Executive Licensing Panel - minutes

Centre 0149 (Royal Derby Hospital)

Interim Inspection Report

Friday, 6 July 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Dan Howard Howard Ryan	Director of Strategy and Corporate Affairs Chief Information Officer Data Analyst
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Richard Chamberlain	Senior Governance Manager Temporary Committee Clerk (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 Royal Derby Hospital is located in Derby and has held a treatment and storage licence with HFEA since 1995. The centre provides intra uterine insemination using partner/donor sperm treatments and storage.

1.2. The panel noted that, in 2017, the centre reported 133 cycles of partner insemination with 24 pregnancies. This represents a clinical pregnancy rate of 18%, which is in line with the national average.

1.3. The panel noted that, in 2017, 1 of the 24 pregnancies resulting from partner insemination treatment was a multiple pregnancy.

1.4. The panel noted that the centre has not provided any intra uterine insemination treatments with donor sperm in the time since the last inspection in 2016.

1.5. The panel noted that the inspection took place on 9 May 2018.

1.6. The panel noted that at the time of the inspection, two major area of non-compliance were identified concerning the Quality Management System (QMS) and medicines management. Two 'other' areas of non-compliance were also acknowledged regarding screening and CE marking. Since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to address all the non-compliances identified in the report, and has committed, where required, to audit the effectiveness of those actions within the agreed timescales.

1.7. The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence, particularly noting the positive feedback provided by patients in relation to their experiences.

2. Decision

2.1. The panel was pleased the PR had recognised that there had been no patient feedback to the HFEA since the time of the last inspection, and was actively encouraging patients to comment on their experiences, through the Choose a Fertility Clinic function, available on the HFEA website.

2.2. The panel was also pleased to note that most of the non-compliances identified at the interim inspection had been addressed, acknowledging that, with regards to screening, an audit is due for submission by 9 August 2018.

2.3. The panel was satisfied the centre was fit to have its treatment (insemination using partner/donor sperm) and storage licence continued.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

17 July 2018

Interim Licensing Report

Centre name: Royal Derby Hospital
Centre number: 0149
Date licence issued: 1 November 2016
Licence expiry date: 31 October 2020
Additional conditions applied to this licence: None
Date of inspection: 9 May 2018
Inspectors: Shanaz Pasha (lead), Mhairi West
Date of Executive Licensing Panel: 6 July 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 a short notice interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. The focus of an interim inspection is:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we note the positive comments made by patients in relation to their experiences.

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

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following actions, and has committed, where required, to audit the effectiveness of those actions within the agreed timescales:

Major areas of non compliance:

- The PR should ensure that the centre's quality management system processes are effective.
- The PR should ensure compliance with medicines management regulations.

'Other' areas of practice that require improvement:

- The PR should ensure with immediate effect that patients, their partners and donors are assessed for possible past or present Ebola virus exposure or infection.
- The PR should ensure appropriately CE marked medical devices are used where available.

Information about the centre

The Royal Derby Hospital is located in Derby and has held a licence with the HFEA since 1995.

The centre provides intra uterine insemination using partner/donor sperm treatments and storage.

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]

In 2017, the centre reported 133 cycles of partner insemination with 24 pregnancies. This represents a clinical pregnancy rate of 18%, which is in line with the national average.

The centre has not provided any intra uterine insemination treatments with donor sperm in the time since the last inspection in 2016.

Multiple births[2]

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

In 2017, one of the twenty four pregnancies resulting from partner insemination treatment was a multiple pregnancy.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes 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 to review witnessing in patient records. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes 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 are stored in accordance with the consent of the gamete providers.

On inspection, reports of audits of all stored gametes and of the accuracy of storage logs and consent records were reviewed. The 'bring-forward' system was discussed with staff

[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%.

and storage records were reviewed. These activities indicate that the centre's processes for storing gametes 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.

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, welfare of child, infection control and medicines management.

The centre's procedures for auditing and acting on the findings of audits are broadly compliant with requirements because the centre does not systematically document the timescales for the implementation of corrective and preventative actions identified by audits or the dates that those actions are implemented. It is acknowledged that the laboratory has robust systems in place which should be mirrored within the broader QMS. See recommendation 1.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- The use of the most recently issued HFEA consent form versions;
- Use of CE marked medical devices;
- HFEA Clinic Focus articles regarding: assessment of Zika and Ebola virus risk and encouraging patients to provide feedback on their treatment experiences on the HFEA website.

The centre's procedures for implementing learning are broadly compliant with requirements because:

- One item of plastic ware used in the laboratory was not CE marked to the appropriate standard (see equipment and materials section of report);
- The centre has not systematically implemented assessment of Ebola virus risk for all patients and partners;
- The centre has not specifically directed or encouraged patients to provide feedback on the HFEA website regarding their treatment experiences.

See recommendations 1, 3 and 4.

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. Nurses irregularly administer or dispense hcG trigger injections to patients in the clinic without a written and signed prescription from an appropriate practitioner. The centre did not have patient specific directives or a patient group directive to direct their drug administration or dispensing practice.
See recommendation 1.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Infection Control
It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, we reviewed infection control practices and found them to be compliant with guidance.

Equipment and Materials
It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of a sample of media and plastic ware were reviewed in the course of the inspection. We found the centre to be broadly compliant with HFEA requirements to use CE marked medical devices wherever possible as one item of plastic ware used in the laboratory (bijou tube) was not CE marked to the appropriate standard. See recommendation 4.

Patient experience
During the inspection, we spoke to two patients about their experiences at the centre. No patients provided feedback directly to the HFEA in the time since the last inspection. The centre's most recent patient survey responses for a twelve month period were also reviewed. Feedback was positive, with fifteen of the individuals providing written feedback giving compliments about the care received.

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 sufficient, information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

There were also several negative comments regarding on site car parking facilities and these were discussed with the PR. He advised the inspectors that actions have already been taken to address this matter. Patients are informed of the limited parking spaces and are advised of alternative travel options in the patient appointment letter.

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 exceptions noted elsewhere in this report and that the centre does not have a standard operating procedure for reporting incidents to the HFEA. See recommendation 1.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2016, recommendations for improvement were made in relation to one major and two 'other' areas of non compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

The centre has only provided partner intra uterine insemination treatments; their success rates are not subject to ongoing monitoring through the HFEA risk tool and therefore the centre has not been issued with any performance alerts.

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 provided its annual IUI treatment return for 2017 within the required timescale.

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 that inspection in 2016, legal parenthood consenting processes were found to be robust.

The centre has not undertaken any treatments with donor sperm since 2015. Therefore, this area of practice was not audited by the inspection team at this inspection.

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas of non compliance

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

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
None 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 partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Quality Management System The centre does not systematically document the timescales for the implementation of corrective and preventative actions identified by audits or the dates that those actions are implemented**.**	The PR should ensure that the centre’s quality management system processes are effective. The PR should review the centre’s processes for the documentation of timescales for the implementation of corrective and preventative actions identified by audits or the dates that those actions are implemented. A summary of the review should be sent to the centre’s inspector by 9 August 2018.	Thank you for your constructive comments. We have an efficient and regular audit process in place already. The corrective and preventative actions (CAPA) noted during the audit are implemented also in time, reaudited, documented and uploaded on to the Q-Pulse. We shall now ensure that it is robust with ensuring the timelines of each process are documented. In addition to Q-Pulse, we will document the timescales for the implementation of CAPA in the summary excel document (that	The Executive acknowledges the PR’s response and commitment to implementing this recommendation, and receipt of the required SOP. No further action required.

The centre does not have a standard operating procedure for reporting incidents to the HFEA. The clinic's processes for implementing learning are not consistently effective because guidance issued by the HFEA has not been implemented in two instances, as noted in the main body of the report. SLCs T32 and T36	A copy of the standard operating procedure for reporting incidents to the HFEA should be sent to the centre's inspector by 9 August 2018. The PR should review the centre's processes for incorporating guidance from the HFEA into clinic practice, and ensure that these are effective. A summary of the review and any corrective action should be sent to the centre's inspector by 9 August 2018.	our QM showed the HFEA inspectors during the inspection visit). This excel sheet would be stored in the 'share drive'. SOP for reporting incidents to the HFEA is already made and a copy is attached herewith. PR shall ensure that the monthly HFEA newsletter is now sent to all the key members. Further, the nursing team have now registered to get the newsletter to them directly as well. HFEA update is now becoming our regular agenda items at monthly QM meetings. With respect to reviewing our corrective actions, we have made plans to do an audit on the practice of asking relevant questions to potentially capture any Ebola risk patients.	
2. Medicines Management Nurses irregularly administer or dispense hcG trigger injections to patients in the clinic without a written and signed prescription from an	The PR should ensure compliance with medicines management regulations. The PR provided assurance at the inspection that this practice	As advised, right from the day of inspection, we have changed our practices of administering or dispensing Hcg trigger only with a prescription from a clinician.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required

appropriate practitioner. The centre does not have patient specific directives or a patient group directive to direct their drug administration or dispensing practice. SLC T2 and The Human Medicines Regulations 2012	will be stopped forthwith. The PR should undertake a review of the centre's medicines management policies and practices. A summary of the review should be sent to the centre's inspector when responding to this report.	This practice is now incorporated in our regularnotes audit. We are in the process of exploring the possibility of putting a patient group directive in place.	

‘Other’ areas of practice that requires improvement

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

An ‘other’ area of non compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
3. Screening Centre staff make no consideration of possible past or present Ebola virus exposure or infection when assessing patients, their partners and donors. The likelihood of past or present Ebola exposure or infection is considered extremely unlikely, hence this non compliance being listed as an ‘other’. SLC T50d	The PR should ensure with immediate effect that patients, their partners and donors are assessed for possible past or present Ebola virus exposure or infection. The PR should ensure that patient information is available regarding the risks associated with the exposure to this virus. The PR should consider, with expert advice if necessary, if there is any risk to patients and donors resulting from the past failure to perform Ebola assessment. If risk is present, appropriate risk control measures should be implemented. The PR should inform the centre’s inspector of the	Since the inspection, we have incorporated the information on Ebola on to our already made up label sticker for Zika. We have incorporated this to 'Zika questionnaire' prior to starting IUI and IVF too. An audit on reviewing these processes is already commenced. Evidence of Travel label in the notes are incorporated in our notes audit. We shall seek advice from the experts (DOH help desk, appropriate microbiology experts) as appropriate in this matter (as we did in the past on Zika advice)	The Executive acknowledges the PR’s response and commitment to implementing this recommendation. No further action beyond submission of the audit due by 9 August 2018.

	actions taken to implement this recommendation when responding to this report. Three months after implementing corrective actions, the PR should audit their effectiveness. A summary report of this audit should be provided to the centre's inspector by 9 August 2018.		
4. CE Marking One item of plastic ware used in the laboratory (bijou tube) was not CE marked to the appropriate standard. SLC T30	The PR should ensure that CE marked medical devices are used where possible. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. It is expected that an appropriately CE marked medical device is in use by 9 August 2018.	The lab has already switched to the use of CE marked tube to provide the prepared sperm sample for insemination. We are trialling this process to ensure the process is seemless and not compromising success rates.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required.

Additional information from the Person Responsible
We are putting up posters in the waiting area and directly asking patients to provide feed back on the unit to HFEA