Executive Licensing Panel - minutes

Centre 0198 (St Jude's Women's Hospital)

Interim Inspection Report

Tuesday, 10 December 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Richard Sydee (Chair) Howard Ryan Helen Crutcher	Director of Finance and Resources Data Analyst Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

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 St Jude's Women's Hospital is a privately-owned clinic located in Wolverhampton and has held a licence with the HFEA since 2002. The centre provides a full range of fertility services. Other licensed activities of the centre include storage of gametes and embryos.

1.2. The panel noted that, in the 12 months to 31 July 2019, the centre had provided 100 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 twelve months to 31 May 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 9 cycles of partner insemination, with one 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 twelve months to 31 May 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%. This represents performance that is not likely to be statistically different to the 10% multiple live birth rate target for this period.

1.6. The panel noted that an unannounced inspection took place on 13 August 2019.

1.7. The panel noted that at the time of inspection there were two major areas of non-compliance regarding medicines management and legal parenthood. There were also two 'other' areas of non-compliance concerning infection control and suitability of premises. Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations surrounding medicines management and suitability of premises and, where required, to audit the effectiveness of those actions within the required timescales. The PR has given a commitment to fully implement the recommendations regarding legal parenthood and infection control.

1.8. The panel noted that the inspectorate recommended the continuation of the centre's treatment and storage licence.

2. Decision

2.1. 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

Richard Sydee

Date

17 December 2019

Interim Licensing Report

Centre name: St Jude's Women's Hospital
Centre number: 0198
Date licence issued: 18 September 2017
Licence expiry date: 17 September 2021
Additional conditions applied to this licence: None
Date of inspection: 13 August 2019
Inspectors: Mhairi West and Polly Todd
Date of Executive Licensing Panel: 10 December 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 (SLCs).

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 progress made in meeting the HFEA multiple birth rate target, which has reduced significantly since the last inspection.

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

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

Major areas of non compliance:

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

'Other' areas of non compliance:

- The PR should ensure that the premises are suitable.

The PR has given a commitment to fully implementing the following recommendations:

Major areas of non compliance:

- The PR should ensure that the processes for recording consent to legal parenthood are robust and compliant with statutory and regulatory requirements.

'Other' areas of non compliance:

- The PR should ensure that infection control measures and practices are compliant with regulatory requirements and best practice.

Information about the centre

St Jude's Women's Hospital is a privately-owned clinic located in Wolverhampton and has held a licence with the HFEA since 2002. The centre provides a full range of fertility services. Other licensed activities of the centre include storage of gametes and embryos.

The centre provided 100 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2019. In relation to activity levels this is a small centre.

The centre has a satellite agreement with its unlicensed sister clinic, St Jude's Hospital Newcastle-under-Lyme, but no activity has taken place there since the last renewal inspection of centre 0198.

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 12 months to 31 May 2019 show the centre's success rates are in line with national averages.

In 2018, the centre reported nine cycles of partner insemination with one 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 12 months to 31 May 2019 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%. 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 inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and to review patient records. These activities indicated 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

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

and 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; 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, consent to legal parenthood, witnessing and consent to storage.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements with the exception noted in the section 'Legal parenthood' below.

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:

- patient support
- information provision
- consent
- data protection and confidentiality
- data submission to the HFEA
- the use of CE marked medical devices
- the centre's audit of legal parenthood

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 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 as the keys to the cupboard where controlled drugs are stored were accessible to unauthorised personnel.

See recommendation 1.

Prescription of intralipid 'off label'

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

Infection Control

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

During the inspection, we reviewed infection control practices and found them to be broadly compliant with guidance for the following reasons:

- the chair for use in the men's sample production room has deep 'button areas' so the centre cannot be assured that it can be suitably cleaned.
- there are fabric curtains in the patients' toilet but there was no indication as to when these are cleaned or changed.

See recommendation 3.

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 selection of laboratory plasticware and 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

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only six patients have provided feedback in the last 12 months, giving an average five star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. The PR was asked to consider ways to promote the use of this facility and this will be followed up at the next inspection.

The centre's own most recent patient survey responses were therefore reviewed. Feedback was comparable to that provided to the HFEA provided individual comments to the HFEA complimenting staff at the clinic.

No patients were available to speak to inspectors during this visit.

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 compliant with HFEA requirements except those mentioned elsewhere in this report and that noted below:

- one fire extinguisher has not been serviced since 2016, and another had not been serviced since March 2018.

See recommendation 4.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in May 2017, recommendations for improvement were made in relation to four major and five 'other' areas of non compliance.

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

On-going monitoring of centre success rates

Since the last renewal inspection in May 2017, 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 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 the inspection in May 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.

The following issues were noted on inspection:

- In one record the patient had written their date of birth instead of the date of signing on one page of the 'Consent to being the legal parent' (PP) HFEA consent form, this had been corrected but the correction was not signed or initialled by the patient. No live birth resulted from this treatment, therefore this is considered a 'near miss'.
- In another record the patient had written their date of birth instead of the date of signing on one page of the 'Consent to your partner being legal parent' (WP) HFEA consent form. The error had not been corrected and the treatment had resulted in a live birth. However the couple were married at the time of the treatment therefore there was no consequence with regards to the legal parenthood of the child born. This is also considered a 'near miss'.

The inspection team was concerned that 'near-misses' were noted in two out of five sets of records audits during the inspection. The inspection team also reviewed the centre's audits of consent to legal parenthood for patients treated with donor sperm or embryos created with donor sperm in both 2017 and 2018. The audit of consent to legal parenthood for patients treated in 2017 identified the issue with the WP form described above, but no corrective actions were documented or carried out.

Two records of five sets of WP and PP forms reviewed did not contain NHS/CHI/HCN/passport numbers. We do not consider a recommendation is required but we would expect that the PR ensures that all consent forms are accurately and fully completed and this is audited regularly.

During the inspection the team discussed with the PR the possibility of a patient receiving treatment with donor sperm being married or in a civil partnership with someone other than the partner they are attending the clinic with. Given the potential consequences for the legal parenthood of any children resulting from that treatment, the inspection team advised the PR that this is taken into consideration when assessing the marital status of patients.

These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are partially compliant with HFEA requirements.

See recommendation 2.

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	Executive review
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.

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 The keys to the cupboard where controlled drugs are stored were accessible to unauthorised personnel. SLC T2. DH: Controlled Drugs (Supervision of management and use) Regulations 2013.	The PR should ensure that the keys to the cupboard where controlled drugs are kept are only accessible to authorised personnel. The PR should inform the centre’s inspector of the actions taken to comply with this recommendation when responding to this report.	We have complied with this recommendation. We now keep the keys to the CD cupboard in a separate and secure key locker kept in the nurses room. This is accessible only to authorised clinical staff.	The executive acknowledge the PR’s response and implementation of this recommendation. No further action required.
2. Legal Parenthood The following issues were noted on inspection. • in one record the patient had written their date of birth instead of the date of	The PR should ensure that the processes for recording consent to legal parenthood are robust and compliant with statutory and regulatory requirements.	The issues raised are noted, and are being addressed. A report on corrective actions to be implemented will be sent to the clinic's inspector on or before 13th February 2020.	The executive acknowledge the PR’s response and commitment to implementation of this recommendation.

signing on one page of the 'Consent to being the legal parent' (PP) HFEA consent form, this had been corrected but the correction was not signed or initialled by the patient. No live birth resulted from this treatment, therefore this is considered a 'near miss'. • In another record the patient had written their date of birth instead of the date of signing on one page of the 'Consent to your partner being legal parent' (WP) HFEA consent form. The error had not been corrected and the treatment had resulted in a live birth. However the couple were married at the time of treatment, and there was no consequence with regards to the legal parenthood of the child born. The audit of consent to legal parenthood for patients treated in 2017 identified the	The PR should review the process for performing audits to ensure documentation and implementation of corrective action. The PR should submit a summary of their review of the audit process and provide a copy to the centre's inspector by 13 November 2019. The PR should review all audits of consent to legal parenthood, and ensure that any required actions in response to audit findings have been documented and corrected. A summary report of this review of audit results should be provided to the centre's inspector by 13 February 2020.		No further action other than the review of all audit results to ensure that all corrective actions have been implemented, due by 13 February 2020.

issue with the WP form described above, but no corrective actions were documented or carried out. Schedule 3, HF&E Act, 1990 (as amended). SLC T36.			

‘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
3. Infection Control The following issues regarding infection control practices were noted on inspection. • the chair for use by the men has deep ‘button areas’ so the centre cannot be assured that it can be suitably cleaned. • there are fabric curtains in the patients’ toilet but there was no indication as to when these are cleaned or changed. DH Health and Social Care Act 2008: Code of practice on the prevention and control of infections and related guidance.	The PR should ensure that infection control measures and practices are compliant with regulatory requirements and best practice. The PR should address the issues identified and review the centre’s infection control practices to determine why these have occurred. The PR should provide an update on the actions to be taken when responding to this report. It is expected that the issues identified will be addressed by 13 November 2019.	The PR is committed to achieving and maintaining full compliance with best practice in infection control. Infection control training is mandatory for all staff. All issues identified during the inspection have been noted and are being rectified and should be completed by the deadline of 13/11/19.	The executive acknowledge the PR’s response and commitment to implementation of this recommendation. The PR should provide confirmation to the centres inspector when the issues identified have been rectified. Further action required.

DH Health Building Note 00-09: 'Infection control in the built environment' 2013.			
4. Suitability of Premises The fire extinguishers have not been serviced since March 2018 and one had not been serviced since 2016. SLC T17. Regulatory Reform (Fire Safety) Order 2005.	The PR should ensure that the premises are suitable. The PR should ensure that fire extinguishers are subject to regular maintenance programme and are serviced within the required time period. The PR should provide an update on the actions to be taken when responding to this report. It is expected that the issues identified will be addressed by 13 November 2019.	All fire extinquishers and indeed our fire safety policies and procedures have been reviewed. Where indicated, some fire extinguishers have been serviced or replaced. A new company (Chase Fire Safety) have been appointed to oversee maintenance of fire safety equipments in the clinic.	The executive acknowledge the PR's response and implementation of this recommendation. No further action required.

Additional information from the Person Responsible