Executive Licensing Panel - minutes

Centre 0162 (Queens Medical Centre Fertility Unit)

Executive Update – Addendum to the Executive Licensing Panel Minutes

Friday, 25 May 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Caylin Joski-Jethi (Chair) Dan Howard Kathleen Sarsfield-Watson	Head of Intelligence Chief Information Officer Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Mhairi West	Senior Governance Manager Inspector

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. Background

1.1. The panel noted that Executive Licensing Panel considered the interim inspection report for the Queens Medical Centre Fertility Unit (centre 0162) at the meeting held on 10 April 2018.

1.2. The panel noted that on receipt of the minutes from the 10 April 2018 Executive Licensing Panel meeting, the Person Responsible (PR) at the centre noted that point 1.3 of the minutes were incorrect.

1.3. The panel noted that the inspector has checked and updated the report to reflect the correct outcomes, and apologises to the panel that it was the report that was incorrect and steps have been taken to ensure this will not happen again.

2. Recommendation

2.1. The panel considered the papers, which included an executive update, amended interim inspection report and licensing minutes for the last three years.

2.2. The panel noted the Executive's recommendation that an addendum is made to the minutes, and that the report and the minutes are resent with the correct information. It is suggested that paragraph 1.3 as below:

The panel noted that in 2016, the centre reported 243 cycles of partner insemination, with 15 pregnancies. This equates to a 6% clinical pregnancy rate which is consistent with the national average. In relation to activity levels this is a small sized centre.

is replaced as follows:

Data submitted for 2016 indicate that the centre performed 243 cycles of partner insemination with 46 pregnancies. This equates to a 19% clinical pregnancy rate which is consistent with the national average. In relation to activity levels this is a small sized centre.

2.3. The panel noted that the PR has viewed the amended inspection report.

3. Decision

3.1. The panel agreed that an addendum should be made to the minutes of the 10 April 2018 Executive Licensing Panel meeting, with regards to paragraph 1.3 as follows:

Data submitted for 2016 indicate that the centre performed 243 cycles of partner insemination with 46 pregnancies. This equates to a 19% clinical pregnancy rate which is consistent with the national average. In relation to activity levels this is a small sized centre.

4. Chair's signature

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

Signature

Name

Caylin Joski-Jethi

Date

4 June 2018

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Interim Licensing Report

Centre name: Queens Medical Centre Fertility Unit
Centre number: 0162
Date licence issued: 1 July 2016
Licence expiry date: 30 June 2020
Additional conditions applied to this licence: None
Date of inspection: 16 January 2018
Inspectors: Susan Jolliffe (lead), Vicki Lamb, Janet Anderson-Pearce (observer)
Date of Executive Licensing Panel: 10 April 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. 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 progress made in implementing the actions identified at the last inspection; our on-going monitoring of the centre's performance and usually, the centre's own assessment of its service. However, the centre did not return its self-assessment questionnaire prior to the inspection.

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 we note the positive feedback made by patients in regard to their experiences.

The Executive Licensing Panel is asked to note that there are recommendations for improvement in relation to two major and one 'other' area of non-compliance as follows:

The PR has provided evidence that the following recommendation has been implemented:

'Other' areas of practice that require improvement:

- The PR should ensure that the data relating to treatment activity published on the centre's website, is less than three years old.

The PR has provided a commitment to implement the following recommendations:

'Major' areas of non-compliance**:**

- The PR should ensure storage of gametes is only extended beyond the statutory storage period when there is compliance with the 2009 storage regulations, both in relation to patient consent and evidence of either premature infertility or of likely premature infertility in the future.

- The PR should ensure that the liquid nitrogen is stored in suitable premises, with safe access and egress.

Information about the centre

Queen's Medical Centre Fertility Unit has been licensed by the HFEA for treatment and storage of gametes since 1995. The centre is an NHS clinic located within the Queen's Medical Campus, which is part of Nottingham University Hospitals NHS Trust.

The centre provides a service for the diagnosis and treatment of sub-fertility and insemination with partner or donor sperm. The centre also incorporates the andrology department which provides a service for those wishing to donate sperm and for those wishing to store their sperm for the preservation of fertility.

In 2016 the centre reported 243 cycles of partner insemination. In relation to activity levels this is a small centre.

Details of Inspection findings

Quality of Service

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

Pregnancy outcomes[1]

For the year Aug 2016 to July 2017 the centre reported 58 cycles of donor insemination with 19 clinical pregnancies. This represents a clinical pregnancy rate of 32%, which is in line with the national average.

Success rate data for 2017 was not required to be submitted by the time of the inspection, however data submitted for 2016 indicate that the centre performed 243 cycles of partner insemination with 46 pregnancies. This equates to a 19% clinical pregnancy rate which is consistent with the national average.

Multiple births[2]

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

The IUI data report showed an outcome of five triplets in 2016. This was discussed at the inspection, and evidence and assurance given that protocols have changed resulting in a reduction in multiple pregnancy rate from 20% in 2016 to 8% in 2017.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes and that identification errors do not occur. The following laboratory activity was observed in the course of the inspection: donor sperm preparation pre-freeze. This was witnessed using a manual witnessing system in accordance 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 procedures and to preserve their

[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%.

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, the accuracy of storage logs and consent records were reviewed. The 'bring-forward' system was also discussed with staff 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 not completely effective, because a review of five sets of patient records showed one instance of a period of lapsed storage consent from the patient between the expiry of the original storage consent and the signing of a consent to storage extension, and also the completion of the Medical Practitioners Statement (MPS) form outside the required period; and one further case in which the MPS form was completed after the required period (See recommendation 1).

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 current level of activity being carried out.

Quality Management System (QMS)

It is important that centres audit all their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The centre's 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
- HFEA Clinic Focus articles regarding screening requirements and equipment failures

The centre is broadly effective in implementing learning from guidance from the HFEA (see recommendation 3) because the centre has not ensured compliance with guidance that centres' websites should include outcome data which is less than three years old.

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 compliant with guidance.

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 are approved for the provision of fertility treatment, to ensure the safety of gametes and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of all consumables was reviewed in the course of the inspection. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection, four patients were available to speak with the inspectors about their experiences at the centre and there was patient feedback provided directly to the centre for the inspection team to review. Feedback was positive.

On the basis of this feedback 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 fully compliant with HFEA requirements, except in those areas identified elsewhere in this report.

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 three major and three 'other' areas of non-compliance.

The PR subsequently provided information and evidence that all but one of the recommendations were fully implemented within the timescale agreed.

The following recommendation has not yet been implemented:

- The PR should ensure that the liquid nitrogen is stored in suitable premises, with safe access and egress.

In responding to the report immediately after the inspection, the PR had agreed to implement the recommendation, but the capital to relocate the storage area has taken longer than expected to be allocated. A risk assessment was completed showing it is low risk, and a capital bid has now been ringfenced for relocation in 2018. (See recommendation 2)

On-going monitoring of centre success rates

Since the last renewal inspection in January 2016 the centre has not received any performance related risk tool 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 is complaint 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.

At the inspection on 27/01/2016 we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA. Actions had been taken in response to the audit findings.

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

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

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			

‘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. **Storage of gametes** A review of five sets of patient records showed one case in which there was a period of lapsed storage consent between the expiry of the original storage consent and the signing of storage extension consent, with completion of the MPS form outside the required period. There was also a further case in which the MPS form was completed after the required period (The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009; SLC T79).	The PR should ensure storage is only extended beyond the statutory storage period when there is compliance with the 2009 storage regulations, both in relation to patient consent and evidence of either premature infertility or of likely premature infertility in the future. In all cases where there has been a failure to comply with the 2009 storage regulations, the PR should seek independent legal advice on how to proceed, including whether affected patients ought to be informed. Proposed actions in response	A full report investigating both of these cases has been undertaken (report submitted to the inspection team 12th February 2018), and concluded that at the time of this inspection both patient's consents were fully compliant with the storage regulations. We recognise that there was a period where the consent form used was not the most up to date version of the form but as patient 1. had clearly declared on the original 96(6) form that he wished storage to take place for the maximum period (in 1996) and had written to us to re-state this after 10 years, we believe consent was	The PR has investigated both cases identified on inspection. Whilst it is clear the PR has undertaken a detailed review and evaluation of these cases, given the complexities of the requirements and the introduction of new regulations that have taken place since the samples were placed in storage, the executive would recommend that the PR seeks legal advice so as to assure himself that his conclusions are accurate. The executive notes that these appear to be two isolated historical cases with evidence of infertility of the gamete

	to this advice should be forwarded to the HFEA for review prior to any action being taken. The outcome of this investigation, including the centre's intended actions and the timescales for their implementation should be submitted to the HFEA by 16 April 2018.	effectively in place. Moreover following chair's letter of 2016 (CE(16)02) and in line with current code of practice (guidance note 5D page 52) material may be stored without further written consent of the gamete provider providing the original storage conditions may be met. Patient 2. Had an MPS form signed after the original (supposed) expiry date. However the same applies as patient 1. applies in this case since he was first stored in 1993. On a 00(6) form he clearly stated that he wished for storage up to 55th birthday and had a 00(9) form completed by his GP to state that he required long-term storage. Again we believe that this is fully compliant. A clinical risk assessment for disposal was performed for both men and they were known to be permanently sterile, the risk of disposal was deemed too high and continued efforts were made	provider and that the systems for checking storage consent were considered to be robust on inspection. Further action is required to satisfy the recommendation, the PR should provide an update by 16 July 2018. Further action required.

		to obtain completed up to date forms, which are currently in place. As the cases were fully compliant in 2018 in that both patients had already been contacted and consents are now vaild, there are no further actions possible. However we continue to monitor storage consent expiry closely for all patients and in the last 5 years have developed and utilised more robust and timely bring forward systems to ensure that these cases are not common. We insist that all patients provide clinical evidence of infertility prior to extension of storage and use significant staff resources to ensure that we comply with the 2009 regulations.	

2. **Safety and suitability of premises and facilities** The centre's liquid nitrogen tank is stored at a distance that exceeds the recommendations of the British Compressed Gas Association for the movement of heavy pressurised vessels. SLCs T2 and T17. Health Technical Memorandum 02-01: Medical gas pipeline systems Part B: Operational management	This was an issue at the last inspection and at that time there was the expectation that the cryostore would move to a new location. This has not happened, but new dewars have been purchased that are more efficient and therefore reduce the movement of the heavy pressurised nitrogen storage reservoirs. The current location and processes have been risk assessed and graded as low risk. In view of this, this issue has not been escalated to a critical non-compliance. The PR should ensure that the liquid nitrogen is stored in suitable premises, with safe access and egress. The centre has identified a more suitable location and plan to move in the near future. An action plan and timeline for works should be made known in the response to this report. The PRshould liaise with the centre's inspector regarding	Two new bulk vapour phase freezers have been purchased and installed and are currently being validated. It was confirmed in Dec 2017 that new estates and capital have been secured to move the Fertility Unit and the Cryostore to a ground floor location which will remove the current issues with nitrogen transport. It is anticipated that the redevelopment of the new estate will be completed by the end of 2018, and the HFEA will be kept informed as the project gets underway. A planned schedule of works has been attached. In the interim staff continue to mitigate and reduce risks by adhering to previously discussed measures	The PR has taken appropriate action, and has sent a planned schedule of works to the lead inspector. Further action required.

	the licensing of the proposed location. It is expected that the move will have taken place by 31 December 2018.		

‘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
3. **Website information** The website for the centre showed intra-uterine insemination confirmed pregnancy rates for stimulated intra-uterine insemination (IUI) from 2008-2014 only, i.e. for treatments from more than three years before the inspection (Chairs letter: CH(11)02 Responsible use of websites: the duty of centres).	The PR should ensure that the data relating to activity, pregnancy rates and live birth rates on the centre’s website is less than three years old. The website should be updated by 16 April 2018 and the centre’s inspector informed when this has occurred.	Work is underway to update the entire website and to ensure that the pregnancy data on there is current and accurate. The Unit does not manage the website itself as it is controlled by the Trust's Comms Team and Unit staff have no direct access to change it. A meeting with the Comms team has been arranged for 13th February and we aim to rectify this issue in the next few weeks. We will inform the inspectors as soon as the data in question has been updated.	A further update from the centre on 13th February 2018 informed the inspection team that as an interim measure the centre has removed with immediate effect their success rates page from the current website. No further action required.

Additional information from the Person Responsible