Executive Licensing Panel - minutes

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

Renewal Inspection Report

Friday, 2 February 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Caylin Joski-Jethi (Chair) Helen Crutcher Anna Quinn	Head of Intelligence Risk & Business Planning Manager Scientific Policy Manager
Members of the Executive	Bernice Ash Kathleen Sarsfield-Watson Niamh Marren	Secretary Communications Manager (Observing) Regulatory Policy Manager (Observing)
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 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 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 provides basic fertility services to NHS patients and holds a treatment (insemination using partner sperm) licence. As such, the centre procures, processes and uses partner sperm in treatment, but does not create embryos or use them in licensed activities.

1.3. An inspection was carried out at the centre on 12 December 2017.

1.4. The panel noted that at the time of the inspection on 12 December 2017, there were four 'other' areas of non-compliance concerning safety and suitability of premises and facilities, CE marking, staff and screening of patients. Since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations regarding safety and suitability of premises and facilities, staff and screening of patients and has committed, where required, to audit the effectiveness of those actions within the required timescales: The panel noted that with regard to the non-compliance concerning CE devices, the PR has given a commitment to fully implementing the recommendation.

1.5. The panel noted that the inspector commended the centre on the positive feedback received from patients.

1.6. The panel noted the inspectorate's recommendation to renew the centre's treatment (insemination using partner sperm) licence for a period of four years without additional conditions, subject to the recommendations being implemented within the prescribed timescales.

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

2.2. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.3. The panel commended the PR on their engagement with the inspectorate and swiftness in addressing the non-compliances identified at the inspection. The panel was pleased to see the positive patient feedback received during the inspection.

2.4. 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, subject to the recommendations being implemented within the prescribed timescales.

3. Chair's signature

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

Signature

Name

Caylin Joski-Jethi

Date

7 February 2018

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 and donors. The inspection was scheduled (rather than unannounced) 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: 12 December 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: Louise Winstone, Polly Todd and Mhairi West (observer)

Date of Executive Licensing Panel: 2 February 2018

Centre name	North Middlesex University Hospital (Reproductive Medicines Unit)
Centre number	0289
Licence number	L/0289/4/a
Centre address	Sterling Way, Edmonton, London, N18 1QX.
Person Responsible	Dr Ansam Al Habib
Licence Holder	Mr Stanley Okolo
Date licence issued	1 June 2014
Licence expiry date	31 May 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
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 provides basic fertility services to NHS patients and holds a Treatment (insemination using partner sperm) licence. As such, the centre procures, processes and uses partner sperm in treatment, but does not create embryos or use them in licensed activities.

The current licence has not been varied.

Outcomes
In 2016, the centre reported 149 cycles of partner insemination with 28 pregnancies. This represents a clinical pregnancy rate of 19%, which is in line with the national average.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E 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 Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E 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 the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were four 'other' areas of non compliance or poor practice that required improvement.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

'Other' areas that require improvement:

- The PR should ensure that all medical gases are stored according to medical gas safe storage regulations.
- The PR should ensure that staff are appropriately trained and competent in the management of medicines.
- The PR should ensure that the risks of Ebola and Zika infection are considered prior to patients being treated.

The PR has given a commitment to fully implementing the following recommendation:

- The PR should ensure that CE marked medical devices are used wherever possible.

Recommendation to the Executive Licensing Panel

The inspection team notes there are no critical or major non compliances and the centre is to be commended on the positive feedback received from patients.

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 subject to the recommendations made in this report being implemented within the prescribed timescales.

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 and eggs) and embryos 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 prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre does not recruit donors or provide treatment with donor gametes therefore this area of practice is 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

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are broadly 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 so that patients and staff are in safe surroundings that prevent harm.

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 to be accredited 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 (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance. However, see Staff (Guidance note 2) and recommendation 3.

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.

Multiple births (Guidance note 7; General Direction 0003)
The centre is providing only insemination treatments, but such 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.

Procurement of gametes and embryos (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;
- where the sperm is procured at home, the centre keeps 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 therefore this area of practice is not applicable to this inspection.

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

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability 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;
- to identify the recipient of particular gametes;
- to identify any person who has carried out any activity in relation to particular gametes; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes which can affect their quality or safety.

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

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 does not have any transport or satellite arrangements therefore this area of practice is not applicable to this inspection.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are broadly compliant with HFEA requirements. Some of the equipment and materials used in licensed activity are designated for the purpose 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)
The centre has not experienced any adverse incidents. The inspection team was confident after discussion with the PR that procedures are in place to ensure that staff are aware of how to report an incident and investigate it should the need arise.

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

Safety and suitability of premises and facilities (Guidance note 25)
On inspection, there was a free-standing oxygen cylinder in the scanning room. Safe storage regulations require that a cylinder support system should be used and that there is a suitable notice in place identifying the purpose of the cylinder (DH (2006) Medical gases Health Technical Memorandum 02-01: Medical gas pipeline system; see recommendation 1).

Equipment and materials (Guidance note 26)
The sperm pots used to collect sperm samples for use in insemination were CE marked but not at the appropriate level i.e. as a medical device (SLC T30; see recommendation 2).

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 medicine 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 broadly 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

Staff (Guidance note 2)
Staff had not received training in medicines management. It is acknowledged that the centre only has a small amount of non-controlled drugs on site and dispenses these in exceptional circumstances. However, staff training and competence assessment in medicines management should be completed (NMC (2007) 'Standards for medicines management', SLC T12 and T15a; see recommendation 3).

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 before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
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
The centre does not create embryos or perform embryo testing and therefore this area of practice is not applicable to this inspection.

2. The experience of patients

Patient feedback

What the centre does well
During the inspection visit the inspectors spoke to four patients who provided feedback on their experiences. Feedback was positive with all of the individuals commenting that they have compliments about the care that they received. The centre's own patient satisfaction survey covering the period April-August 2017 was also reviewed on inspection. The centre received 27 responses to this survey and all were positive.

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 services.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not undertake egg and sperm sharing arrangements and therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not provide surrogacy treatments and 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 and donors.

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter 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;6)
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 treatment using donor gametes and 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 related to consent to disclosure to researchers are not relevant to basic partner IUI services and therefore this area of practice is not relevant to this inspection.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
The centre does not create embryos therefore this area of practice is not applicable to this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

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

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

What the centre could do better

Screening of patients (Guidance note 17)
The centre does not consider the risks of Ebola and Zika viruses in patients prior to treatment (SLC T50d; see recommendation 4).

Use of embryos for training staff (Guidance note 22)

What the centre does well
The centre does not use embryos for training staff therefore this area of practice is not applicable to this inspection.

4. Information management

▶ **Record keeping and 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 (General Direction 0005).
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, recommendations for improvement were made in relation to five 'other' areas of non compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed 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 the centre has not therefore been issued with any performance alerts.

Areas of practice requiring action

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, 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.

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 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.

A major area of non compliance is identified in the report by a statement that an area of practice is partially 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 require improvement

‘Other’ areas of practice that require improvement is 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.

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
1. Safety and suitability of premises and facilities There was a free-standing oxygen cylinder in the scanning room. Safe storage regulations require that a cylinder support system should be used and a suitable notice in place identifying the purpose of the cylinders. DH (2006) Medical gases Health Technical Memorandum 02-01: Medical gas pipeline system.	The PR should ensure that all medical gases are stored according to medical gas safe storage regulations. The PR should make arrangements for the cylinder in question to be stored correctly and confirm to the centre’s inspector that this has been completed when responding to this report.	This was an additional cylinder to the Rhesus trolley and is not required and now removed. Thank you for pointing this out	The executive acknowledges the PR’s response. No further action is required.
2. CE marking The sperm pots used to collect sperm samples for use in insemination were CE marked but not at the	The PR should ensure appropriately CE marked medical devices are used where available.	We have been in contact with manufacturers but have not gained a definitive answer yet. We are enquiring with alternative sources of sperm pots. It had been difficult to	The executive acknowledges the PR’s response and commitment to ensure that this recommendation is implemented within the required timescales. The

appropriate level i.e. as a medical device. SLC T30.	We would not recommend the implementation of precipitous changes that might impact on the quality of service that is provided to patients. In consideration of this the PR should identify a suitable CE marked alternative by 12 March 2018 and provide confirmation, along with a timeline of introduction to the centre's inspector. The PR should aim to be fully compliant with this requirement no later than 12 June 2018.	communicate with companies during the festive season. Once confirmed we will request change of supplier.	executive asks that the PR keeps the centre's inspector informed of progress in sourcing alternative sperm pots. Further action is required.
3. Staff Staff had not received training in medicines management. NMC (2007) 'Standards for medicines management', SLC T12 and T15a.	The PR should ensure that staff are appropriately trained and competent in the management of medicines. The PR should inform the centre's inspector of the actions taken to address this recommendation when responding to this report. It is expected that all relevant staff will have received appropriate training by 12 March 2018.	Training been completed on the 9th of January 2018 (certificates attached)	The PR has provided evidence that actions have been taken to implement the recommendation. No further action is required.

	The PR should provide confirmation to the centre's inspector when this training has been completed.		
4. Screening of patients The centre does not consider the risks of Ebola and Zika viruses in patients prior to treatment. SLC T50d.	The PR should ensure that the risks of Ebola and Zika infection are considered prior to patients being treated. The PR should review the centre's processes for considering and assessing the risks of infection with Ebola and Zika viruses based on a patient's travel history. As part of the review the PR should consider why the information provided in Clinic Focus articles has previously not been acted upon. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector when responding to this report. Three months after the implementation of corrective actions the PR should audit patient screening practice to	Training been completed on the 9th of January 2018 (certificates attached) - I accept that despite the minimal risks to our patients this should have been implemented within our patient work up. - ZIKA and Ebola virus information leaflet has now been developed (attached). - Checking patients' recent visits to high risk countries has been now added to the patient clerking sheet. The practice will be audited and the results will be submitted to the centre's inspector by the12th of March 2018	The PR has provided evidence that actions have been taken to implement the recommendations and has committed to audit the effectiveness of those actions within the required timescale. Further action is required.

	ensure these actions have been effective. A summary report of this audit should be provided to the centre's inspector by 12 March 2018.		

Responses from the Person Responsible to this inspection report
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.