Executive Licensing Panel - minutes

Centre 0289 (North Middlesex University Hospital (Reproductive Medicines Unit))

Interim Inspection Report

Tuesday, 28 January 2020

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Dina Halai Laura Riley	Director of Strategy and Corporate Affairs Scientific Policy Manager Head of Regulatory Policy
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 the North Middlesex University Hospital (Reproductive Medicines Unit) is located in London and has held a licence with the HFEA since July 2007. The centre provides basic fertility services to NHS patients and has a treatment (insemination using partner sperm) licence.

1.2. The panel noted that, in 2018, the centre had provided 99 cycles of partner insemination treatment. In relation to activity levels this is a very small sized centre.

1.3. The panel noted that seventeen pregnancies had resulted from the 99 cycles of partner insemination; this represents a clinical pregnancy rate of 17%, which is comparable to the national average.

1.4. The panel noted that the centre provides insemination treatments only and is therefore not subject to the requirements of General Direction 0003 regarding multiple births. However, insemination treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. The single biggest risk of fertility treatment is a multiple pregnancy and birth. 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 births minimisation strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

1.5. The panel noted that the short notice inspection took place on 26 November 2019.

1.6. The panel noted that, at the time of inspection, no non-compliances were identified.

1.7. The panel noted that the inspectorate particularly acknowledged the excellent feedback received from patients about the care received at the centre. The centre is well led and provides a good level of patient support.

1.8. The panel noted that the inspectorate recommended the continuation of the centre's treatment (insemination using partner sperm) licence, particularly noting the many positive comments made by patients in relation to their experiences in the centre's own feedback.

2. Decision

2.1. The panel noted that, between June and August 2019, 23 patients had provided feedback through means of the centre's own patient survey, with satisfaction rated 'high' and with no negative comments. Five patients had been spoken to, during the inspection, and also provided extremely positive feedback. However, only seven patients had provided feedback on their experience of the centre, in the last 12 months, through the 'Choose a Fertility Clinic' facility available on the HFEA website; the panel suggested that the centre actively encourages patients to use this mechanism to provide feedback.

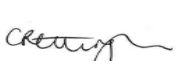
2.2. The panel congratulated the centre on the level of compliance.

2.3. The panel was satisfied the centre was fit to have its treatment (insemination using partner sperm) licence continued.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

4 February 2020

Interim Licensing Report

Centre name: North Middlesex University Hospital (Reproductive Medicines Unit)
Centre number: 0289
Date licence issued: 1 June 2018
Licence expiry date: 31 May 2022
Additional conditions applied to this licence: None
Date of inspection: 26 November 2019
Inspectors: Polly Todd (lead) and David Gibbon (external inspector)
Date of Executive Licensing Panel: 28 January 2020

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 a short notice 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 excellent feedback received from patients about the care received at the centre.

The centre is well led and provides a good level of patient support.

The ELP is asked to note that this report makes no recommendations for improvement.

Information about the centre

The North Middlesex University Hospital (Reproductive Medicines Unit) is located in London and has held a licence with the HFEA since July 2007. The centre provides basic fertility services to NHS patients and has a Treatment (insemination using partner sperm) licence.

The current licence has been varied to reflect a change of licence holder (LH) on 11 June 2018.

The centre provided 99 cycles of partner insemination in 2018. In relation to activity levels this is a very small 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

In 2018, the centre reported 99 cycles of partner insemination with 17 pregnancies. This represents a clinical pregnancy rate of 17%, which is in line with the national average.

Multiple births

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

The centre provides insemination treatments only and is therefore not subject to the requirements of General Direction 0003 regarding multiple births. However, insemination treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. The single biggest risk of fertility treatment is a multiple pregnancy and birth. 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 births minimisation strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes and that identification errors do not occur. The following laboratory activity was observed in the course of the inspection: sperm preparation. The procedure observed was witnessed using a manual witnessing system in accordance with HFEA requirements.

Consent: To the storage of cryopreserved material

This centre does not store gametes or embryos therefore this area of practice was not relevant to this inspection.

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 and witnessing.

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:

- information provision;
- implications of treatment and consent;
- counselling;
- consent;
- screening;
- ovarian hyperstimulation syndrome reporting;
- data protection and confidentiality;
- the use of CE marked medical devices;
- the content of the centre's website; and
- the use of the most recently issued HFEA consent form versions.

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 compliant with guidance.

Prescription of intralipid 'off label'

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

Infection Control

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

During the inspection, we reviewed infection control practices and found them to be compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of the following medical devices was reviewed in the course of the inspection: culture media, plasticware and specimen containers We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible

Patient experience

Patient support

New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

Patient feedback

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 seven 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 is important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.

The centre's own most recent patient survey responses were therefore reviewed. Between June and August 2019, 23 patients provided feedback to the centre. Patient satisfaction was rated 'high' and no negative comments were received. The Hospital Trust also commented that the centre had received consistently positive feedback from patients for the last four years.

During the inspection the inspectors spoke to five patients who also provided extremely positive feedback on their experiences.

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 fully compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

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

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

On-going monitoring of centre success rates

As this centre only provides partner IUI treatment the success rates are not subject to ongoing monitoring through the HFEA risk tools and therefore the centre has 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 provided its annual IUI treatment return to the HFEA within the required timescale.

Legal parenthood

The centre provides treatments with partner sperm only, therefore this area of practice is not relevant to this inspection.

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

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 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.

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
None identified			

‘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
None identified			

Additional information from the Person Responsible

We appreciate the thoroughness of the inspection and all your guidance and support. It was certainly a good opportunity for us to reflect on our practices.