# Executive Licensing Panel - minutes

## Centre 0021 (Hull IVF Unit)

## Interim Inspection Report

Tuesday, 3 September 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

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| Panel members | Clare Ettinghausen (Chair)<br>Laura Riley<br>Yvonne Akinmodun | Director of Strategy and Corporate Affairs<br>Head of Regulatory Policy<br>Head of Human Resources |
| Members of the Executive | Bernice Ash | Secretary |
| External adviser | | |
| Observers | Catherine Burwood<br>Jeffrey Akinmodun<br><br>Dee Knoyle | Licensing Manager<br>Senior Auditor, Government Internal Audit Agency<br>Committee Officer |

## 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:

- 9th 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 Hull IVF Unit is located in Hull and East Yorkshire Women and Children's Hospital and has held a treatment and storage licence with the HFEA since 1992. The centre provides a full range of fertility services, including the storage of gametes and embryos.

**1.2.** The panel noted that, in the 12 months to 31 March 2019, the centre had provided 480 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a small sized centre.

**1.3.** The panel noted that, for IVF and ICSI, HFEA register data, for the year ending February 2019, show the centre's success rates are in line with the national averages.

**1.4.** The panel noted that, in 2018, the centre reported one cycle of partner insemination, with no clinical pregnancy. This represents a clinical pregnancy rate which is comparable to the national average.

**1.5.** The panel noted that, HFEA register data, for the year ending February 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is likely to be statistically significantly lower than the 10% multiple live birth rate target for this period.

**1.6.** The panel noted that an unannounced inspection took place on 19 June 2019.

**1.7.** The panel noted that, at the time of inspection, there was one major area of non-compliance concerning medicines management. There was also one 'other' area of non-compliance regarding egg sharing information. Since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement both recommendations made in the report.

**1.8.** The panel noted that the inspectorate recommended the continuation of the centre's treatment and storage licence, particularly noting the centre's low multiple pregnancy rate and the progress made with developing their patient emotional support pathway that the HFEA issued guidance on earlier this year.

## 2. Decision

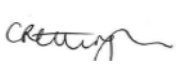
**2.1.** The panel recommended that the centre actively encourages patients to provide feedback, on their experiences of the clinic, by means of the 'Choose a Fertility Clinic' available on the HFEA website.

**2.2.** The panel was satisfied 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**

Clare Ettinghausen

**Date**

10 September 2019

# Interim Licensing Report

**Centre name:** Hull IVF Unit
**Centre number:** 0021
**Date licence issued:** 1 October 2017
**Licence expiry date:** 30 September 2021
**Additional conditions applied to this licence:** None
**Date of inspection:** 19 June 2019
**Inspectors:** Sara Parlett, Polly Todd, Debbie Jefferies (HFEA observer)
**Date of Executive Licensing Panel:** 3 September 2019

## 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 current foci for an interim inspection are:

- **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 centre's low multiple pregnancy rate and the progress made with developing their patient emotional support pathway that the HFEA issued guidance on earlier this year.

The ELP is asked to note that this report makes recommendations for improvement in relation to one major and one 'other' area of non compliance or poor practice.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement both of the following recommendations:

**Major area of non compliance:**

- The PR should ensure that controlled drugs keys are only accessible to authorised personnel.

**'Other' area of practice that requires improvement:**

- The PR should ensure that information given to egg sharers is compliant with CoP guidance.

## Information about the centre

Hull IVF Unit is located in Hull and East Yorkshire Women and Children's Hospital and has held a Treatment and Storage licence with the HFEA since 1992.

The centre provides a full range of fertility services including the storage of gametes and embryos.

The centre provided 480 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2019. 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 IVF and ICSI, HFEA held register data for the year ending February 2019 show the centre's success rates are in line with national averages.

In 2018, the centre reported one cycle of partner insemination with no clinical pregnancy. This represents a clinical pregnancy rate which is comparable to 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 February 2019 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is likely to be statistically significantly below 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 following laboratory activities were observed in the course of the inspection: egg collection, receipt of sperm in the laboratory and sperm preparation. Witnessing was also discussed with laboratory staff. These activities 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.

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[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

On inspection, a review of records of stored gametes and embryos was performed 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 appointments were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

## Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following 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: medicines management; infection control; legal parenthood; witnessing, counselling and consent to storage.

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:

- leadership
- patient support
- information provision
- extension of storage consent
- screening
- egg sharing
- the use of CE marked medical devices
- the centre's audit of legal parenthood
- patient information regarding treatment add-ons

The centre has been effective in ensuring compliance with guidance issued by the HFEA, with one exception:

The headline title of the centre's egg sharing information on its website is: '*Compensated egg sharing programme. A way to reduce the cost of IVF/ICSI treatment*:'. The inspection

team considers this places an emphasis on financial incentive rather than altruism and is not in line with CoP guidance.

The website also states: 'Y*ou can withdraw from the egg sharing arrangement at any time up to the point where embryos created from your eggs are to be transferred to the recipient. If you withdraw consent, you would then have to pay the standard fees for IVF/ICSI and the costs involved in preparing the recipient.*' This suggests the donor would need to reimburse the centre the full fee for the cycle in which she was going to egg share but didn't. This is not compliant with CoP guidance 12.11 which requires the centre to bear any financial loss it sustains as a result of an egg sharer withdrawing consent. Linking financial penalties to a withdrawal of consent could be considered a pressure to continue to consent to use of their gametes. The inspection team considers that this consenting policy does not meet HFEA consenting principles, that consent (including the withdrawal of consent) should not be restricted in any way, and therefore does not meet the requirements of Schedule 3 of the HF&E Act 1990 (as amended). The centre has confirmed that this payment of fees by egg sharers has not occurred in practice.

Recommendation 2.

### 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 for the following reason:

- The keys to the cabinet in which controlled drugs are stored, are kept in a cupboard together with other keys for the clinic. Although the 'key cupboard' is locked the inspection team considered that the safe custody of the controlled drugs is compromised because access to the keys to the cabinet in which these are stored is not restricted to authorised persons only, other staff can also access them. 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 has not prescribed intralipid therapy since 2015 and 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 the following medical devices was reviewed in the course of the inspection: culture medium, vitrification and warming medium and plastic ware. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

## Patient experience

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. No patients have provided feedback in the last 12 months, suggesting that the clinic does not actively seek patient feedback to the HFEA for comparison purposes. The inspection team was informed that the centre is planning to promote this more widely and was considering obtaining electronic tablets for patients to use in the clinic so that they can encourage them to provide feedback directly to CaFC whilst in clinic. The HFEA does expect centres to actively promote this facility and this will be followed up at the next inspection.

The centre's most recent survey of patient feedback from this year recorded 140 responses with a 96% satisfaction rate. Feedback is discussed regularly, and actions are taken to address any issues identified.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

## 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, with the two exceptions noted elsewhere in this report.

## Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2017, 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 of the recommendations were fully implemented within the required timescales.

## On-going monitoring of centre success rates

Since the last inspection in 2017, the centre has received one performance related risk tool alert relating to IVF clinical pregnancy rates in women under 38. This was issued just before the inspection and centre staff have performed a comprehensive investigation and are committed to keeping success rates in this group of patients under review. It is noted that success rates in this group are within the national average.

## 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 and there are currently no significant data submission issues.

## 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 2017, legal parenthood consenting processes were found to be robust.

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.

# 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 | Executive review |
|---|---|---|---|
| None noted. | | | |

### ‘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 | Executive review |
|---|---|---|---|
| 1. **Medicines management**<br>The keys to the cabinet in which controlled drugs are stored, are kept in a cupboard together with other keys for the clinic. Although the ‘key cupboard’ is locked the inspection team considered that the safe custody of the controlled drugs is compromised because access to the keys to the cabinet in which these are stored is not restricted to authorised persons only, other staff can also access them.<br><br>DH (2007) ‘Safer Management | The PR should ensure that controlled drugs keys are only accessible to authorised personnel.<br><br>The PR should establish alternative, appropriate and secure arrangements for the storage of the controlled drugs keys in the absence of an authorised key holder.<br><br>When responding to the report, the PR should provide an update on immediate actions that have been taken. | The drug key combination lock was fitted on 2nd July to ensure that only authorised staff can access them, as opposed to all staff. The combination code will be changed on a regular schedule.<br><br>Prior to installation of the new lock, the Senior Nurse on duty was responsible for carrying the key.<br><br>Access to staff areas is controlled by security fobs and individuals movements are recorded. | The executive acknowledges the PR’s response.<br><br>**No further action required.** |

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| of Controlled Drugs; A guide to good practice in secondary care (England)' section 4.5.2. | | | |

## ‘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 | Executive review |
|---|---|---|---|
| 2. **Egg sharing information**<br>The inspection team considers the centre’s egg sharing information on its website places an emphasis on financial incentive rather than altruism.<br><br>Additionally, the website states that if the egg sharer withdraws consent, the egg sharer would have to pay the standard treatment fees and the costs involved in preparing the recipient. This is not compliant with CoP guidance. The centre has confirmed that this payment of fees has not occurred in practice.<br><br>Schedule 3 of the HF&E Act 1990 (as amended), and CoP guidance 12.11 and 13.1. | The PR should ensure that information given to egg sharers is compliant with CoP guidance.<br><br>The PR should review and revise all relevant written information and provide a copy to the centre’s inspector by 19 September 2019. | The information has been amended to reflect the comments made (relevant documents attached). | The executive acknowledges the PR’s response. The centre’s patient information has been revised and is now compliant with CoP Guidance.<br><br>**No further action required.** |

| Additional information from the Person Responsible |
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| The inspection was unannounced, but both regulators and the IVF team worked cooperatively to demonstrate a high level of compliance. |