Executive Licensing Panel - minutes

Centre 0291 (Fertility Unit Barking, Havering and Redbridge Hospital Trust) Renewal Inspection Report

Thursday, 6 April 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Ian Peacock Joanne Anton	Director of Strategy & Corporate Affairs Systems Manager Head of Regulatory Policy
Members of the Executive	Bernice Ash Siobhain Kelly	Secretary Senior Governance Manager
External adviser		
Observers	Anna Quinn	Scientific Policy 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:

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

1. Consideration of application

1.1. The panel considered the papers, which included a completed application form, inspection report and licensing minutes for the last three years.

1.2. The panel noted that the Fertility Unit, Barking, Havering and Redbridge Hospital Trusts holds a Treatment (insemination using partner sperm) licence and provides basic fertility services.

1.3. The panel noted that the centre has been licensed by the HFEA since 2007.

1.4. The panel noted that, in 2016, the centre reported one cycle of partner insemination with no pregnancies. This is likely to be consistent with the national average.

1.5. The panel noted that at the last renewal inspection in January 2014, the centre was undergoing a period of change and there were a number of non-compliances resulting from a failure to implement recommendations made at the previous inspection. Therefore, only a three year licence was issued at this renewal.

1.6. The panel noted that since March 2016, the centre has provided a satellite service for Guys Hospital.

1.7. An inspection was carried out at the centre on 28 February 2017.

1.8. The panel noted that at the time of the inspection there was one area of practice that required improvement concerning sperm collection pots used for insemination treatment; these needed to be appropriately CE marked as medical devices. The panel noted that the PR had fully implemented this recommendation since the inspection.

1.9. The panel noted that the inspectorate recommends the renewal of the centre's Treatment (insemination using partner sperm) licence for a period of four years without additional conditions.

2. Decision

2.1. The panel endorsed the inspectorate's recommendation to renew the centre's Treatment (insemination using partner sperm) licence for a period of four years without additional conditions.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

18 April 2017

Inspection report

Purpose of the inspection report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients. The inspection was scheduled and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 28 February 2017

Purpose of inspection: Renewal of a licence to carry out Treatment (insemination using partner sperm)

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit, and communications received from the centre.

Inspectors: Polly Todd (lead), Sara Parlett

Date of Executive Licensing Panel: 7 April 2017

Centre name	Fertility Unit, Barking, Havering and Redbridge Hospitals Trust
Centre number	0291
Licence number	L/0291/4/b
Centre address	Queen's Hospital, Rom Valley Way, Romford, Essex RM7 0AG
Person responsible	Jayant Mehta
Licence holder	Yemi Coker
Date licence issued	1 August 2014
Licence expiry date	31 July 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Fertility Unit, Barking, Havering and Redbridge Hospitals Trust has held a Treatment (insemination using partner sperm) licence with the HFEA since 2007 and provides basic fertility services.

At the time of the last renewal inspection in January 2014, the centre was undergoing a period of change, with a new Person Responsible (PR) and uncertainty over the future of the service. There were also a number of non-compliances noted at the inspection which resulted from a failure to implement recommendations made at the previous inspection. The inspection team therefore recommended a three-year licence.

Since the last licence renewal in 2014, the Executive Licence Panel (ELP) has approved the following variation to the centre's current licence:

- change of Licence Holder (LH) in 2015.

Prior to his retirement, the previous PR explained that revised NICE guidelines had significantly reduced the recommended clinical indications for IUI treatment and, as a consequence, it was likely that few new IUI cycles would be performed at the centre. However, in December 2013 it was confirmed that the Trust planned to support the renewal of the centre's current licence whilst also considering plans to establish a full IVF centre at the hospital. Whilst these plans have not been implemented to date, the centre has, since March 2016, provided a satellite service. Guys Hospital (HFEA licensed centre 0102) is the primary centre for this service, providing all licensed activities including egg collection, embryo culture, storage and use in treatment services. This service is provided for NHS and self-funding patients wishing to undergo IVF treatment.

During this inspection, the inspection team had discussions with the PR about the viability of having a licence when so few IUI treatments are undertaken. The PR reported that the Clinical Commissioning Group (CCG) continue to fund IUI treatments for patients with specific medical needs and that the number of these patients referred to the centre justifies the licence requirement. The PR anticipates that the satellite activities now undertaken will support the development of a full IVF service at the centre in the future.

Pregnancy outcomes[1]
In 2016, the centre reported one cycle of partner insemination with no pregnancies. This is likely to be consistent with the national average.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HFE) Act 1990 (as amended), the HFE Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16 (2) (c) of the HFE Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HFE Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to us in accordance with requirements.

The ELP is asked to note that, at the time of inspection, there was one area of practice that required improvement.

Other areas of practice that require improvement:

- The PR should ensure that sperm collection pots used for insemination treatment are appropriately CE marked as medical devices.

Since the inspection visit, the PR has fully implemented the recommendation.

Recommendation to the Executive Licensing Panel

The centre has no critical or major areas of non-compliance. The inspection team also note that at the last inspection there were no areas of practice that required improvement, and acknowledges the commitment and enthusiasm that the PR and the centre staff show towards ensuring regulatory compliance and quality of care. In particular, their preparation for the inspection and engagement in the inspection process, which was to be commended.

The inspection team recommends the renewal of the centre's Treatment (insemination using partner sperm) licence for a period of four years without additional conditions.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre.
2. The experience of patients at this centre.
3. The protection of gametes (sperm) at this centre.
4. How this centre looks after important information.

1. Protection of the patient and children born following treatment

▶ **Witnessing and assuring patient and donor identification**
What the centre does well **Witnessing (Guidance note 18)** The centre's procedures for double checking the identification of gametes and the patient to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.
What the centre could do better Nothing identified at this inspection.

▶ **Donor selection criteria and laboratory tests** Screening of donors before procuring, processing gametes and embryos Payments for donors Donor assisted conception
What the centre does well The centre does not undertake treatment with donor gametes, therefore this area of practice is not applicable to this inspection.
What the centre could do better Not applicable to this inspection.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or their gametes, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management
The centre does not keep, dispense or administer medicines therefore this area of practice is not applicable to this inspection.

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.

Pre-operative assessment and the surgical pathway
The centre provides partner insemination treatment only, therefore this area of practice is not applicable to this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is multiple pregnancy and birth. The centre provides only insemination treatments, but such treatment still exposes patients to the risks of multiple pregnancies and births. Thus, it is important for centres providing insemination treatments to have a multiple births minimisation strategy. The centre's procedures are compliant with HFEA requirements to have a multiple birth minimisation strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

Procurement of gametes (Guidance note 15)
The centre's procedures are compliant with HFEA requirements:

- to document the justification for the use of the patient's gametes in treatment, based on the patient's medical history and therapeutic indications;
- if sperm is procured at home, for the centre to keep a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre does not transport or distribute gametes or embryos, therefore this area of practice is not applicable to this inspection.

Receipt of gametes and embryos (Guidance note15)
The centre does not receive gametes or embryos, therefore this area of practice is not applicable to this inspection.

Imports and exports (Guidance note 16; General Direction 0006)
The centre does not import or export gametes or embryos, therefore this area of practice is not applicable to this inspection.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA requirements. These requirements are important to ensure that the centre has the ability to:

- identify and locate gametes during any step from procurement to use for human application or disposal;
- identify the donor and recipient of particular gametes;
- identify any person who has carried out any activity in relation to gametes, and
- identify and locate all relevant data relating to products and materials coming into contact with particular gametes and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services. The centre has a QMS in place that is compliant

with HFEA requirements. The centre's QMS is ISO 9001:2012 certified and the Trust is currently working towards the 2015 version.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has recently entered into a satellite arrangement with centre 0102. As the responsibility for ensuring that the activities performed by satellite clinics on behalf of a licensed centre lies with the primary centre, the inspection team did not consider it necessary to inspect the satellite activities during this inspection. Whilst the satellite services have not formally been audited by the primary centre, one of the registered medical practitioners working at the centre also works at the primary centre and oversees the satellite services. The inspection team are satisfied with this level of oversight at the centre as the PR has audited practices relating to the satellite services, which was evidenced during the inspection. The inspection team have advised the PR to liaise with the primary centre's PR to ensure that a formal audit be completed by the primary centre within the required timeframes.

Equipment and materials (Guidance note 26)
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 status of medical devices and consumables was reviewed in the course of the inspection. With the exception noted below, all are appropriately CE marked for medical use and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
Whilst the centre has not had any adverse incidents to report to the HFEA since the last inspection, its procedures for reporting adverse incidents are compliant with HFEA requirements. The centre has procedures in place for investigating adverse incidents that may occur. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better
Equipment and materials (Guidance note 26)
Sperm pots used for the collection of sperm for use in insemination, were CE marked for In Vitro Diagnostic use only and not for use as a medical device (SLC T30; see recommendation 1).

Staff engaged in licensed activity

Person responsible (PR)
Staff

What the centre does well

Person responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR entry programme.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements.to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better
Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided, are compliant with HFEA requirements.

Safeguarding
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better
Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre does not create embryos or perform embryo testing, therefore this area of practice is not applicable to this inspection.

What the centre could do better
Not applicable to this inspection.

2 The experience of patients

Patient feedback

What the centre does well

There were no patients available to speak to the inspectors about their experience at the centre on the day of inspection and only two patients provided feedback directly to the HFEA in the time since the last inspection. However, the inspection team reviewed the patient feedback responses provided directly to the centre. These responses were received from IUI patients and those using the satellite services. Feedback was extremely positive, and of the 100 patient responses received between September and December 2016, 99% expressed that they would be either extremely likely, or likely, to recommend the service to family and friends.

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;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg [and sperm] sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)

The centre is not required to provide counselling for basic partner IUI service. Therefore, this area of practice is not applicable to this inspection.

Egg and/or sperm sharing arrangements (Guidance note 12; General Direction 0001)

The centre does not offer egg or sperm sharing arrangements, therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not offer surrogacy arrangements, therefore this area of practice is not applicable to this inspection.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients.

What the centre could do better
Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; CH (11)02)
The centre's procedures for providing information to patients are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better
Nothing identified at this inspection.

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
The centre does not provide treatments using donated gametes, therefore this area of practice is not applicable to this inspection.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Requirements to seek consent to disclosure to researchers are not relevant to basic partner IUI services and therefore this area of practice is not applicable to this inspection.

What the centre could do better
Nothing identified at this inspection.

3. The protection of gametes

Respect for the special status of the embryo

What the centre does well
The centre does not provide treatment services using embryos and therefore this area of practice is not applicable to this inspection.

What the centre could do better
Not applicable to this inspection.

Screening of patients
Storage of gametes

What the centre does well

Screening of patients (Guidance note 15 and 17)
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment and processing of gametes.

Storage of gametes and embryos (Guidance note 17)
The centre does not store gametes or embryos, therefore this area of practice is not applicable to this inspection.

What the centre could do better
Nothing identified at this inspection.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre does not use embryos for training staff, therefore this area of practice is not applicable to this inspection.

What the centre could do better
Not applicable to this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre provided an annual return for treatments undertaken in 2016 within the required timeframe.

What the centre could do better
Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2015, there were no recommendations for improvement.

On-going monitoring of centre success rates

As this centre only provides basic partner IUI treatment, their success rates are not subject to on-going monitoring through the HFEA risk tool, and the centre has not therefore been issued with any performance alerts.

Areas of practice requiring action

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, General 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 area 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 to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. 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			

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 to a 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
- 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
None			

Other areas of practice that require improvement

Areas of practice that require improvement are any area of practice which cannot be classified as either a critical or major area of non-compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. Equipment and materials Sperm pots used for the collection of sperm samples for use in insemination, were CE marked for In Vitro Diagnostic use only and not for use as a medical device. SLC T30.	The PR should ensure that the sperm collection pots used for insemination treatments are appropriately CE marked as medical devices. We would not recommend precipitous changes that might impact on the quality of treatment, however, the PR should ensure that a plan is developed and implemented, so that appropriately CE marked medical devices are used for insemination treatments. This plan should be provided to the centre's inspector by 28 May 2017 and should include timescales by which the suitably CE marked products will be in use.	As of 20/03/2017, all the IUI patients receiving treatment in our unit will be asked to prodcue their semen sample in sperm pots appropriatley CE marked as Class IIa medical device for IVF use. These pots have a four digit CE number and are MEA/LAL/HSSA tested.	The Executive acknowledges the PR's prompt implementation of this recommendation. No further action.

	It is expected that the plan will be fully implemented by 28 August 2017.		

Reponses from the person responsible to this inspection report

I am in agreement with this inspection report and thank the inspectors for their guidance and support during the inspection. I regret the delay in the payment of the inspection fees. The trust finance department has been alerted of this delay and they have assured me that the invoice has been flagged for immediate payment.