Executive Licensing Panel - minutes

Centre 0094 (Barts Health Centre for Reproductive Medicine) Interim Inspection Report

Wednesday, 19 October 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Jessica Watkin Anna Rajakumar	Director of Strategy & Corporate Affairs Policy Manager Scientific Policy Manager
Members of the Executive	Dee Knoyle Siobhain Kelly	Secretary Interim Head of Corporate Governance
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 Barts Health Centre for Reproductive Medicine is located in London. The centre provides a full range of fertility services and has held a licence with the HFEA since 1992.

1.2. The panel noted that the centre's licence is due to expire on 30 September 2018.

1.3. The panel noted that the inspection took place on 19 July 2016.

1.4. The panel noted that in the 12 months to 31 May 2016, the centre provided 1220 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

1.5. The panel noted that for IVF and ICSI, HFEA-held register data for the period March 2015 to February 2016 showed the centre's success rates were in line with national averages.

1.6. The panel noted that for the year 2015, the centre reported 289 cycles of partner insemination with 33 clinical pregnancies. This represents a clinical pregnancy rate of 11% which is likely to be similar to the national average.

1.7. Between March 2015 and February 2016, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 10%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

1.8. The panel noted that at the time of this interim inspection on 19 July 2016, two major areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has committed to implementing the recommendations.

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

2. Decision

2.1. The panel had regard to its decision tree and was satisfied that 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

Juliet Tizzard

Date

24 October 2016

Interim Licensing Report

Centre name: Barts Health Centre for Reproductive Medicine
Centre number: 0094
Date licence issued: 1 October 2014
Licence expiry date: 30 September 2018
Additional conditions applied to this licence: None
Date of inspection: 19 July 2016
Inspectors: Janet Kirkland MacHattie, Andrew Glew
Date of Executive Licensing Panel: 19 October 2016

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 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

The inspection team recommends the continuation of the centre's licence. In particular we note the progress made by the centre in meeting the HFEA multiple birth rate targets.

The Executive Licensing Panel is asked to note that there are recommendations for improvement in relation to two major areas of non compliance.

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

'Major' areas of non compliance:

- The PR should ensure that medical gases are stored in line with statutory and regulatory guidance.
- The PR should ensure that a third party agreement is in place with the premises where surgical sperm retrievals are performed.

Information about the centre

The Barts Health Centre for Reproductive Medicine is located in London and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services.

The centre provided 1220 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2016). 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 March 2015 to February 2016 show the centre's success rates are in line with national averages.

For the year 2015 the centre reported 289 cycles of partner insemination with 33 clinical pregnancies. This represents a clinical pregnancy rate of 11% which is likely to be similar to the national average.

Multiple births[2]

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

Between March 2015 and February 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10% 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: active patient identification, putting embryos into storage and sperm preparation. All of the procedures observed were witnessed using a manual 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 all stored gametes, the sperm storage spreadsheet and the 'bring-forward' system were discussed with staff and one storage record was 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: 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 disclosure, welfare of the child and controlled drugs and safe storage of medicines audit. 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 centre's audit of legal parenthood
- learning from adverse incidents
- HFEA Clinic Focus articles regarding: screening requirements, zika virus and the most recent alert regarding storage expiry dates.

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 discussed and an audit performed in April 2016 by a member the Trust's pharmacy team was reviewed. The audit did not identify any major non-conformances.

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: egg collection dishes and embryo catheter. 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. Thirty patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive with 18 of the individuals providing written feedback giving compliments and 11 complaints about the care received. Most of the negative comments were with regards to difficulties experienced trying to contact the centre by telephone. The PR advised the inspectors that actions had been taken to address this area of concern and that they had increased the number of staff on the administrative team. The inspection team are satisfied that appropriate action is being taken and this will be reviewed at the next inspection.

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

- has had some difficulties responding to patient telephone calls promptly, although appropriate action has been taken to improve this aspect of their service;
- 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.

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 broadly compliant with HFEA requirements for the following reasons:

Safety and suitability of the premises:
Medical gases are not stored safely or in suitable location with adequate ventilation (see recommendation 1). Six gas cylinders containing carbon dioxide were stored in two cupboards in the centre; one in the same corridor as the treatment and recovery room and the other outside the laboratory. Some of the cylinders were not secure and a gas change over unit was balanced on top of one of the cylinders. The inspection team were also concerned whether the level of ventilation in these areas is suitable. The PR has subsequently informed the centre's inspector that they also have a further four small mixed gas cylinders (two secured and two unsecured) in the laboratory.

Third party agreements:
The centre occasionally performs surgical sperm retrievals in theatres within the Trust however a third party agreement is not in place (recommendation 2).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2014 recommendations for improvement were made in relation to 15 'other' area(s) 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 2014 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.

An interim inspection performed at the centre in 2013 identified inconsistencies in legal parenthood consent completion. As a result the PR was asked to audit their practices in this area to ensure they were suitable, to report the findings of the audit to the HFEA and to respond to those findings. The PR sent the report of the audit to the HFEA within the required timeframe. The audit showed that 14 couples were affected by legal parenthood consent anomalies however this was reduced to 13 as one of the couples was married or in a civil partnership at the time of the treatment. On this inspection we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA.

Since this time the centre has been proactive in contacting those affected, both in person and in writing. The couples were invited to meet with senior centre and Trust staff to discuss the implications of the consent anomalies in each case. The couples were also advised to seek independent legal advice, the cost of which was borne by the Trust. The executive considers that the centre has provided appropriate support and guidance to those affected.

To date, seven couples have made application to the Families Division of the High Court, in two instances adoption has been granted and in two others a declaration of parenthood has been made. Two further cases have recently been considered by the Courts and the outcome is awaited. Five couples have not responded to communications from the centre and one who initially responded has not proceeded with any action to date. The PR intends to write to the couples (recorded delivery) once again to inform them of implications of their consent anomaly and the options open to them based on legal advice currently being sought. The PR has committed to keep the centre's inspector updated in this regard.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR was able to provide that confirmation and assurance.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed three sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood and the offer of counselling was seen to be in place prior to treatment in all cases. In summary, the inspection team considers the processes currently used to obtain consent to legal parenthood are compliant with HFEA requirements.

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical areas of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical area of non compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None identified			

‘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	Executive Review
1. Medical gases are not stored safely or in suitable location with adequate ventilation. SLC T17; Health Technical Memorandum 02-01: Medical gas pipeline systems Part B: Operational management (Department of Health, 2006).	The PR should ensure that medical gases are stored in line with statutory and regulatory guidance. The PR should take immediate action to ensure that medical gas cylinders and the gas change over unit are secure and not at risk of toppling. The PR should seek the advice of a suitably qualified individual as to the safety and suitability of the storage of medical gases on the premises.	The four J size gas cylinders have now been secured and we are awaiting a review from the Trust team regarding the suitability of the sotrage of medical gases. - September 2016 The change-over unit is pending and a new request for securing the small cylinders within the laboratory will be made - September 2016	The inspector acknowledges the PR’s response and will continue to liaise with the PR regarding the outcome of the review from the Trust team as to the suitability of the storage of medical gases and the securing of the changeover unit and small cylinders. The PR has in the interim provided the following assurance: ‘I am happy that the position and security of the cylinders are safe for staff to continue to use and not accessible by patients. The risk is on the Trust risk register so is visible to our Clinical

	The PR should inform the centre's inspector of actions taken towards implementing this recommendation when responding to the report.		Academic Group Managers so they can monitor the progress of the works.' Further action required.
2. Surgical sperm retrievals are occasionally performed in theatres within the Trust, however a third party agreement is not in place (recommendation 2). SLC T111.	The PR should ensure that a third party agreement is in place with the third party premises where surgical sperm retrievals are performed. The PR should provide the centre's inspector with a copy of the agreement by 17 October 2016.	A TPA is being drafted and we have the name of the GM that will need to authorise it - September 2016	The executive acknowledges the PR'S response. The PR should provide a copy of the agreed TPA when it is finalised, this should be no later than 17 November 2016. Further action required.

‘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	Executive Review
None identified			

Additional information from the Person Responsible
Our legal team are drafting a letter to send to the six couples that have not taken any steps to apply for either a declaration of parentage or to go through the adoption process. Once we have this is will be sent out by recorded delivery.