Executive Licensing Panel - minutes

Centre 0258 (The Fertility Centre at Whittington Health)

Interim Inspection Report

Friday, 14 July 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Juliet Tizzard (Chair) Anjeli Kara Jessica Watkin	Director of Strategy & Corporate Affairs Regulatory Policy Manager Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel noted that Fertility Centre at Whittington Health is located in north London and operates as a satellite IVF centre for CRM London (centre 0199). The centre has held a licence with the HFEA since July 2007. In relation to activity levels, this is a small centre.

1.2. The panel noted the centre has recently started to recruit sperm donors, and anticipates recruiting five donors and completing 20 donor inseminations in the 12 months from when the licence was varied in November 2016. At the time of this inspection, the centre had recruited three sperm donors but has not yet undertaken any donor treatments.

1.3. The panel noted that the centre did not report any cycles of partner insemination, therefore comparison of success rates with national averages are unable to be made.

1.4. The panel noted that the inspection took place on 16 May 2017.

1.5. The panel noted that at the time of the inspection on 16 May 2017, two major and one 'other' area of non-compliance or poor practice were identified. The panel noted that since the inspection, the Person Responsible (PR) had fully implemented the recommendation regarding the provision of information to the HFEA. The PR had provided a commitment to fully implementing the recommendations regarding the major areas of non-compliance concerning the Quality Management System (QMS) and medicines management.

1.6. The panel noted that the inspectorate recommends the continuation of the centre's Treatment (insemination using partner/donor sperm) and Storage licence.

2. Decision

2.1. The panel was satisfied the centre was fit to have its centre's Treatment (insemination using partner/donor sperm) and Storage licence continued.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

25 July 2017

Interim Licensing Report

Centre name: The Fertility Centre at Whittington Health
Centre number: 0258
Date licence issued: 1 July 2015
Licence expiry date: 30 June 2019
Additional conditions applied to this licence: None
Date of inspection: 16 May 2017
Inspectors: Polly Todd (lead), Douglas Gray
Date of Executive Licensing Panel: 14 July 2017

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.

The Executive Licensing Panel is asked to note that there are recommendations for improvement in relation to two major and one 'other' areas of non-compliance or poor practice.

Since the inspection visit the PR has fully implemented the following recommendation:

'Other' areas of practice that require improvement:

- The PR should ensure that information required by the HFEA is provided within the timeframes specified.

Since the inspection visit the PR has given commitment to fully implement the following recommendations:

'Major' areas of non-compliance:

- The PR should review the centre's QMS to ensure it is effective and that all required audits are comprehensive and are completed in a timely manner, including those outstanding for witnessing and consent.
- The PR should ensure that staff are trained and have demonstrated competence for the tasks they perform and that this is documented.

Information about the centre

The Fertility Centre at Whittington Health is in north London and has held a licence with the HFEA since July 2007. In relation to activity levels, this is a very small centre.

Following the licence renewal inspection in February 2015, concerns were raised regarding the lack of progress made by the PR towards implementing the recommendations of the inspection report. As such, the decision to renew the centre's licence was adjourned pending further engagement by the PR. As the licence was due to expire in June 2015, the ELP issued Special Directions to allow the centre to continue licensed activities for three months after the expiry of the licence or until a new licence was issued (whichever was sooner). The centre's licence was subsequently renewed in September 2015 without any additional conditions, the PR having provided evidence that all the non-compliances had been addressed.

The centre's current licence was varied in November 2016 to reflect the following:

- change of centre name;
- change of postal address
- variation of licenced activities from treatment (insemination using partner sperm) to treatment (insemination using partner/donor sperm) and storage;
- appointment of a licence holder.

The centre has recently started to recruit sperm donors, and anticipates recruiting five donors and completing 20 donor inseminations in the 12 months from the licence variation. At the time of this inspection, the centre had recruited three sperm donors but has not yet undertaken any donor treatments.

The centre operates as a satellite IVF centre for CRM London, HFEA licenced centre 0199.

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]

In 2016, the centre did not report any cycles of partner insemination therefore comparison of success rates with national averages cannot be made. (See recommendation 3).

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. On the day of inspection there were no procedures taking place for the inspectors to observe, although the centre's procedures and witnessing records were reviewed. On this basis, the centre's witnessing procedures were considered compliant with HFEA requirements.

[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 $p \leq 0.002$.

Consent: To the storage of cryopreserved material

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

On inspection, 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 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 current level of activity being carried out. However, this is a very small team, some of whom are part time and have multiple roles within the centre or other clinical areas. The PR is reminded that as donor recruitment and licensed activity increases, he should ensure that appropriate staffing levels are maintained.

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 not compliant with requirements because:

- there is no process in place for reviewing the performance of the QMS to ensure ongoing and continuous improvement;
- there was no evidence that the QMS had been reviewed or that an audit of consent to treatment had been conducted within the last two years;
- the witnessing audit provided for review was inadequate in that it only audited the disposal of sperm.

Whilst it is recognised that some progress has been made with the QMS, it is noted that this was a major non-compliance at the licence renewal inspection in 2015 which has not been fully resolved. (See recommendation 1).

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 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, and administration of medicines were reviewed and were found to be partially compliant with guidance because:

- staff have not received training in medicines management;
- staff will, on occasion, administer a Human Chorionic Gonadotrophin (HCG) 'trigger' injection to patients at the time of scanning. This is however, contrary to the centre's standard operating procedure (SOP) which directs that the patient will administer this at home using medication previously prescribed. There is no Patient Group Directive (PGD) or written instruction in place for the administration of HCG in this scenario. (See recommendation 2).

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 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, no patients were available to speak with the inspectors about their experiences at the centre and there was no patient feedback provided directly to the centre for the inspection team to review. The inspection team were able to review the messages of thanks and appreciation provided by patients to the centre team. 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;

Monitoring of the centre's performance

The centre has only provided partner IUI treatments prior to the licence variation in November 2016 and has not undertaken any donor insemination treatments to date. The centre was therefore not subject to on-going monitoring of success rates via the HFEA risk tool prior to this inspection.

Compliance with HFEA standard licence conditions

The pre-inspection assessment and observations during the visit to the centre, indicate that the centre is non-compliant with the following HFEA requirements:

- the centre has not completed or submitted the self-assessment questionnaire as required by the HFEA prior to this inspection. (See recommendation 3).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2015, recommendations for improvement were made in relation to six major and two 'other' areas of non-compliance.

The PR subsequently provided information and evidence that all the recommendations were fully implemented. However, during this inspection, the inspectors continued to have concerns regarding one recommendation (see recommendation 1):

- The PR should review the provision of the quality management system to ensure that audits are documented and that corrective actions required are fully implemented.

On-going monitoring of centre success rates

Prior to the variation of licenced treatments in November 2016, the centre provided only basic partner IUI treatments and therefore their success rates were not subject to on-going monitoring through the HFEA risk tool. The centre has not undertaken any treatments using donor sperm since November 2016 and has therefore not been issued with any performance 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 broadly complaint with requirements to submit information to the HFEA because;

- the centre has not provided an annual return for partner IUI treatments undertaken in 2016. (See recommendation 3).

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.

The centre has not provided treatments using donated gametes to date, therefore the inspection team could not review consent to legal parenthood. The centre has procedures in place to ensure that the offer of counselling is made, and effective consent to legal parenthood is obtained prior to treatment, which are suitable.

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. Quality Management System On inspection, the following issues were noted: • there is no process in place for reviewing the performance of the QMS to ensure ongoing and continuous improvement; • there was no evidence that the QMS had been reviewed or that an audit of consent to treatment had been conducted within the last two years; • the witnessing audit provided for review was	The PR should review the centre’s QMS to ensure it is effective and that all required audits are comprehensive and are completed in a timely manner, including those outstanding for witnessing and consent. The PR should provide a summary report of the review and an action plan with timescales for implementation of any changes required to the centre’s inspector by 16 August 2017. It is expected that the implementation of the actions identified will be completed by	The centre is fully aware that the QMS requires some attention, and now that the sperm storage and donor sperm treatment licence has been acquired, this is the next area of focus for the quality manager. The QMS will be reviewed and updated by the PR and quality manager in the coming months, and a revised audit schedule drawn up. Critical outstanding audits, including a witnessing audit and an audit of consent forms, will be performed before 16/8/17. Any other overdue audits will be conducted before 16/11/17.	The Executive acknowledges the PR’s response and commitment to implementing this recommendation. Further action required.

inadequate in that it only audited the disposal of sperm. Whilst it is recognised that some progress has been made with the QMS, it is noted that this was a major non-compliance at the renewal inspection in 2015 which has not been fully resolved. SLC T36; CoP guidance note 23.	16 August 2017and a copy of the outstanding audits be provided to the centre's inspector by 16 November 2017.		
2. Medicines management During the inspection, the following issues were noted: • staff have not received training in medicines management; • staff will, on occasion, administer a Human Chorionic Gonadotrophin (HCG) 'trigger' injection to patients at the time of scanning. This is however, contrary to the centre's standard operating procedure (SOP) which directs	The PR should ensure that staff are trained and have demonstrated competence for the tasks they perform and that this is documented. It is expected that completion of staff training and competency assessment in medicines management and HCG administration, will be completed and evidence provided of this by 16 November 2017. The PR should review current practice relating to nurses administering HCG and	The nursing competency document will be reviewed and updated to ensure that it fully addresses compenetcies relating to medicines management. Staff competency in this area will then be reassessed, for all staff to whom this is applicable. Competency assessments will be subitted by 16/11/17. It is noted that the administration of HCG is sometimes performed by nurses in the clinic, as	The Executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required.

that the patient will administer this at home using medication previously prescribed. There is no Patient Group Directive (PGD) or written instruction in place for the administration of HCG in this scenario SLC T12; T15a. NMC 2010 'Standards for medicines management'.	ensure it is directed by a valid SOP or PGD or written instruction for administration. The PR should provide a summary report of this review, with actions taken to the centre's inspector by 16 August 2017.	opposed to by patients at home via prescription, and that this is not concordant with the current SOP. The SOP will be reviewed and amended such that it details the different ways in which HCG may be supplied and administered. The new SOP will be circulated to all nursing staff.	

‘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. **Provision of information to HFEA** The centre has not submitted its self-assessment questionnaire as required by the HFEA prior to this inspection. The centre has not provided an annual return for partner IUI treatments undertaken in 2016. General Directions 0005; SLC T4; Guidance note 32.1 (a) (b)	The PR should ensure that information required by the HFEA is provided within the timeframes specified. The PR should submit the annual return for treatments undertaken in 2016 to the HFEA when responding to this report. The PR should investigate the barriers to the submission of information to the HFEA and provide a summary report including corrective actions taken when responding to this report.	The centre regrets that it did not submit its IUI data for 2016, and admits that this was an unfortunate oversight. Following a discussion with Polly Todd on 14/6/17, in which it was explained that due to some technical issues experienced in the wake of the recent migration of IDEAS to a new server, submission of the IUI data will be delayed until 16/6/17. If any further delays are anticipated then Polly will be informed ASAP. Please see summary report below.	The Executive acknowledges the PR’s response. The Executive has received confirmation from the PR that the 2016 IUI data has now been submitted. The Executive will continue to monitor the centres submission of data and their SAQ. No further action required.

Additional information from the Person Responsible

Summary report following investigation of the non-submission of data from 2016

Myself and Erica Foster investigated why last year's IUI data was not submitted via the portal in the usual manner at the correct time. The 'prompt' that we relied on to remind us to submit this data came in the form of an email from the HFEA informing us of the upcoming February deadline. For some reason, I can find no evidence of having received this email this year, and we forget to submit the data.

We recognise, however, that relying on an email prompt from the HFEA is an insufficient method by which to ensure data is submitted on time, and are grateful that this has been brought to our attention. We have implemented a system whereby reminders for the IUI submission deadline appear on all our personal work email calendars, and as an alert on IDEAS. As a back-up, I have also set-up an email rule whereby all emails received from the HFEA will be directly forwarded to Erica Foster and Yvonne Nicholson, as a way of spreading the risk of these reminders (and other important imformation) being accidentally mislaid or deleted.

We acknowledge that once we begin performing donor insemination cycles our HFEA data submission obligations will intensify significantly, and we can assure the HFEA that we have robust protocols in place for ensuring that this crucial information is submited within the required timeframes.