Executive Licensing Panel - minutes

Centre 0289 (North Middlesex University Hospital (Reproductive Medicines Unit)) Interim Inspection Report

Friday, 29 January 2016

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Panel members	Juliet Tizzard (Chair) Joanne Anton Anjeli Kara	Director of Strategy & Corporate Affairs Policy Manager Regulatory Policy Manager
Members of the Executive	Dee Knoyle	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 North Middlesex University Hospital (Reproductive Medicines Unit), centre 0289, has held a licence with the HFEA since July 2007. The centre has a treatment (intrauterine insemination using partner sperm) licence and provides basic fertility services.

1.2. The panel noted that the centre's licence is due to expire on 31 May 2018.

1.3. The panel noted that the inspection took place on 7 December 2015.

1.4. The panel noted that in 2014 the centre reported 184 cycles of partner insemination with 37 pregnancies. This represented a clinical pregnancy rate of 20%. This was consistent with the national average. In relation to activity levels this is a small centre.

1.5. The panel noted that there were recommendations for improvement in five other areas of non-compliance. The panel noted that the Person Responsible (PR) has committed to implementing the recommendations within the prescribed timescales.

1.6. The panel noted that there were positive comments made by patients in relation to their experiences.

1.7. The panel noted that the inspectorate recommends the continuation of the centre's treatment (intrauterine insemination using partner sperm) 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 (intrauterine 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

Juliet Tizzard

Date

9 February 2016

Interim Licensing Report

Centre name: North Middlesex University Hospital (Reproductive Medicines Unit)
Centre number: 0289
Date licence issued: 1 June 2014
Licence expiry date: 31 May 2018
Additional conditions applied to this licence: None
Date of inspection: 7 December 2015
Inspectors: Louise Winstone (lead) and Shanaz Pasha
Date of Executive Licensing Panel: 29 January 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 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. 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 positive comments made by patients in relation to their experiences.

The ELP is asked to note that there are recommendations for improvement in relation to five 'other' areas of non compliance or poor practice.

The PR has committed to implement all recommendations within required timescales, these being:

'Other' areas of practice that require improvement:

- The PR should ensure that the centre have a standard operating procedure (SOP) in place that incorporates action to be taken if staff encounter a non clinical emergency.
- The PR should ensure that CE marked medical devices are used wherever possible.
- The PR should ensure that a cleaning schedule is in place for all clinical areas in line with infection prevention and control requirements.
- The PR should ensure that the emergency call bell is regularly checked.
- The PR should ensure that the centre has a SOP in place which details the actions to be taken by staff in the event of fridge malfunction or fail.

Information about the centre

The centre is located within the North Middlesex University Hospital Trust (Reproductive Medicines Unit) and has held a licence with the HFEA since July 2007. The centre's licence was renewed in February 2014 for a period of four years without additional conditions.

The centre provides basic fertility services to NHS patients and holds a treatment (intrauterine insemination using partner sperm) licence.

The centre provided 184 cycles of partner insemination in 2014. In relation to activity levels this is a 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[1]

In 2014 the centre reported 184 cycles of partner insemination with 37 pregnancies. This represents a clinical pregnancy rate of 20%, which is consistent with the national average.

Witnessing

Good witnessing processes are vital in ensuring 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: the identification of the patient's partner, the receipt of sperm into the laboratory, sperm preparation and the identification of the patient and gametes prior to insemination. 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 centre does not store gametes.

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.

[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 when $p \leq 0.002$.

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 prescribed SOPs 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 treatment, infection control and confidentiality.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

The centre does not have a SOP in place that describes action to be taken if staff encounter a non clinical emergency (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 centre's audits of witnessing, consent to treatment, infection control and confidentiality
- the use of CE marked medical devices
- the HFEA reports of adverse incidents from 2010-2012, 2013 and 2014.

The centre is broadly effective in implementing learning from guidance from the HFEA however they had not fully implemented guidance issued in 2013 in relation to CE marked medical devices (see recommendation 2).

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.

Infection Control

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

During the inspection, we reviewed infection control practices and found them to be broadly compliant with guidance because the cleaning of the premises is not documented when performed. The centre staff were able to confirm that the rooms are cleaned daily by the Trust domestic staff, however there was nothing documented to confirm that this was done (see recommendation 3).

Equipment and Materials

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

The CE mark status of the following medical devices was reviewed in the course of the inspection: sperm wash buffer, sperm collection pots, sperm preparation tubes and 5ml pipettes. We found the centre to be broadly compliant with HFEA requirements to use CE marked medical devices wherever possible. While the majority of medical devices in use were CE marked, the 5ml pipettes used to prepare sperm for treatment were not (see recommendation 2).

Patient experience

During the inspection, we spoke to one patient about her experience at the centre. A further 23 patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with 17 of the individuals providing written feedback giving compliments about the care received.

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;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

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, the inspection team identified the following areas requiring improvement:

- The correct functioning of the emergency call bells in the patient cubicles is not routinely checked (see recommendation 4).
- A record of the daily temperature of the fridge, which stores the sperm wash buffer and drugs, is documented however, 'out of range' temperatures were not specified and the centre does not have a documented procedure in place for staff to follow if the fridge malfunctions (see recommendation 5).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2013, recommendations for improvement were made in relation to two major and two 'other' areas of non compliance.

The PR 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, their success rates are not subject to on-going monitoring through the HFEA risk tool 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.

The clinic provided its annual IUI treatment return for 2014 within the required timescale.

Annex 1

Areas of practice that require the attention of the Person Responsible

This 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 identified at this inspection			

‘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
None identified at this inspection			

‘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
1. Quality Management System: The centre does not have a documented procedure in place that incorporates action to be taken if staff encounter a non clinical emergency. SLC T33b	The PR should ensure that the centre has a SOP that describes the action to be taken if staff encounter a non clinical emergency. The PR should provide a copy of the SOP to the centre’s inspector by 7 March 2016.	Risk assessment was in place but has been reviewed again. SOP for fire , lone worker policy are part of Trust policies along with mandatory training procedures within the Trust which all staff are able to demonstrate..	The inspector acknowledges the PR’s response. The SOP is be submitted to the centre’s inspector by 7 March 2016. Further action is required.
2. Infection Control: The cleaning of the premises is not documented when performed. SLC T26	The PR should ensure that a documented, monitored cleaning schedule is in place in the clinical areas and confirm that these are in place when responding to this report. Within 3 months the PR should conduct an audit to determine whether the cleaning checks have been carried out.	The Trust generally monitors MITE the contractors for Trust cleaning. MITE classifies the RMU as an OPD . However after the inspection MITE have agreed to provide these charts and have been positive in structuring a specific chart for the RMU which started on 21/12/2015. An audit will be supplied as	The inspector acknowledges the PR’s response. The audit is to be submitted to the centre’s inspector by 7 March 2016. Further action is required.

	A summary of the audit should be sent to the centre's inspector by 7 March 2016.	soon as sufficient data is produced.	
3. CE marking: The following medical device used by the centre is not CE marked: 5ml syringes. SLC T30	The PR should ensure that CE marked medical devices are used where possible. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. When responding to this report, the PR should confirm when the equipment identified in this report will be either replaced with a suitable alternative, or the current product will obtain the appropriate certification. It is expected that suitable products will be in place by 7 June 2016.	We accept this finding from the inspector and we had actually moved to CE marked centrifuge tubes since the last inspection. We also matched the change to pipettes from the same manufacturers using the same supplier in good faith that this was also CE marked. On the day of the inspection we contacted the supplier who confirmed the pipettes were not CE marked but MEA approved. We understand there is a general problem within all UK clinics and as soon as we are able to locate CE marked pipettes we will alter the supplier. We are however told by the current supplier that CE marked pipettes may become available in April 2016.	The inspector acknowledges the PR's response. Further action is required.
4. Emergency equipment: The correct functioning of the	The PR should ensure that all equipment, especially that which relates to patient safety is	We accept this finding and an appropriate checklist has been drawn up and has been used	The inspector acknowledges the PR's response.

emergency call bells is not routinely checked.	demonstrably fit for use. The PR should ensure that the emergency call bells are routinely checked and that this check is documented. Within 3 months the PR should conduct an audit to determine if the checks have been carried out. A summary of the audit should be sent to the centre's inspector by 7 March 2016.	to check the workings of the emergency system. As soon as sufficient data is produced and audit will be performed and sent to the HFEA	The audit is to be submitted to the centre's inspector by 7 March 2016. Further action is required.
5. Critical equipment: There is no documented procedure in place which details the actions to be taken by staff in the event of fridge malfunction and 'out of range' temperatures were not specified for this item of equipment. SLC T27	The PR should ensure that the centre has documented procedures for staff to follow should the fridge malfunction. The PR should submit an SOP to the centre's inspector by 7 March 2016.	We accept there was no SOP although a plan existed of using labour ward fridge. The only items of relevance stored is the buffers for sperm preparation for IUI. Pregnyl (HCG) is stored in small amounts. An SOP is formed expalining the actions needed to prevent damage to goods intended to be kept cold.	The inspector acknowledges the PR's response. The SOP is be submitted to the centre's inspector by 7 March 2016. Further action is required.

Additional information from the Person Responsible
We are grateful to the Inspectors for picking up points rigourously and in entering constructive dialogue with the RMU which we can see is looking through the eyes of the patients while enhancing general safety.