Executive Licensing Panel - minutes

Centre 0196 (Jessop Fertility)

Interim Inspection Report

Friday, 20 July 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Erin Barton Kathleen Sarsfield Watson	Director of Strategy and Corporate Affairs Policy Manager Communications Manager
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 Jessop Fertility is located in Sheffield and has held a licence with the HFEA since 2001. The centre provides a full range of fertility services.

1.2. The panel noted that, in the 12 months to 30 April 2018, the centre provided 1091 cycles of treatment (excluding partner intrauterine insemination). In relation to activity level this is a large sized centre.

1.3. The panel noted that, between 1 February 2017 and 31 January 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.4. The panel noted that in 2017, the centre reported 317 cycles of partner insemination with 57 pregnancies. This represents a clinical pregnancy rate of 18%, which is likely to be in line with the national average.

1.5. The panel noted that, between 1 February 2017 to 31 January 2018, HFEA held register data showed that centre's success rates for IVF and ICSI are in line with national averages.

1.6. The panel noted that the inspection took place on 22 May 2018.

1.7. The panel noted that at the time of the inspection, three 'other' areas of non-compliance were identified concerning the website, patient screening and record keeping. Since the inspection, the Person Responsible (PR) has provided assurance that all the recommendations made in the report have been fully implemented, and where required and by the date specified, will provide an update or summary of audits conducted to ensure the corrective actions taken are effective

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

2. Decision

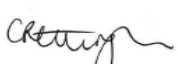
2.1. The panel particularly noted the PR's timely response to the inspector's comments, following the inspection.

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

30 July 2018

Interim Licensing Report

Centre name: Jessop Fertility
Centre number: 0196
Date licence issued: 1 October 2016
Licence expiry date: 30 September 2020
Additional conditions applied to this licence: None
Date of inspection: 22 May 2018
Inspectors: Shanaz Pasha (lead), Andrew Leonard
Date of Executive Licensing Panel: 20 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 an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. The focus of an interim inspection is:

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

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

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

Summary for the Executive Licensing Panel

Summary for licensing decision

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

The ELP is asked to note at the time of the inspection there were recommendations for improvement in relation to three 'other' areas of non compliance or poor practice.

Since the inspection visit the PR has provided assurance that the following recommendations have been fully implemented:

'Other' areas of practice that require improvement:

- The PR should review the contents of the centre's website to ensure success rates are presented in accordance with guidance**.**
- 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 records are maintained of how, and by whom, patients and donors has been reliably identified.

Where required and by the dates specified, the PR will provide an update or summary of audits conducted to ensure the corrective actions taken are effective.

Information about the centre

Jessop Fertility is located in Sheffield and has held a licence with the HFEA since 2001.

The centre provides a full range of fertility services.

The centre provided 1091 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2018. In relation to activity levels this is a large 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 period 1 February 2017 to 31 January 2018 show the centre's success rates are in line with national averages.

In 2017, the centre reported 317 cycles of partner insemination with 57 pregnancies. This represents a clinical pregnancy rate of 18%, which is likely to be in line with the national average.

Multiple births[2]

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

Between 1 February 2017 and 31 January 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: vitrification, placement of samples into storage and embryo transfer. All the procedures observed were witnessed using an electronic witnessing system in accordance 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, reports of audits of stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed, the 'bring-forward' system was discussed with staff and storage records were reviewed. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Quality Management System (QMS)

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

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing, consent to storage, infection control, legal parenthood and controlled drugs.

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

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

- the use of CE marked medical devices
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding Zika and Ebola screening requirements.

The centre is broadly effective in implementing learning from guidance from the HFEA because the centre has not ensured compliance with guidance regarding:

- the content of the centre's website. The success rate data is not broken down by maternal age and the treatment type. Live birth rate per treatment cycle and information about the national rate for the same year, maternal age and treatment type is not provided. See recommendation 1.
- centre staff do not make specific consideration of possible past or present Ebola virus exposure or infection when assessing patients, their partners and donors. See 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 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 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, thawing medium, pipettes and other plastic ware used to culture and manipulate gametes and embryos. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience
During the inspection, we spoke to one patient couple about their experiences at the centre. Sixteen patients provided feedback directly on the HFEA website. The centre's most recent patient survey responses for the year 2017 were reviewed; 238 questionnaires were completed. Feedback was positive with 109 of the individuals providing written feedback making 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 and donors sufficient information to enable them to make informed decision

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, except with regard to the following issue:

- The centre does not maintain documented records of by whom each patient and donor has been reliably identified. See recommendation 3.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2016, recommendations for improvement were made in relation to three 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

Since the last renewal inspection in April 2016 the centre has received two risk tool alerts related to performance, to which the PR has responded appropriately, providing evidence and information that the issues have been addressed.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The clinic is compliant with requirements to submit information to the HFEA.

Legal parenthood

Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At that inspection in 2016, 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 audit. 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.

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’ areas 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
None identified			

‘Other’ areas of practice that require improvement

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Website Success rates published on the centre’s website are not presented in accordance with HFEA guidance. CoP Guidance 4.12	The PR should review the contents of the centre’s website to ensure success rates are presented in accordance with guidance. The PR should audit the centre’s website against the regulatory requirements and arrange to make the amendments needed to ensure compliance. The PR should inform the centre’s inspector of actions that have been taken by 22 August 2018.	The website is currently being redeveloped. The success rates will be displayed in a much clearer format. We are also developing a tool on IDEAS to extract the live birth rate per cycle started so we can display this figure as well as placing a link to the HFEA website in the success rates page.	The executive acknowledges the PR’s response and commitment to implement this recommendation. No further action required.
2. Patient Screening Centre staff do not make specific consideration of possible past or present Ebola virus exposure or infection when	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.	Travel abroad form updated to include Ebola as well as Zika. Updated form emailed to inspector day after inspection. Form also sent with inspection report.	The Executive acknowledges the PR’s response and actions to implement this recommendation.

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 and T52h	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 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 22 August 2018.		No further action beyond submission of the audit due by 22 August 2018.
3. Record Keeping The centre does not maintain a documented record of by whom each patient and donor has been reliably identified. SLC T46b	The PR should ensure that a record is maintained of how, and by whom, patients and donors have been reliably identified. The PR should undertake a review of the centre's processes for establishing the	Post inspection this was discussed with the administration team. The check is carried out by an electronic check on ideas. The current process is that when ID is taken, it is verified with the patient, a copy taken for the notes and the ID check on	The Executive acknowledges the PR's response and that the centre has a process in place for recording the staff member who confirms the identity of a patient or donor. This matter is therefore probably not one of non compliance, however the audit report is also noted which

	identity of patients. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centres inspector by 22 August 2018. Within three months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 22 November 2018.	IDEAS completed. This is a tick box with a password protected named sign off. The person completing the check also records the type of ID provided. Therefore this complies with the requirements for verifying ID. An audit has been conducted of 50 patients from 2017/18. One of the 50 checks on IDEAS was not completed although a copy of the ID was present in the notes. This audit will be added to next years audit schedule so it is continually checked. Audit report form included in email to inspector	shows that one of 50 patients was identified by an unknown staff member. The inspection team therefore suggest it would be appropriate for the centre to perform the recommended audit to ensure the staff member identifying a patient or donor is always identifiable in the centre's patient data management system. No further action beyond submission of the audit due by 22 November 2018.

Additional information from the Person Responsible
Thank you to the inspectors for a constructive inspection which has helped improve systems. A full close out report will be competed and signed off by the ACU board.