Executive Licensing Panel - minutes

Centre 0119 (Birmingham Women's Hospital)

Interim Inspection Report

Tuesday, 11 September 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Caylin Joski-Jethi (Chair) Lisa Whiting Kathleen Sarsfield Watson	Head of Intelligence Data and Insights Analyst Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Julie Katsaros	Senior Governance Manager Inspector (Induction)

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 the Assisted Conception Unit at Birmingham Women's Hospital has been licensed by the HFEA since 1992 and currently holds a treatment (including embryo testing) and storage licence. The centre provides a full range of fertility services.

1.2. The panel noted that, in the 12 months to 21 May 2018, the centre provided 1261 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large sized centre.

1.3. The panel noted that other licensed activities at the centre include storage of gametes and embryos and embryo testing.

1.4. The panel noted that, between 1 March 2017 and 28 February 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.5. The panel noted that, for IVF and ICSI, HFEA held register data, for the period 1 March 2017 to 28 February 2018, shows the centre's success rates are in line with national averages.

1.6. The panel noted that, in 2017 the centre reported 16 cycles of partner insemination with one clinical pregnancy, which is in line with the national average.

1.7. The panel noted that the inspection took place on 24 July 2018.

1.8. The panel noted that at the time of the inspection, three major area of non-compliance were identified concerning CE marking, infection control and equipment and materials. Two 'other' areas of non-compliance were also acknowledged regarding medicines management and traceability. Since the inspection, the Person Responsible (PR) has given a commitment to implementing all the recommendations made in the report.

1.9. The panel noted that the inspectorate recommends the continuation of the centre's treatment (including embryo testing) and storage licence, particularly commending the centre in achieving and maintaining a significantly low multiple birth rate.

2. Decision

2.1. The panel was pleased to see the centre's multiple birth rate is in line with the 10% target and all success rates are in line with the national averages, demonstrating their commitment to delivering safe and effective care to patients.

2.2. The panel was also pleased to note the centre's commitment to gaining patient feedback, and using this to improve any issues communicated.

2.3. The panel was satisfied the centre was fit to have its treatment (and embryo testing) and storage licence continued.

3. Chair's signature

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

Signature

Name

Caylin Joski-Jethi

Date

17 September 2018

Interim licensing report

Centre name: Birmingham Women's Hospital
Centre number: 0119
Date licence issued: 1 December 2016
Licence expiry date: 30 November 2020
Additional conditions applied to this licence: None
Date of inspection: 24 July 2018
Inspectors: Louise Winstone, Polly Todd and Julie Katsaros
Date of Executive Licensing Panel: 11 September 2018

Purpose of the report

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

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

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

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we commend the centre in achieving and maintaining a significantly low multiple birth rate.

The ELP which considered the renewal inspection report at the meeting on 9 September 2016, requested that the executive provide the panel with an update, at the next available meeting, confirming whether the outstanding recommendations were implemented within the prescribed timescales. The executive apologises for the oversight in not providing this update to ELP but can confirm that all of the recommendations were implemented within the prescribed timescales.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including three major and two 'other' areas of non-compliance.

The PR has given a commitment to fully implementing the following recommendations:

Major areas of non-compliance:

- The PR should ensure that CE marked medical devices are used where possible.
- The PR should ensure adherence to infection control best practice guidance and requirements.
- The PR should ensure that all critical equipment is subject to monitoring and that corrective actions are documented.

'Other' areas of practice that require improvement:

- The PR should ensure that medicines management practice is compliant with regulatory and best practice requirements.
- The PR should ensure that all gametes are traceable from procurement to patient treatment or disposal.

Information about the centre

The Assisted Conception Unit at Birmingham Women's Hospital has been licensed by the HFEA since 1992 and currently holds a Treatment (including embryo testing) and Storage licence. The centre provides a full range of fertility services.

The centre provided 1261 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2018. In relation to activity levels this is a large centre.

Other licensed activities at the centre include storage of gametes and embryos and embryo testing.

The centre's current licence was varied in December 2016 to reflect a change of Licence Holder.

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 2017 to 28 February 2018 show the centre's success rates are in line with national averages.

In 2017 the centre reported 16 cycles of partner insemination with one clinical pregnancy, which is in line with the national average.

Multiple births[2]

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

Between 1 March 2017 and 28 February 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. This represents performance that is not likely to be statistically different from 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 with staff and review witnessing in patient records. These activities indicated that witnessing procedures are compliant with HFEA requirements.

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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 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 $p \leq 0.002$.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed 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.

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 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, consent to storage, legal parenthood consent, infection control and medicines management.

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

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, knowledge of new legal requirements on the importation and coding of gametes and embryos and awareness of consultation on HFEA Code of Practice update.

The centre has been effective in ensuring compliance with guidance issued by the HFEA with exception of the use of non-CE marked medical devices (see recommendation 1).

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:

- Staff pre-populate the page numbers for the carry-over of controlled drugs in the register. This should be done at the time of carry-over of stock and witnessed by two people.

See recommendation 4.

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 partially compliant with guidance because:

- Sharps bins in the theatre area and on the emergency resuscitation trolley had been filled above the designated fill line;
- The trim that seals the join of the flooring to the wall was coming away from the wall in several places in the male production rooms and in (what staff refer to as) the sofa room;
- In consultation room four, the curtains have not been changed since 13 June 2017, staff report that this is done on an annual basis;
- Fabric on one of the chairs in the 'recovery anti-room' is ripped;
- Soiled toilet brushes were in the patient toilets;
- The water cooler in the reception area had a daily cleaning log but the last check was documented 30 June 2018;
- A theatre gown in the theatre recovery area is used multiple times by staff to put over their uniforms when leaving the clinic areas;
- Dirty linen was stored for a long period of time in a well-used patient corridor by the lift awaiting collection.

See 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 all medical devices was reviewed in the course of the inspection. We found the centre to be partially compliant with HFEA requirements to use CE marked medical devices wherever possible because the following medical devices are not CE marked for their intended purpose: sperm collection pots and flush media used during egg collection.

See recommendation 1.

Patient experience

During the inspection, the inspectors spoke to one patient couple about their experiences at the centre. This feedback was positive. The centre’s most recent patient feedback, collected between 1 April 2017 and 31 March 2018 and which included responses from 191 patients, was also reviewed. This feedback was generally positive. The negative comments that were received included concerns regarding delays and waiting times. This was discussed with the PR who provided evidence and assurance that all negative feedback is actively responded to and actions are taken.

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 the centre is compliant with HFEA requirements with the following exceptions:

- The discard of sperm that is not used in treatment is not recorded for traceability purposes (see recommendation 5).
- The fridge in the andrology laboratory that is used to store media for the preparation of sperm for use in treatment is not subject to temperature monitoring (see recommendation 3).
- The drug fridge is not monitored appropriately. A traffic light system is used to record the monitoring of the drug fridge temperature with a supplementary page for documenting actions when a deviation is detected from the green section. On one

particular day, there was a tick in the amber box, but no action recorded (see recommendation 3).

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 six 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

Since the last renewal inspection in June 2016, the centre has received one performance related risk tool alert relating to clinical pregnancy rates for IVF in women aged under 38, to which the PR responded 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 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 June 2016, legal parenthood consenting processes were found to be robust.

To provide assurance of the compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures and the legal parenthood consenting audits with staff. Five sets of records where treatment with donor sperm had recently been provided were audited by the inspection team. In two out of the five records, the patients received treatment with donor sperm in circumstances where consent to legal parenthood was required. 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

This 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 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.

A major area of non-compliance is identified in the report by a statement that an area of practice is partially 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. CE marking The sperm collection pots and flush media used during egg collection are not CE marked for their intended purpose. SLC T30.	The PR should ensure that CE marked medical devices are used where possible. We would not recommend precipitous changes that might impact on the quality of treatment, however the PR should ensure that a plan is developed and implemented so that appropriately CE marked medical devices are used. This plan should be provided to the centre’s inspector by 24 October 2018 and should include the timescales by	All devices identified by the inspection team have now been replaced with CE marked versions. The CE marked flushing media is being introduced over the next month. A complete audit of devices will be submitted by October 24th.	The executive acknowledges the PR’s response and commitment to implementing this recommendation. The audit is to be provided by 24 October 2018. Further action is required.

	which products identified in this report will be replaced with a suitably CE marked alternative. The plan should be fully implemented by 24 January 2019.		
2. Infection control On inspection the following issues were noted: • Sharps bins in the theatre area and on the emergency resuscitation trolley had been filled above the designated fill line; • The trim that seals the join of the flooring to the wall was coming away from the wall in several places in the male production rooms and (in what staff refer to as) the sofa room; • In consultation room four, the curtains have not been changed since 13 June 2017, staff report this is done on an annual basis;	The PR should ensure adherence to infection control best practice guidance and requirements. The PR should review infection control practices and procedures and address the issues identified in this report. A summary report of this review, with timescales for implementation should be provided to the centre's inspector by 24 October 2018. Three months after implementing corrective actions the PR should audit infection control practice to ensure that corrective actions have been effective in achieving compliance. The PR should ensure the centre's	The report will be submitted by October 24th. Immediate issues suich as the sharps bins,theatre gown and the dirty linen have been addressed, and a walk around with estates has been carried out to look at issues such as the flooring trim. A new chair has been ordered for the recovery room.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The summary report of the review of infection control practices and procedures is to be provided by 24 October 2018 and the follow up audit by 24 January 2019. Further action is required.

• Fabric on one of the chairs in the 'recovery anti-room' is ripped. • Soiled toilet brushes were in the patient toilets; • The water cooler in the reception area had a daily cleaning log but the last check was documented 30 June 2018; • A theatre gown in the theatre recovery area is used multiple times by staff to put over their uniforms when leaving the clinic areas; • Dirty linen was stored for a long period of time in a well-used patient corridor by the lift awaiting collection. SLC T2. Department of Health: Health Building Note 00-09: Infection control in the built environment (2013) section 3.105.	auditing practices are sufficient in scope to detect such issues in the future. A summary report of this review should be provided to the centre's inspector by 24 January 2019.		

Healthcare-associated infections: prevention and control in primary and community care 2017, section 1.1.4.4.			
3. Equipment and materials The fridge in the andrology laboratory that is used to store media for the preparation of sperm for use in treatment is not subject to temperature monitoring. The drug fridge is not monitored appropriately. A traffic light system is used to record the monitoring of the drug fridge temperature with a supplementary page for documenting actions when a deviation is detected from the green section. On one particular day, there was a tick in the amber box, but no action recorded. SLC T24.	The PR should ensure that all critical equipment is subject to monitoring and that corrective actions are documented. The PR should inform the centre's inspector of actions taken when responding to this report. Within three months, the centre should carry out an audit 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 24 January 2019.	Medical engineering are currently addressing the monitoring of the andrology fridge, in order to add it to the alarm system. Failure to record actions when monitoring the drug fridge temperature has been addressed with relevant staff members. The report will be submitted by January 24th .	The executive acknowledges the PR's response and commitment to implementing this recommendation. The PR has confirmed by email that since the inspection, there is now a manual daily check of the fridge temperature. A summary report of the findings of the audit is to be provided by 24 January 2019. Further action is required.

‘Other’ areas of practice that require improvement

‘Other’ 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
4. Medicines management Staff are pre-populating the page numbers for the carry-over of controlled drugs in the register. This should be done at the time of carry-over of stock and witnessed by two people. SLC T2. DH (2007) ‘Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)’.	The PR should ensure that medicines management practice is compliant with regulatory and best practice requirements. The PR should review medicines management practice and provide a summary report of this review together with corrective actions taken to the centre’s inspector by 24 October 2018. Three months after corrective actions have been implemented the PR should audit medicines management practice to ensure actions taken have been effective in achieving compliance.	The practice of pre-populating the page numbers in the controlled drugs register has ceased. A review of medicines management practice will be submitted by October 24th.	The executive acknowledges the PR’s response and commitment to implementing this recommendation. The summary report of medicines management practice is to be provided by 24 October 2018 and the follow up audit by 24 January 2019. Further action is required.

	A summary report of this review should be provided to the centre's inspector by 24 January 2019.		
5. Traceability The discard of sperm that is not used in treatment is not recorded for traceability purposes. SLC T99.	The PR should ensure that all gametes are traceable from procurement to patient treatment or disposal. The PR should review the centre's processes for documenting the discard of sperm not used in treatment to ensure that all traceability records are consistent and accurate. 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 24 October 2018. Within three months, the centre should carry out an audit of traceability practices to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit	The sperm discard step has now been added to the Matcher electronic witnessing system and to the paperwork. Detailed review will be submitted by October 24th.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The summary of the review of the centre's processes for documenting the discard of sperm is to be provided by 24 October 2018 and the follow up audit by 24 January 2019. Further action is required.

	should be provided to the centre's inspector by 24 January 2019.		

Additional information from the Person Responsible