broadly compliant with guidance because:

- the controlled drugs cupboard is not attached to an outside or solid wall, but is situated on a work surface;
- a review of the controlled drugs register showed that:
    - alterations are made by overwriting rather than using a margin or footnote;
    - the amount of drug administered, the time the drug is administered and the amount of drug discarded were not always documented;
    - each entry is not consistently signed off by two staff members.

(recommendation1)

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, inspectors reviewed infection control practices and found them to be broadly compliant with guidance. Some of the chairs and stools used within the treatment rooms have coverings which are not wipe clean (recommendation 2).

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: egg collection media; sperm preparation media; liquid paraffin; vitrification freeze and thaw media; embyoglue; PVP; cumulase; and a range of laboratory consumables used in gamete and embryo processing. The inspection team found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre however 35 patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive about the care received. The centre's own patient feedback forms were also seen in which the feedback to the centre was also positive.

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

From observations during the visit to the centre, the inspection team identified the following non compliances:

- the centre's website does not comply with Code of Practice guidance section 4.5. Some live birth success rate data is more than three years old and for most of the centre's data provided; no national success rates are included for reference. There is also no link to the HFEA advice on interpreting success rates (recommendation 4).
- medical gas cylinders are stored in an outdoor store but twelve unused and three used cylinders are not chained or secured (see recommendation 5).

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 other HFEA requirements.

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

In responding to the report immediately after the inspection, the PR had agreed to implement the recommendations, and the PR subsequently provided information and evidence that all the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

Since the last renewal inspection in June 2014, the centre received four MPR alerts however, the PR responded to them appropriately.

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 generally compliant with requirements to submit information to the HFEA. As of April 2016, the centre have had a technical issue with the electronic data interface (EDI) through which information is reported to the register. This has recently been rectified and the centre have submitted all outstanding information.

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 was reviewed at this inspection and was completed using the correct methodology. The audit showed that two couples were affected by legal parenthood consent anomalies and included appropriate corrective actions to assist the patients and to ensure legal parenthood consent was collected appropriately.

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 correspondence and provided the required assurances regarding the parenthood consent collection procedures used, staff training and competence and audit.

At this inspection, the PR provided an update concerning the two patient couples with anomalous parenthood consents described in the centre's original audit in 2014. Both couples have been fully informed of the situation and the consequences it may have, however one couple did not wish to seek legal correction at this time'.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed five sets of records where treatment with donor sperm had been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood was in place prior to treatment in all cases.

In summary, the inspection team considers 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 carried out.

Critical areas of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical area of non compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
None 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	Inspection team’s response to the PR’s statement
1. Medicines management The controlled drugs cupboard is not attached to an outside or solid wall, but is situated on a work surface. A review of the controlled drugs register showed that: • alterations were made by overwriting rather than using a method in line with the regulations; i.e. using a margin note or footnote. • the amount of drug administered, the time the drug is administered and the amount of drug discarded were not always documented. • each entry was not always	The PR should review medicines management procedures and provide a summary of actions taken in relation to observations made in this report, and steps taken to ensure compliance with broader medicines management requirements by 14 September 2016. Within three months of the implementation of corrective actions, the centre should carry out an audit of medicines management procedures to ensure that the corrective actions have been effective in ensuring compliance. A summary report of the audit should be supplied to the	Works request submitted & awaiting completion. Actioned. Compliance audit to be carried out in 3 months. Actioned. Compliance audit to be carried out in 3 months. Actioned. Compliance audit to	The Executive acknowledges the PR’s commitment to addressing this non-compliance. The Executive awaits the review in September and the audit in December. **Further action is required**

signed off by two staff members. Department of Health (DH) (2007) 'Safer Management of Controlled Drugs; a guide to good practice in secondary care (England) section 4.7.14 and section 4.11.1.1; SLC T2 and T17.	centre's inspector by 14 December 2016.	be carried out in 3 months.	

‘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	Inspection team’s response to the PR’s statement
2. Infection Control Some of the chairs and stools used within the consultation rooms have coverings which are not wipe clean. The centre’s own infection control audit did not identify the non wipe seats used within the treatment rooms. SLC T17, T23 and T36.	The PR should provide a summary of their intended actions and a timeframe when responding to this report. The PR should audit their infection control practices against regulatory requirements to ensure compliance with all elements of infection control. A summary of this should be provided by 14 September 2016.	Added to Centres Risk Register. Replacement request submitted to Directorate Management for action	We understand the PR has committed to replacing the chairs and stools, although a timeframe has not been provided. We request the PR provides an update by 14 September 2016 at which point they should also provide a summary of their audit. **Further action required.**
3. Quality Management System: The centre’s own audit programme is not suitably robust because; • the centre has not audited medicines management practices; • two satellite services have not been audited in the last	The PR should complete the outstanding audits and send a copy to the centre’s inspector by 14 September 2016.	Audit Schedule revised to include & implemented.	The Executive awaits the audits to be received before 14 September. **Further action required**

two years, nor does this area of practice feature on the audit schedule. • the centre's own infection control audit did not identify the non wipe seats used within the treatment rooms SLC T36.			
4. The centre's website The centre's website does not comply with the requirements of Code of Practice 4.5.	The PR should review the information provided on the centre's website and should ensure it is compliant with the requirements of Code of Practice 4.5. The PR should inform the inspector of the changes made by 14 September 2016.	Acknowledged and corrective update requested from Trust IT Department.	The Executive acknowledges the PR's response and his commitment to fully implement this recommendation. The Executive awaits confirmation of changes made before 14 September. **Further action required**.
5. Premises and Facilities The storage area for medical gases contains gas cylinders which are not stored securely (not chained in an upright position). British Compressed Gases Association (BCGA), guidance note 2 'Guidance for the storage of gas cylinders in the workplace', revision 5: 2012.	The PR should comply with guidance by securing the cylinders and inform the inspector once this has been completed by 14 September 2016.	Acknowledged and corrective update requested from Trust IT Department.	The Executive notes that the PR has made a commitment to fully implement this recommendation and awaits confirmation due by 14 September 2014. **Further action required.**

SLC T17.			

Additional information from the Person Responsible