HFEA Executive Licensing Panel Meeting

7 February 2014

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

Minutes – Item 2

Centre 0289 – (North Middlesex University Hospital - Reproductive Medicines Unit) – Renewal Treatment (insemination using partner sperm) Inspection Report

Members of the Panel:	**Committee Secretary:**
Mark Bennett – Director of Finance & Facilities (Chair)	Dee Knoyle
Nick Jones – Director of Compliance & Information	**Observing:**
Joanne Anton - Policy Manager	Sam Hartley – Head of Governance and Licensing

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:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel considered the papers, which included a completed application form, inspection report and licensing minutes for the past three years.

2. The Panel noted that this centre provides treatment only services: intrauterine insemination (IUI) with partner sperm. The Panel noted that in relation to activity levels this is a small centre.

3. The Panel noted that the centre has been licensed by the HFEA since July 2007 and has a two-year licence due to expire on 31 May 2014.

4. The Panel noted that in 2012, the centre reported 196 cycles of partner insemination with 19 pregnancies. This is consistent with the national average.

5. The Panel noted that at the time of the inspection on 26 November 2013, the Inspectorate observed two major and two other areas of non-compliance. The Panel noted that, since the inspection, the centre has provided evidence that it has fully implemented three of the recommendations. The Panel noted the PR's commitment to implement the outstanding recommendation within the prescribed timescales.

6. The Panel noted the Inspectorate's recommendation that some improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides.

7. The Panel noted the Inspectorate recommended the renewal of the centre's Treatment (insemination using partner sperm) licence for a period of four years without additional conditions, subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

Decision

8. 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.

9. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and that he has discharged his duty under section 17 of the HF&E Act 1990 (as amended).

10. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

11. The Panel agreed to renew the centre's Treatment (insemination using partner sperm) licence for four years, without additional conditions.

Signed: Date: 19 February 2014

Mark Bennett (Chair)

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 (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: 26 November 2013
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: Lisa Beaumont (Lead) and Sara Parlett

Date of Executive Licensing Panel: 7 February 2014

Centre name	North Middlesex University Hospital (Reproductive Medicines Unit)
Centre number	0289
Licence number	L/0289/3/a
Centre address	Sterling Way, Edmonton, London, N18 1QX.
Person Responsible	Dr Ansam Al Habib
Licence Holder	Mr Stanley Okolo
Date licence issued	01 June 2012
Licence expiry date	31 May 2014
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 North Middlesex University Hospital Trust (Reproductive Medicines Unit) and has held a licence with the HFEA since July 2007. However due to resourcing issues, licensed treatment did not commence until September 2009.

The centre provides treatment only services: intrauterine insemination (IUI) with partner sperm, to NHS patients. The centre provided 196 cycles of treatment in 2012, which makes this a small centre in terms of activity.

The current licence was issued in June 2012 for a period of two years, and expires in May 2014. Following the last renewal inspection in November 2011, the ELP granted a renewal of the licence for two years only, due to an insufficient track record of providing treatment and outstanding actions remaining from the previous inspection.

The centre has had the following variations to its licence granted by ELP in January 2012:

- Change of PR to Dr Ansam Al Habib
- Change of Licence Holder (LH) to Mr Stanley Okolo

Activities of the centre:

Type of treatment	2012
Intrauterine insemination (IUI)	196

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	N/A
Storage of sperm	N/A
Storage of embryos	N/A
Research (if applicable)	N/A

Outcomes [1]
In 2012, the centre reported 196 cycles of partner insemination with 19 pregnancies. This equates to a 10% clinical pregnancy rate which is consistent 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 PR is suitable and has discharged her duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their 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 a number of areas of practice that required improvement, including two major and two 'other' areas of non-compliance or poor practice.

Since the inspection visit, the centre has provided evidence that the following recommendations have been fully implemented:

Major areas of non compliance:

- the PR should ensure the fridge used to store reagents for processing sperm is validated and
- the PR should ensure that validation of all critical processes is completed.

'Other' areas of non compliance:

- the PR should ensure the centre's 'medical records security' standard operating procedure (SOP) clearly states how long patient records must be kept.

The PR has provided a response confirming her commitment to implement the following recommendation:

'Other' areas of non-compliance:

- the PR should ensure that, whenever possible, only CE marked medical devices are used.

Implementation of this recommendation will be subject to on-going monitoring by the centre's inspector.

Recommendation to the Executive Licensing Panel

Some improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides.

The inspection team is satisfied that activities carried out at the centre are necessary in order to provide licensed treatment services.

The inspection team recommends the renewal of the centre's treatment licence for a period of four years without additional conditions subject to compliance with the

remaining outstanding recommendation made in this report being implemented within the prescribed timescale.

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 (Guidance note 18)

What the centre does well.

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 noted at time of inspection.

Patient and donor selection criteria and laboratory tests

- Screening of patient and / or donors prior to procuring, processing and / or transporting gametes and embryos (Guidance notes 11 and 15)
- Payments for donors (Guidance note 13)
- Donor assisted conception (Guidance note 20)

What the centre does well.

Screening of patients
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.

Payments for donors
The centre does not recruit donors and therefore this area of practice is not applicable to this inspection.

Donor assisted conception
The centre does not provide treatment with donor gametes therefore this area of practice is not applicable to this inspection.

What the centre could do better.

Nothing noted at time of inspection.

Good clinical practice

What the centre does well.

Multiple births (Guidance note 7)
The centre does not provide treatment involving the transfer of embryos therefore this area of practice is not applicable to this inspection.

Process Validation (Guidance note 15)
The centre has partially validated all critical processing procedures to ensure that these procedures are effective and do not render the gametes clinically ineffective or harmful to the recipient.

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

- identify and locate gametes during any step from procurement to use for human application or disposal,
- identify the provider and recipient of particular gametes,
- identify any person who has carried out any activity in relation to particular 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 (Guidance note 23)
The centre has a quality management system in place that is compliant with HFEA requirements. The centre uses its quality management system to ensure optimum outcomes and improve the quality and safety of the treatment and services it provides to patients.

Third party agreements (Guidance note 24)
The centre has agreements in place which cover the supply of any goods and services which may affect the quality or safety of gametes.

Equipment and materials (Guidance note 26)
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, with the two exceptions noted below.

Premises (Guidance note 25)
The centre conducts all of the licensed activities in an appropriate environment, in line with good clinical practice. All diagnostic testing is carried out by a suitably accredited laboratory.

Adverse incidents (Guidance note 27)
The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all of the adverse incidents that have occurred and

shares the lessons learned in order to continuously improve the services it offers.

What the centre could do better.

Process Validation (Guidance note 15)
The centre has not undertaken a full validation of its critical processing procedures (Standard Licence Condition (SLC) T72). This was cited as a non-compliance at the last inspection in November 2011. After the 2011 inspection, the centre submitted a template process validation document detailing the process validation methodology they would use. This document was reviewed on this inspection and was considered to be incomplete. The centre's planned retrospective treatment record review, formal comparison of centre success rates against national averages and reference to appropriate published studies had not been documented.

See recommendation 1

Equipment and materials (Guidance note 26)
The fridge used to store reagents for processing sperm has not been validated (SLC T24).

See recommendation 2

It was observed that both the temperature of the fridge and the incubator are monitored via the temperature display of the equipment itself, rather than by an independent probe. The PR should consider whether this procedure is sufficiently robust.

The following medical devices used by the centre are not CE marked: serological pipettes and test tubes (SLC T30).The laboratory manager has undertaken a risk assessment based on historical use and sperm toxicity assays and considers there to be no risk. The centre has sourced CE marked alternatives to use once the remaining stock has been finished. The PR anticipates that they will use CE marked pipettes by January 2014 and CE marked test tubes by January 2015.

See recommendation 4

Staff engaged in licensed activity

What the centre does well.

Person Responsible (Guidance note 1)
The PR has a key role to play in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision the licensed activities are authorised. The PR has the primary (legal) responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:

- that suitable practices are used in undertaking the licensed activities;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with.

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 (PREP number T/1201/8).

Staff (Guidance Note 2)
The centre has suitably qualified and competent staff to carry out all of the licensed activities and associated services.

What the centre could do better.

Nothing noted at time of inspection.

Welfare of the child (Guidance note 8)

What the centre does well.

The centre's procedures for taking into account the welfare of the child are compliant with HFEA requirements. The centre takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth.

What the centre could do better.

Nothing noted at time of inspection.

2. The experience of patients

Patient feedback

What the centre does well.

During the inspection visit the inspectors spoke to two patients who provided feedback on their experiences. A further 39 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 26 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they 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;
- 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 noted at time of inspection.

Treating patients fairly

What the centre does well.

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

Surrogacy (Guidance note 14)
The centre does not undertake surrogacy 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. The centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Treating patients fairly (Guidance note 29)
The centre appears to treat prospective and current patients fairly, and ensures that all licensed activities are conducted in a non-discriminatory way.

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 well being of prospective and current patients.

Counselling (Guidance note 3)
Whilst not a HFEA requirement for IUI centres, it was noted that the centre does offer a counselling service.

What the centre could do better.

Nothing noted at the time of inspection.

Information

What the centre does well.

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.

Provision of costed treatment plans (Guidance note 4)
The centre provides NHS funded treatment only therefore this area of practice is not applicable to this inspection.

What the centre could do better.

Nothing noted at time of inspection.

Consent

What the centre does well.

The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients have provided all relevant consents before undergoing any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research
The centre does not provide any patient identifying information to the HFEA register therefore this area of practice is not relevant to this inspection.

What the centre could do better.

Nothing noted at time of 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.
What the centre could do better.

▶ **Storage of gametes and embryos**
What the centre does well. 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.

▶ **Distribution and / or receipt of gametes and embryos**
What the centre does well. The centre does not distribute gametes or embryos therefore this area of practice is not applicable to this inspection.
What the centre could do better.

▶ **Use of embryos for training staff** (Guidance note 22)
What the centre does well. The centre does not create or store embryos therefore this area of practice is not applicable to this inspection.
What the centre could do better.

4. Information management

Record keeping and submitting information to the HFEA

What the centre does well.

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

Obligations and reporting requirements (Guidance note 32)
Centres providing basic partner treatment services only, are only required to submit an annual return to the HFEA providing details of the number of treatments provided and the outcomes of those treatments (General Direction 0005). This enables the HFEA to satisfy its statutory reporting responsibilities and to provide information to patients via the HFEA website about centres' success rates. The centre has provided an annual return for treatments undertaken in 2012, within the required timeframe.

What the centre could do better.

Record keeping and document control (Guidance note 31
The centre's 'medical records security' SOP does not clarify clearly the retention periods for patient records. It correctly states that records must be retained for 30 years, however it then states if treatment is unsuccessful, information should be kept for eight years. The PR explained that the eight year period reference relates only to the centre's outcome register but the inspection team considered that this is not sufficiently clear (SLC T103 and General Direction 0010).

See recommendation 3

Section 3: Monitoring of the centre's performance

Following the renewal inspection in November 2011, recommendations for improvement were made in relation to one area of major non-compliance and five 'other' areas of non-compliance.

The PR provided information and evidence that all but one of the recommendations were fully implemented. The following recommendation has not been implemented:

- The centre should complete the validation of all critical processes (laboratory and clinical) (SLC T72).

Refer to the 'good clinical practice' section of this report for further details.

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, 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		Thank	

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 and
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. The centre has not completed a full validation of the critical processing procedures. SLC T72 **This was an issue at the previous two inspections.**	The PR should ensure that all critical procedures are validated. Evidence of validation should be submitted to the centre's inspector by the time the PR responds to this report.	Completed form of Validation of the critical processing procedures was faxed on the 18th of December 2013	The centre has submitted documentation demonstrating that validation of all critical processes has been completed. No further action required.
2. The fridge used to store reagents for sperm processing has not been validated. SLC T24	Post inspection, the PR submitted evidence demonstrating that this validation has been completed.	N/A	N/A

Other areas of practice that require improvement

Areas of practice that requires 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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
3. The centre's 'medical records security' SOP does not clarify clearly the retention periods for patient records. SLC T103 and General Direction 0010.	The PR should review and revise the referenced SOP. A copy of the SOP should be sent to the centre's inspector by 26 February 2014.	The SOP was amended and a copy was emailed on the 18th of December 2013.	The centre has submitted a revised 'medical records security' SOP, which details accurately the retention periods for patient records. No further action required.
4. The following medical devices used by the centre are not CE marked: • serological pipettes • test tubes. SLC T30	The PR should ensure that wherever possible CE marked medical devices are used and should advise the centre's inspector when this change has been made. This recommendation should be implemented by 26 May 2014.	The centre's inspectors will be informed as soon as this change has been made.	The inspection team note the intended action by the PR. The implementation of this action will be monitored by the Executive as part of the post inspection monitoring process.

Response from the Person Responsible to this inspection report
Dear Lisa and Sara, Thank you for all the advice, support and encouragement during the inspection visit.. We agree with all the raised points. Plans are now in action to achieve improvements. Kind regards Ansam AL-Habib PR, North Middlesex University Hospital (Reptoductive Medicine Unit)