Inspection Report

Date of Inspection: 2 November 2011
Purpose of inspection: Renewal of Treatment (Insemination using Partner Sperm)
Length of inspection: 8 hours
Inspectors: Bhavna Mehta
Sara Parlett

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 26 February 2010 and 25 November 2011

Date of Executive Licensing Panel: 13 January 2012

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Executive Licensing Panel which makes the decision about the centre's licence renewal application.

Centre details

Centre name	North Middlesex University Hospital (Reproductive Medicines Unit)
Centre number	0289
Licence number	L0289/2/c
Centre address	Sterling Way, Edmonton, London, N18 1QX
Person Responsible	Mr Stanley Okolo
Licence Holder	None
Date licence issued	01/06/2010
Licence expiry date	31/05/2012
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The centre is a part of the North Middlesex Hospital NHS Trust. The centre provides NHS funded intrauterine insemination (IUI) treatments to patients from the local area. The centre does not store gametes. At the time of this inspection, the centre was trialing a pathway for self funding patients who do not meet the Primary Care Trust criteria.

The unit is open five days per week, Monday to Friday between 8:30 am and 5:00 pm.

The centre has been licensed by the HFEA since July 2007, but due to resourcing issues, licensed treatments were not conducted until September 2009. Following a renewal inspection in February 2010, the Person Responsible (PR) informed the Authority in June 2010, that licensed treatments had been stopped at the centre as the building in which the centre was housed was to be demolished as part of a Trust development plan and that the centre was to relocate to another part of the Trust site. Licensed treatments re-commenced in January 2011, following a desk based assessment of the application and variation of the licence to change the premises and the name of the centre.

Variation to Licence

The PR has applied to vary the centre's licence to change the:

0. PR from Mr Stanley Okolo to Ms Ansam Al-Habib and
1. To appoint Mr Stanley Okolo as the centre's Licence Holder

These applications are the subject of separate items to be considered by the ELP.

Activities of the Centre:

Type of treatment	Number of treatment cycles in 2010*
IUI (P)	98

Outcomes*

For the year 2010 the centre reported 98 cycles of partner IUI with six pregnancies. This equates to a 6% pregnancy rate.

*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.

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- The PR is suitable and he has discharged his 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.

There are some matters outstanding from the previous inspections which have yet to be addressed. The centre's inspector has sought to and will continue to address these outstanding issues by requiring compliance within three months by continuously monitoring compliance with the recommendations.

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one major area of non-compliance and five other areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has confirmed and provided evidence that:

Other areas of practice that require improvement:

- the two incidents have been reported retrospectively to the HFEA (SLC T118).
- The written information has been reviewed and corrected to ensure accuracy of information (GN 4.2)

The PR has given a commitment to fully implement the following recommendations:

Major areas of non compliance:

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

Other areas of practice that require improvement

- The centre's quality management system (QMS) should include training and reference manuals (SLC T33).
- The centre should add sufficient information to the quality indicators (QI) for witnessing, traceability and clinical data to make them meaningful as a QI (SLC T35).
- The centre should develop and review SOP for traceability of patient records, equipment failure or malfunction (SLC T33 (b)).
- Carry out audits for the provision of patient information and traceability (SLC T36).

Recommendation to the Executive Licensing Panel

The inspection team considers that, overall there is sufficient information available to recommend the renewal of this centre's licence for a period of 4 years without additional conditions. In making this recommendation it is noted that the PR has responded to all the recommendations made in this inspection report and further improvement is required in only a few areas of practice.

Details of inspection findings

1. Protection of patients and children born following treatment

Focus

The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- 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
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned appropriately

▶ Witnessing and assuring patient and donor identification (Guidance Note 18)

What the centre does well.

The centre ensures that the patients receive treatment using the correct gametes.

The laboratory manager was able to demonstrate compliance with the requirements that the identification of gametes and the patient to whom they relate, is verified at all critical points in the laboratory processes. A sample of witnessing records in the laboratory was reviewed at inspection which provided evidence that the identification of patients is verified and that all critical stages of treatment are witnessed, with one exception stated below.

The nurses and consultants carry out the inseminations with the sperm prepared in the laboratory. At inspection, the consultants and the laboratory manager were able to demonstrate compliance with the requirements that the identification of gametes and the patient to whom they relate, are verified at all critical points of the clinical process (SLC T71). Six witnessing steps were observed on the day of inspection and were seen to be complaint with requirements, with one exception stated below.

The centre has set a quality objective for 2011/12 to check that all witnessing checks are complete (SLC T35). The centre's last audit of witnessing documentation in patient records was reviewed at inspection. The audit included both the laboratory and clinical witnessing practice. The audit report recorded that there was a 100% compliance with the witnessing requirements and that no corrective actions were required (SLC T36).

What the centre could do better.

At inspection, it was observed that one member of staff did not double check patient identifying information in patient records against the preparation tube. However, on further discussion with staff, a review of patient records and staff training and competency records, it was clear that the error observed at inspection was a one off.

In one out of the four patient records audited by the inspection team, cross – checking identifying information that the patient provides against the patient's medical records was not recorded: (SLC T71).

Patient selection criteria and laboratory tests

- Procuring, processing and transporting gametes and embryos (Guidance Note 15)

What the centre does well.
Discussions with staff and documentation provided by the centre demonstrated, to the satisfaction of the inspectors, that all patients are selected on the basis of the patient's medical history and therapeutic indications in accordance with professional body guidelines and locally agreed commissioner treatment criteria, and that the rationale for treatment is recorded in the patient's medical records (SLC T49).

Discussions with the laboratory manager and the PR confirmed that the diagnostic semen analysis is undertaken in the hospital's laboratory which has been accredited by Clinical Pathology Accreditation (CPA) UK Ltd (SLC T21).

What the centre could do better.

Nothing noted at this inspection.

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)

What the centre does well.
Quality Management System
The quality manager explained that since the last inspection, the centre has moved to new premises and that the service is being developed further to meet regulatory requirements.

The centre has a QMS and quality manual in place (SLCs T32 and T33). The centre provided an index list of all QMS documents prior to inspection and a sample of documents were viewed as part of this inspection process. Staff reported that any changes in procedures are discussed at staff meetings and training provided to ensure consistency.

The centre has set quality objectives of 100% compliance with CoP requirements for 2010/11 including for the provision of information, witnessing practice and taking consent, as assessed by retrospective audit of patient records (SLC T 35). The report of the last audit was reviewed at inspection. This showed that audits of patient records have been conducted by the staff to verify that the witnessing checks are carried out as required by the CoP; that the correct and relevant information has been given to patients, that Welfare of the Child (WoC) assessments are documented and that the correct consent to treatment form has been completed and recorded in the patient's file. Any errors or omissions are documented and corrective actions have been implemented (SLC T36).

Traceability
The centre's traceability SOP was reviewed and describes the process by which traceability of consumables and reagents which come into contact with gametes is ensured, (SLC T33b).

The centre's logs of all reagents and materials used was reviewed on inspection and demonstrated that all relevant traceability data is recorded. A spot check of consumables in use in the laboratory against those recorded as being in use in the laboratory logs demonstrated that data is recorded accurately (SLC T102).

Validation of equipment

At the time of the move to the present premises, the PR has provided evidence to demonstrate compliance with the requirement that all critical equipment has been validated (SLC T24). The staff explained that the hospital's estates department is responsible for the maintenance and regular servicing of equipment. The service records list was reviewed at inspection which documents the centre's critical equipment.

Equipment and materials

The inspector observed that key equipment, critical to the processing of gametes, is subject to appropriate monitoring (scheduled preventative maintenance, regular calibration and parameter monitoring) (SLC T24). Staff also provided a log recording the regular cleaning and decontamination of equipment in the laboratory and clinical areas (SLC T26). Staff were able to confirm that all consumables in use in the laboratory are sterile and CE marked where applicable. (SLC T30).

Premises – suitability of the premises and air quality

A tour of the centre confirmed that licensable activities are carried out on the licensed premises which are within the same building (HF&E Act S.12 (1) and SLC T1). Documented evidence of the centre's cleaning logs reviewed at inspection demonstrated compliance with this requirement (SLC T26).

The centre's air quality is monitored six monthly by an external company. Room pressures are checked daily. The monitoring log was reviewed at inspection. Documented evidence, dated October 2011, was provided on the day of inspection that the processing of gametes takes place in an environment of at least grade A air quality in the critical work area with a background environment air quality of grade C (SLC T20).

Third party agreements

The centre staff were able to demonstrate that there are third party agreements in place for all goods and services that influence the quality and safety of gametes and the agreements were available for review on the day of inspection (SLC T111).

What the centre could do better.

Quality Management System

The centre's QMS does not include the following:

- Training and reference manuals (SLC T33 (c)).
- SOPs for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, including, but not limited to:
    - submitting data to the HFEA in compliance with General Direction 0005 ([see SLC T33b),
    - record keeping for full traceability to be kept for at least 30 years (or for such longer period as may be specified in Directions) after clinical use, or the expiry date, in an appropriate archive acceptable to the Authority (SLC T48),
    - providing information to patients (GN 4),
    - establishing and maintaining data security measures and safeguards against any unauthorised data additions, deletions or modifications to patient files or records; and the transfer of information (SLC T44(a)),
    - establishing and maintaining procedures to resolve all data discrepancies (SLC T 44(b)),
    - for appropriate monitoring, to ensure that the critical parameters are maintained within acceptable limits at all times. (SLC T 27).

Discussion with staff and a review of documentation demonstrated that QIs for witnessing, traceability and the clinical data have not been established (SLC T35).

Not all the activities, authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, have been audited against compliance with the approved protocols, the regulatory requirements and the centre's QIs. Some of the activities not yet audited include the provision of patient information (SLC T36).

Validation of equipment
At inspection it was noted that the temperature of two pieces of equipment is monitored weekly via the temperature display of the equipment itself rather than an independent probe. This could be considered inadequate monitoring.

The acceptable temperature range for the refrigerator is specified on the laboratory checklist. On two occasions over the past year the temperature was recorded as being out of this specified range, but with no action taken (therefore was not subject to appropriate corrective action) (SLC T24).

Validation of processes:
At inspection staff explained that critical processing procedures (SLC T72), including the intervals between the testing of the air quality, have not been validated. However, the planned process validation methodology has been documented. This was reviewed on inspection and appeared comprehensive

Adverse incidents
The centre has documented procedures for reporting serious adverse events and reactions that may occur SLC T118). However, at inspection, discussion with staff identified that two incidents reportable to the HFEA recorded at the centre have not been reported (SLC T118). Both incidents were reported to the Trust's incidents team and the related reports of the investigations were reviewed at inspection. The PR explained that these two incidents had not been reported as he did not consider that either fell into the definition of an adverse incident.

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the centre does well.

Person Responsible
The PR has academic qualifications in the field of medicine as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii) and has more than two years of practical experience which is directly relevant to the activities to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1135/7). The PR is the nominated medical practitioner who oversees medical activities at the centre (SLC T16). He is registered with the General Medical Council (GMC) and is on the specialist register for Obstetrics and Gynaecology.

Staff
The other consultant at the centre is also registered with the GMC and is on the specialist register for Obstetrics and Gynaecology.

The consultant was able to confirm that staff working under the auspices of the licence are qualified and suitable persons to participate in the activities authorised by the licence

(HF&E Act Schedule 17 (1) (a). She explained that all staff have professional body registration checks, references are obtained and Criminal Record Bureau (CRB) checks are carried out where required, as per the Trust human resources policy, prior to employment. She also confirmed that continued professional body registration is also periodically checked and all staff members participate in induction and on-going mandatory training as determined by the Trust policy. The centre has a local policy in addition to support the staff professional development and performance appraisals (SLCs T12 and T14).

The consultant stated that workforce requirements had been assessed within the last year and will continue to be monitored. At the time of inspection, it was reported that a half time nursing post had become vacant in the last two weeks but the centre is in the process of recruiting a replacement. The consultant explained that provided the recruitment to the vacancy is not delayed, the staff complement is sufficient in all disciplines (SLC T12).

The andrologist is registered with the Health Professionals Council (HPC) as a clinical scientist (SLC T14).

From the documents reviewed at inspection, the staff were able to demonstrate evidence of the assessment of the competence to perform their designated tasks (SLC T15 (a)).

What the centre could do better.

Nothing noted at this inspection.

Welfare of the Child (Guidance Note 8)

What the centre does well.

From discussions with staff, a review of the welfare of the child (WoC) information provided by centre staff, interviews with two patients and a review of patient records, the inspectors conclude that before any woman is provided with treatment services; proper account is taken of the welfare of any child who may be born as a result of treatment and of any other child who may be affected by the birth (SLC T56). The clinical staff were able to appropriately describe the process for conducting a WoC assessment and their actions in the event that matters of concern arise, giving examples of how this has been managed with specific case instances.

Five sets of patient records were audited on inspection. In each instance the file contained WoC questionnaires completed by the patient and partner and also evidence of their review by a member of staff prior to the commencement of treatment..

The centre has established a QI that all patient records should contain a completed copy of the WoC assessment for each partner before treatment commencing. The centre has a documented SOP to guide the WoC assessment (SLC T33(b)) and staff were able to provided good descriptive evidence of their training and competence to conduct WoC assessments, including observation of practice (SLC T15 (a))

The centre's audit plan for 2011/12 includes the WoC assessment audit (SLC T36) which is to be concluded before the end of this financial year.

What the centre could do better.

Nothing noted at this inspection.

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28) PN
- Provision of a costed treatment plans (Guidance Note 4)

What the centre does well.

Treating patients fairly
Members of staff reported that there are policies in place on treating patients fairly, which ensure all licensed activities are conducted in a non-discriminatory manner and that careful consideration is given as to how the centre may meet the needs of individual patients and their circumstances (GN 29).

Confidentiality and privacy
A tour of the centre confirmed that all confidential information is stored securely with access restricted to authorised personnel only. Areas where conversations personal to individual patients and partners may occur were seen to be private and opportunities to be overheard reduced to a minimum.

All staff are asked to read and sign a confidentiality agreement on the maintenance of confidentiality (SLC T43). Maintaining confidentiality also forms part of the Trust mandatory induction and training (SLC T15 (a)).

Complaints
The centre has a complaints policy and information on how service users may make a complaint is displayed in patient areas. Staff described the process for dealing with complaints and said that the centre has not received any complaints to date (GN 28.1).

Provision of a costed treatment plan
The centre has only this year started to treat self –funding patients who do not meet the PCT criteria. The centre manager explained that this scheme is being trialled until the end of this financial year and if successful, patient information and the methodology will be finalised. At the time of inspection, self-funding patients and their partners were being given clear written information regarding the anticipated costs of their treatment based on the NHS fees structure GN 4.3.

What the centre could do better.

Nothing noted at this inspection.

Information

- Information to be provided prior to consent (Guidance Note 4)

What the centre does well.

Staff explained that patients are provided with information about the centre and success rates. Other information is provided as relevant to the treatment. The centre submitted the patient information as part of this licence renewal application. This information was audited prior to inspection and found to provide information about the nature of the treatment, consequences and risks, analytical tests, confidentiality and consent.

What the centre could do better.

One written patient information leaflet reviewed quoted a percentage success rate. The staff explained that the success rate quoted referred to the national average not the centre's success rate; it was noted and discussed with staff that this information may be misconstrued as referring to the centre's success rate. (GN 4.2 (e)).

Consent

- Consent to treatment (Guidance Note 5)

What the centre does well.

Information provided prior to consent
Staff who are involved in the information giving process confirmed that prospective patients are sent all relevant consents and related written information regarding their proposed treatment. The proposed treatment and implications of that treatment are then discussed at separate one to one consultations with the clinician directing their treatment.

Five sets of patient notes were reviewed at inspection and appropriate consents were in place in all cases.

What the centre could do better.

Nothing noted at this inspection.

3. Protection of gametes and embryos

Focus

The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)] • Licensed activities only take place on licensed premises
What the centre does well. Following a tour of the licensed centre premises, review of documentation provided by the centre and discussions with staff, the inspection team consider that they have sufficient information to determine that all activities for which the centre is licensed are conducted within the precincts to which that licence applies.
What the centre could do better. Nothing noted at this inspection.

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
  - maintaining up-to-date awareness and understanding of legal obligations
  - responding promptly to requests for information and documents from the HFEA
  - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

Record keeping

- Record keeping and document control (Guidance Note 31)

What the centre does well.

All patient and partner records seen at the time of inspection were considered to be legible and well organised. Each record reviewed included a copy of the person's passport which is retained for identification purposes. Each record seen also provided details of the person's medical history, WoC documentation, clinical and laboratory test results and relevant documented consent forms (SLC T46). The staff member responsible for the management of medical records confirmed that records are protected from unauthorised amendment and are retained securely (SLCs T47).

What the centre could do better.

Patient records are kept for 25 years in line with Trust policy. SLC T48 requires patient records be kept for at least 30 years (or for such longer period as may be specified in Directions) after clinical use, or the expiry date, in an appropriate archive acceptable to the Authority.

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)]

- Obligations and reporting requirements of centres (Guidance Note 32)

What the centre does well.

Data submissions are submitted as required.

What the centre could do better.

Nothing noted at this inspection.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)

What the centre does well.

From discussions with staff, a tour of the centre premises and facilities and from documentation seen, the inspection team conclude that the centre ensures information about people who are receiving or have received treatment or donated gametes and embryos and children born as a result of assisted conception is not disclosed unless authorised to do so and that the dignity and privacy of those being treated or donating gametes is protected at all times (SLCs T43 and T33(b)).

What the centre could do better.

Nothing noted at this inspection.

5. Changes / improvements since the previous inspection on 26 February 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
Procurement and processing (GN15) Licence condition T72; Act Schedule 3A (11), 2006/86/EC	Validate critical procurement and processing procedures, including the choice to monitor air quality at annual intervals, must be validated in accordance. By the date of the next inspection	At inspection, staff explained that critical processing procedures have not been validated. The quality manager explained that since the last inspection, the centre has moved to these new premises and that the service has been developed to meet regulatory requirements. Staff acknowledged the urgency of validating the centre's critical processes. The inspection team acknowledge that the centre staff have implemented many of the QMS requirements. To meet the requirements of SLC T 72, The PR should ensure that all critical processes are validated. Further action required - see page 20 of this report (Areas of practice that require the PR's attention).
Quality management (GN23) Licence condition T32 to T36; Schedule 3A (10) 2006/86/EC, Appendix 1 F.	The PR should demonstrate compliance with licence condition T33(b) (The documentation must form part of the QMS: SOPs for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence). The centre must put in place a QMS and implement this system to continually improve the quality and effectiveness of the service provided).	The QMS was reviewed at inspection. Some SOPs have been developed and are part of the documentation of the QMS. A sample of the SOPs was reviewed at this inspection. Some issues were identified some issues, such as with past review date and that air quality SOP, sperm preparation SOP and IUI SOP should be reviewed. Discussion with the centre staff demonstrated how the QMS is used to continually improve the quality and effectiveness of the service provided. The centre's audit report was reviewed which

		showed that the corrective actions identified have been implemented. Further action required – see page 20 of the report Areas of practice that require the PR's attention).
Staff (guidance note 2) T12 T15	The PR should commence a programme to review and assess the competence of all staff at the centre.	Discussion with the quality manager and a review of the staff competency folders provided evidence that the competencies of all staff are reviewed annually. Staff keep their CPD up to date to ensure that their membership is renewed. This then feeds into the staff annual appraisal. No further action required.
Third party agreements (guidance note 24) T113 T114	The PR should ensure that all third party agreements contain such detail as required by T113 and T114.	The third party agreements were reviewed at inspection and they contained the detail required by SLC T113 and T 114. No further action required.
Staff Licence condition T8-10	Consideration should be given to the variation of the licence regarding the nominated PR. As soon as possible.	The PR has submitted an application to appoint a new PR .

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 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. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several “other” areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review

None of the critical processes have been validated. SLC T72. This was an area of concern at the last inspection.	The centre should complete the validation of all critical processes (laboratory and clinical) by 29 February 2012. The PR should submit a detailed plan, including a list of all critical processes to be validated. Reports should be provided to the centre's inspector regarding the plan's implementation until all process validations have been completed. The plan should be submitted with the PR's response to this report.	We are in the process of reviewing the Validation SOP and application for Critical process validation is planned for end of January 2012: A retrospective process validation will assess each key stage of the process, focusing on the following: • Review and verification of the applicable Standard Operating Procedures (SOPs) • Review of the IUI Database • Review and verification that the laboratory personnel have been suitably trained • Review and verification that all equipment utilised is appropriately validated • Review and confirmation of consumable and material traceability • Listing of appropriate published scientific studies and clinical results • Review of the centre's current and last years success rate • Review of ten patient records • Review and comparison of the centre's and national success rates as published by	The PR's comments are noted. However, the PR has not submitted a detailed plan of the critical processes to be validated. The PR should review the requirements of Standard Licence Condition T72 to identify the critical processes applicable to the centre's licence and submit a list of all the critical processes that are to be validated. The validation methodology was reviewed at inspection which provided assurance that when implemented, the validation requirements would be met. The PR may wish to use the Association of Clinical Embryologists (ACE) validation templates, available on the ACE website. The validation of critical processes and equipment must be completed by 29 February 2012 and evidence in support of this sent to the Executive. Further action required.

		the HFEA	

Other areas of practice that requires 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
The centre's QMS does not include the following: 1. Training and reference manuals (SLC T33 (c)). 2. SOPs for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, including, but not limited to: • for submitting data to the HFEA in compliance with Directions 0005 ([see T33b), • for record keeping for full traceability	The PR must develop SOPs for all licensed activities. The PR should provide an action plan and a timeline to meet these requirements to be completed by 29 February 2012. By the time the PR responds to this report.	Those points were discussed in the weekly meeting (16/11/2011). It has been agreed that by mid February 2012 the following would be discussed to be finalised: 1. Training Guidelines 2. SOPs for: - Submission of data to HFEA - Traceability of records. - Providing of patients information. - Control of access to health data and records - Procedures to resolve data discrepancies - Procedures of operation of Lab	The PR's comments that the SOPs for all licensed activities will be developed by mid February are noted. The PR is requested to confirm to the Executive when this action has been completed. Further action required.

kept for at least 30 years (or for such longer period as may be specified in Directions) after clinical use, or the expiry date, in an appropriate archive acceptable to HFEA (SLC T 48) • for providing information to patients • for establishing and maintaining data security measures and safeguards against any unauthorised data additions, deletions or modifications to patient files or records; and the transfer of information (SLC T 44(a)) • for establishing and maintaining procedures to resolve all data discrepancies (SLC T 44(b)) • for appropriate monitoring, to		equipment and plan of action in the event of malfunctions or failure	

ensure that the critical parameters are maintained within acceptable limits at all times. (SLC T 27).			
Required standards of quality and safety, in the form of quality indicators for all activities authorised by this licence have not been established for witnessing and traceability. (SLC T35)		QI are in place for : -Witnessing - Traceability QI for Submission of data to be finalised in the next monthly meeting.	The Executive acknowledges that the centre has established QIs for witnessing and traceability. However, it was not sufficiently clear what was being measured, against what, how and the threshold for further action. The PR is referred to http://www.hfea.gov.uk/docs/Quality_Manual_June_2011.pdf for clarification. Further action required.
Not all the activities, authorised by this licence have been audited against compliance with the approved protocols, the regulatory requirements and the centre's quality indicator monitoring in the last two years. Some of the activities not yet audited include the provision of patient information and traceability (SLC T36).	As not all activities and processes are listed on the centre's audit schedule for 2011/12, it is likely that the centre will not meet this requirement. It is recommended that the PR identifies and adds all outstanding activities and processes to be audited to the audit plan and confirm this to the lead inspector.	Audit Plans 2012/2013: - Witnessing procedures - Provision of patient information -Incident reporting - Consent procedures - Assessment of the welfare of the child. -Procurement and processing procedures. - Data submission to the HFEA - Lab equipment validation (including air quality)	It is noted that the activities listed are to audited in 2012/2013. However, SLC T36 required activities to be audited every two years. The RR should audit, before the end of the current audit plan (2011/12), the activities not yet audited, namely, the provision of patient information and traceability (SLC T36). Further action required.

	By the time the PR responds to this report.	- Traceability - Security of notes and confidentiality training - OHSS cases	
At inspection, it was identified that two incidents reportable to the HFEA have not been reported to the HFEA (SLC T118).	The PR should ensure that these are reported as required by SLC T118. By the time the PR responds to this report.	- The two incidents have been reported to HFEA retrospectively. - The success rate information on the IUI patients information leaflet has been amended to include the national and centre's most recent success rate(by end of September 2011)	Noted. No further action required.
The centre's written information was open to misinterpretation. The success rate quoted was a reference to the national average and not to the centre's success rate. The likely outcomes of the proposed treatment (data provided should include the centre's most recent live birth rate and clinical pregnancy rate per treatment cycle, verified by the HFEA, and the national live birth rate and clinical pregnancy rate per	The PR should review all written information to ensure accuracy of information as required by GN 4.2 By the time the PR responds to this report.		The PR's comment above is noted. No further action required.

treatment cycle) (GN 4.2 (e)).			

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

13 January 2012

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

Minutes – Item 1

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

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information(Chair) Nick Jones, Director of Compliance Mark Bennett, Director of Finance & Facilities	Lauren Crawford

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also 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 noted that the centre is part of the North Middlesex Hospital NHS Trust, and provides NHS funded intrauterine insemination (IUI) treatments.

2. The Panel noted that the centre was first licensed in July 2007 and in 2011 their licence was varied to reflect a move to new premises and the name change of the centre.

3. The Panel noted that although licensed since 2007 licensed treatments only commenced in September 2009, due to resource issues. Treatments were halted once more in the summer of 2010 because the building in which the centre was based was demolished. Licensed treatments recommenced in January 2011.

4. The panel noted that the centre reported 98 treatment cycles for partner IUI in 2010 which resulted in 6 pregnancies.

5. The Panel noted that, at the time of the inspection, there were a number of areas of practice that required improvement: one major, and six other areas of non-compliance or poor practice.

6. The Panel noted that, since the previous inspection on 2 November 2011, the Person Responsible (PR) has provided evidence that two areas for improvement have been fully implemented.

7. The Panel noted that the PR has not yet submitted any evidence in regards to an action from the last Renewal Inspection Report (February 2010), which was to provide the Executive with an action plan and timeline for developing SOP's for licensed activities.

8. The Panel noted the Inspectorate's recommendation to renew the centre's licence for a four year period with no additional conditions.

9. The Panel confined its consideration to the evidence before it.

The Panel's Decision

10. The Panel referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and contained the supporting information required by General Direction 0008.

11. The Panel was satisfied that the qualifications and character of the PR is such as is required for the supervision of the licensed activities and that the PR will discharge the duties under section 17 of the HF&E Act 1990 (as amended).

12. The Panel was satisfied that the licence renewal application concerns treatment services which relate to gametes or embryos intended for human application.

13. The Panel was satisfied that the premises to be licensed are suitable for the conduct of licensed activities based on evidence provided within the report.

14. The Panel referred to 'Guidance on periods for which new or renewed licences can be granted'. The Panel took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states [The Executive Licensing Panel] will normally only grant a renewal licence for treatments/ storage non-medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.

15. In considering the length of the licence, the Panel noted the outstanding recommendations from the inspection on 2 November 2011. The Panel also considered the minutes of its meeting on 6 May 2010 where the Panel endorsed the Inspectorate's recommendation that the centre should submit an action plan and timeline for the development of SOP's. There was no evidence in the current inspection report that this had been done.

16. The Panel also noted from its minutes of 6 May 2010 that the PR was encouraged to submit a Change of PR Application as soon as possible, and that this has only just been done. The application to vary the license to change the PR was considered by the Panel at this meeting (13 January 2012).

17. In light of the fact that licensed treatments had only been provided between September 2009 and summer 2010 and since January 2011, the Panel considered that the centre had an insufficient track record for which to grant a 4 year licence.

18. The Panel agreed to renew the centre's licence for a period of two years with no additional conditions and endorsed the Inspectorate's recommendations in the report.

19. The Panel urged the new PR to address the outstanding recommendations, within the agreed timeframes.

Signed ..... Date 20/1/12.

Peter Thompson (Chair)