Executive Licensing Panel - minutes

Centre 0055 (The James Cook University Hospital) Interim Inspection Report

Friday, 4 November 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) David Moysen Anjeli Kara	Director of Strategy & Corporate Affairs Head of IT Regulatory Policy Manager
Members of the Executive	Dee Knoyle	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 The James Cook University Hospital, centre 0055 is located in Middlesbrough and has held a treatment and storage licence with the HFEA since 1992. The centre provides a full range of fertility services.

1.2. The panel noted that the centre's licence is due to expire on 31 January 2019.

1.3. The panel noted that the inspection took place on 23 August 2016.

1.4. The panel noted that in the 12 months to 30 June 2016, the centre provided 325 cycles of treatment. In relation to activity levels this is a small centre.

1.5. The panel noted that HFEA-held register data for the year ending 31 March 2016 showed the centre's success rates in terms of clinical pregnancy rates were in line with national averages.

1.6. The panel noted that in 2015, the centre reported nine cycles of partner insemination with no pregnancies. This was in line with the national average.

1.7. The panel noted that HFEA-held register data for the year ending 31 March 2016 showed the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 20%. This represents performance that is not likely to be significantly different to the 10% maximum multiple live birth rate target for this period. The panel noted that the centre's multiple births minimisation strategy was reviewed, along with the last audit of multiple births and the centre's practice in this area was considered compliant. However, the Person Responsible (PR) was encouraged to continue to reduce the centre's multiple pregnancy rate.

1.8. The panel noted that at the time of the interim inspection on 23 August 2016, one major and three other areas of non-compliance were identified. The panel noted that since the inspection the PR has started to address the non-compliances and has committed to fully implementing the outstanding recommendations within the prescribed timescales.

1.9. The panel noted that there were positive comments made by patients in relation to the service provided.

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 noted the non-compliances and that the PR is addressing them. The panel was pleased to see that the centre has improved since the renewal inspection.

2.2. 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

14 November 2016

Interim Licensing Report

Centre name: The James Cook University Hospital
Centre number: 0055
Date licence issued: 1 February 2016
Licence expiry date: 31 January 2019
Additional conditions applied to this licence: None
Date of inspection: 23 August 2016
Inspectors: Andrew Leonard; Shanaz Pasha
Date of Executive Licensing Panel: 4 November 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 renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC). Centres usually receive an unannounced or short notice interim inspection at the mid-point of the licence period.

This centre was last inspected in August 2015 for renewal of their treatment and storage licence after which a three year, rather than the usual four year, licence was granted. The Executive Licensing Panel (ELP) required that the centre be inspected within one year. This is a report of the interim inspection carried out in response to the ELP. The inspection was announced as we wished to ensure key staff were available to discuss the actions taken to implement the recommendations made in the licence renewal inspection report. A normal interim inspection was also performed focussing on:

- **Quality of care:** the quality of care 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 an evaluation of the centre's performance based on the above. The aim is to provide the Authority's ELP with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

The inspection team recommends the continuation of the centre's licence. In particular, we note the many positive comments made by patients regarding the service.

The ELP is asked to note that recommendations for improvement were made in relation to one major and two 'other' areas of non compliance or poor practice.

In responding to the report the PR has provided assurance that the following recommendations have been fully implemented.

Major areas of non compliance:

- The PR should ensure that all corrective actions identified in response to audits and non conformance reporting are reliably implemented.

'Other' areas of practice that require improvement:

- The PR should ensure that documented SOPs are present describing the processes by which nursing staff dispense medicines and manage the drugs fridge and respond to its failure.

The PR has also given a commitment to fully implement the following recommendations within the required timeframes:

'Other' areas of practice that require improvement:

- The PR should ensure that medicines management practices are audited by a trained and qualified individual;

- The PR should ensure that, wherever possible, CE marked medical devices are used to provide licensed treatment services.

Information about the centre

The James Cook University Hospital is located in Middlesbrough and has held a treatment and storage licence with the HFEA since 1992. The centre provides a full range of fertility services.

The centre provided 325 cycles of treatment in the 12 months to 30 June 2016. In relation to activity levels this is a small centre.

The ELP on 16 October 2015 approved the renewal of the centre's licence for a reduced term of three years, because the inspection report accompanying the renewal application made recommendations to address one critical, eight major and four other non compliances or areas of poor practice. The ELP recommended the centre be revisited within a year and this inspection was carried out in response to that recommendation.

Details of Inspection findings

Quality of Service

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

Pregnancy outcomes[1]

HFEA held register data for the year ending 31 March 2016 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

In 2015, the centre reported nine cycles of partner insemination with no pregnancies. This was in line with the national average.

Multiple births[2]

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

HFEA held register data for the year ending 31 March 2016 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period. The multiple pregnancy rate was discussed and the centre's multiple births minimisation strategy was reviewed, along with the last audit of multiple births. The centre's practice in this area was considered compliant. The PR was encouraged to continue to reduce the centre's multiple pregnancy rate.

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 because no activity was undertaken. Discussions with laboratory staff and review of the centre's witnessing audit and the

[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%.

documentation of witnessed checks in patient records, indicate that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

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

On inspection, 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; and 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 (SOPs) 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, consent to disclosure to researchers, use of embryos in training, consent to treatment, legal parenthood, infection control, traceability and multiple births minimisation.

- The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements, because on two recent occasions (concerning the audits of consent to disclosure and the use of embryos in training) corrective actions have not been implemented in a timely manner. Thus the procedure which ensures corrective actions are implemented is not absolutely reliable (see recommendation 1).
- An audit of medicines management practices in the centre has not been performed in the last two years. Medicines management practices in the procedure room were said to have been audited but evidence of this has not been provided (see 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 centre's audits of storage consent and legal parenthood
- the use of CE marked medical devices
- recent changes to the interpretation of storage consent periods
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- the use of the HFEA information leaflet concerning legal parenthood
- The HFEA reports of adverse incidents from 2010-2012 and 2013
- HFEA Clinic Focus articles regarding: screening; equipment failures and zika virus

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 correctly.

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 there are no SOPs to direct the dispensing of medicines by nursing staff or the management of the medicines fridge and how to respond if it should fail (see recommendation 2).

Prescription of intralipid 'off label'

The centre does not prescribe intralipid to patients.

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 number of medical devices was reviewed in the course of the inspection including: egg and embryo culture media, vitrification media, sperm processing media, media for preparing embryos for ICSI, ICSI needles and a variety of plasticware. The centre is broadly compliant with HFEA requirements to use CE marked medical devices wherever possible because 200 microlitre pipette tips (long) were being used which were not CE marked. The inspection team notes the centre has taken actions to find appropriately CE marked tips but has so far been unsuccessful and therefore subjects each batch of tips to sperm toxicity testing before use (recommendation 3).

Patient experience

During the inspection, the inspection team spoke to one patient couple about their experiences at the centre. Another 20 patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was very positive with 19 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:

- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- has staff who are supportive and professional;
- has respect for the privacy and confidentiality of patients in the clinic;
- provides a clean and well organised environment for patient treatment;
- 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 non-compliant with HFEA requirements because:

- SOPs have not been prepared which document the processes by which medicines are dispensed by nursing staff and the drugs refrigerator is managed, including the actions to take in response to the refrigerator failing (recommendation 2).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2015, recommendations for improvement were made in relation to one critical, eight major and four 'other' areas of non compliance.

The PR subsequently provided information and evidence that all but one of the recommendations were fully implemented within the required timescales. The implementation of all recommendations was reviewed on inspection and was considered to have been effective.

The following recommendation has been implemented but one aspect of it was not completed within the required timescales:

- The PR should ensure that embryos are only used for training purposes if both gametes providers have consented, and that embryos intended for training purposes are not used for any other purpose.

This critical non compliance arose because one set of embryos was used in training without the gamete providers' consent. All necessary actions to implement the recommendation to address this matter going forward were taken, however the patient couple were not contacted in a timely manner to advise them of the incident, to respond to their questions or

to offer them support and counselling. This corrective action was specified in the recommendation in the renewal inspection report as well as in the centre's audit of embryos used in training. The centre reported that the late implementation of this action was an oversight as the person to whom the action was assigned went on long term sick leave, and the action was not picked up by other staff in their absence. This was rectified in June of this year when the oversight came to light (recommendation 1).

On-going monitoring of centre success rates

Since the last renewal inspection in August 2015 the centre has not received any risk tool alerts relating to success rates. The centre responded appropriately to the one risk tool alert it has received concerning the multiple pregnancy rate.

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 HFEA register team advised that the centre's data submissions to the register are compliant with requirements.

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 it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies. On this inspection, the inspection team 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 confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed five 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 was in place prior to treatment in all cases.

The centre's last legal parenthood audit was reviewed. It showed that effective consent for legal parenthood had been documented in all cases.

In summary, the inspection team considers the centre's processes for obtaining consent to legal parenthood 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. QMS On two recent occasions, corrective actions have not been implemented in a timely manner (SLC T36).	The PR should ensure corrective actions identified are implemented in all cases. The PR should ensure that a process is developed within the QMS which guarantees that all corrective actions are implemented and provides oversight to the PR and other staff regarding corrective actions and timescales for their implementation. The actions taken to implement this recommendation should be communicated to the centre's inspector by 23 November 2016.	Please find attached a new SOP designed to ensure that actions and responses are accurately and timely completed in the future.	A process has been developed and documented in the SOP provided, which will ensure that the status of all corrective actions is reviewed at the fortnightly multi-disciplinary team meetings, until the corrective actions are implemented, audited for effectiveness, then closed. No further actions are required.

‘Other’ areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
2. Medicines management • There are no SOPs to direct the following procedures: The dispensing of medicines by nursing staff; The management of the drugs fridge and the response if it fails (SLC T33b). • An audit of medicines management practices in the centre has not been performed in the last two years. An audit of medicines management practices in the theatre was not available (SLC T36). This has been graded as an ‘other’ non compliance because the processes used appeared compliant.	The PR should ensure the development of documented SOPs for the procedures identified. Copies of the SOPs should be provided to the HFEA by 23 November 2016. The PR should ensure medicines management practices are audited by a trained and qualified individual and a report of the audit is provided to the centre's inspector by 23 November 2016	Please find attached completed SOP for the management of dispensing of medicines by nursing staff as requested. We have developed a form for auditing the management of dispensing of medicines by nursing staff and will provide the initial audit as soon as it is ready.	The SOP effectively documents the processes by which medicines are supplied and stored in the drugs fridge, then dispensed by nursing staff. The PR has committed to provide the audit of medicines management practices. Further actions are required
3. Equipment and materials The following medical devices	We would not recommend the	As I highlighted in my last response, we have been	The ‘long’ pipette tip is used to limit the risk of contamination of the pipette with sperm

used by the centre are not CE marked: 200 microlitre pipette tips (long) (SLC T30). The inspection team notes the centre has taken actions to find appropriately CE marked tips but has so far been unsuccessful.	implementation of precipitous changes that might impact on the quality of treatment that you are providing to your patients. In consideration of this, the PR should review the use of these pipette tips and should advise the HFEA in his response to this report, either of the anticipated time by which a CE mark is expected to be obtained by the manufacturer, or of other actions that will be taken to ensure compliance.	tirelessly looking for CE marked pipette tips. To date, we have been unable to source a CE marked alternative. However, until we source this alternative we will be carrying out toxicity tests on those tips. I would like to reassure you that all the other items we use are all now CE marked (apart from that item in question).	and cross contamination of other sperm samples. The inspector has been advised by the centre of actions taken in response to the inspection findings, to try and find CE marked long pipette tips. One potential CE marked tip was not CE marked at the appropriate level. No appropriately CE marked 'long' tips have been found. The centre has started to use a tip which is toxicity tested by the manufacturer using the mouse embryo assay but which is not CE marked. These tips are subjected to sperm toxicity testing at the centre. The laboratory team considers them to be the best option in the absence of CE marked alternatives, but have committed to continue to seek CE marked alternatives. The inspection team notes the actions taken by the centre, the lack of availability of appropriately CE marked tips, the centre's commitment to continue to seek CE marked alternatives, and that the non CE marked tips used are mouse embryo and sperm toxicity tested and are being used as a risk control measure to assure safe practice. The inspection team therefore makes no further recommendations at this time.

Additional information from the Person Responsible