Renewal Inspection Report

The North Middlesex University Hospital
Fertility Unit
0289

Date of Inspection: 11 December 2008
Date of Licence Committee: 28 May 2009

Centre Details

Name of the applicant	Mr. Stanley Okolo
Person Responsible	Mr. Stanley Okolo
Centre name	The North Middlesex University Hospital Fertility Unit
Centre number	0289
Centre address	Sterling Way London N18 1QX
Has the applicant licensed before	No
If yes: Centre number and address of previous premises	
Type of inspection	Renewal
Inspector(s)	Dr. Neelam Sood
	Dr. Andrew Leonard
Date of visit	11/12/2008
Date of any previous visit	09/01/2008
Fee paid	Yes
NHS/ Private/ Both	NHS

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About the Inspection:

This inspection visit was carried out on11/12/2008 and lasted for 6 hours.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

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 Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The centre is a part of North Middlesex Hospital NHS Trust and has been licensed since July 2007 but did not carry out any licensable activity because of resource issues. Prior to recommencement of activity the unit has applied for a licence for a newly built facility, the North Middlesex Fertility Unit. It is intended that subject to approval of this application, the unit will be providing NHS funded intrauterine (IUI) treatments to patients from the local area.

The unit will open for five days per week, Monday to Friday between 8:30 am to 17:00.

The Person Responsible (PR) is registered with the General Medical Council and is a member of the Royal College of Obstetrics and Gynecologist. He is employed as a consultant gynecologist and obstetrician and has extensive experience within the reproductive medicine field.

The centre was subject to an unannounced inspection on the 9th of January 2008.

Activities of the Centre[1]

Intra uterine insemination (IUI)	Nil

Summary for Licence Committee

The centre's appears to have been proactive in the development of systems and processes required to deliver the service. Many areas of firm compliance were identified in the course of the inspection but there were also a number of areas where some improvements were recommended: these are summarised below:

- Revision of the organisation chart to accurately reflect reporting relationships;
- Assessments to ensure that any hazard to patients and/or staff are minimised Development of a documented complaints process;
- Development of a documents adverse incidents process;
- Establishment of third party agreements with clinical and laboratory suppliers;
- Further development of the quality management system to ensure current and future compliance with COP requirements;
- Validation of laboratory equipment and processes;
- Monitoring of air quality;
- Assessment of staff competency and provision of training;
- Development of standard operating procedures for laboratory activities;

It is recommended that a licence be granted for a period of one year. It is recommended that the licence should be issued conditional on the PR providing written confirmation that no treatments will be provided prior to the implementation of the relevant recommendations.

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. 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.

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		X	
2. Quality of the service		X	
3. Premises and Equipment		X	
4. Information	X		
5. Laboratory and clinical processes		X	

Breaches of the Act, Standard Licence Conditions or Code of Practice:
The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
The organisational chart reflects the structure and some lines of responsibility, however lines of responsibility were considered unclear for the clinical staff as the chart does not indicate to whom they report. In addition the laboratory staff were not included on the chart.	The PR should review the organisational chart to ensure that the chart clearly defines accountability and reporting relationships. (Code of Practice Standard 4.1.1 – 4.1.3)	Progress to be monitored at the next inspection
Assessments to ensure that any hazard to patients and/or staff are minimised and that the risks inherent in handling gametes and embryos are identified and minimised have not yet been carried out as laboratory standard operating procedures have not yet been developed. This is non compliant with the requirements of S.6.3.6.	Assessments should be carried out to ensure that any hazards to patients and/or staff are minimised and that the risks inherent in handling gametes and embryos are identified and minimised to be compliant with Code of Practice, Standard S.6.3.6.	To be implemented before the provision of IUI services.
The Centre does not have a documented adverse incident management procedure.	The centre should establish, implement and comply with documented procedures to report, investigate, register and transmit information about serious adverse events and serious adverse reactions which occur on any premises to which a licence relates and any relevant third	To be implemented before the provision of IUI services.

	party premises in compliance with Standard Licence Conditions at A.4. and S.9.4.2.	
The centre has not established a documented procedure for recording complaints, their investigation or corrective action taken to effect resolution in compliance with Code of Practice, Standard S.9.2.2.	Documented procedures to record patient complaints and actions taken to effect their resolution should be established	To be implemented before the provision of IUI services.
No third party agreements (TPAs) have been established with laboratory suppliers.	The PR is aware of this requirement and is in the process of ensuring its completion. (Code of Practice Standard 3.1.28, 4.1.10)	Progress to be monitored at the next inspection
An outline for the processes and documentation required to establish the quality management system (QMS) was not present in the quality manual (QM), in breach of Code of Practice, Standards, S.5.1.2 (d)	That the PR should consider the requirements of S.5.4.2 (d) and ensure an outline for the processes and documentation required to establish the QMS as is described within the quality manual.	Progress to be monitored at the next inspection.
A document control system is in place and documents provided prior to the inspection included evidence that they had been subjected to review. However some of the documents contained were not being controlled according to all of the requirements of S.5.2.5.	The PR should review documents to ensure they contain appropriate document control information compliant with Code of Practice, Standards S.5.2.6 (b), and are scheduled for annual review to ensure accuracy and appropriateness, and future compliance with Code of Practice, Standards, S.5.2.5 (b),	Progress to be monitored in the course of the next inspection.
A procedure for cleaning the laboratory and key items of equipment has not been written contrary to Code of Practice, Standards S.6.3.1 and Standard Licence Conditions A.10.15 and A.10.23. Actions to take in the event of their malfunction or re-validation after repair are not documetned, contrary to Licence Conditions A.10.12 – A.10.16	A documented procedure for cleaning of laboratory and key items of equipment should be established, to comply with Code of Practice, Standards S.6.3.1 and Standard Licence Conditions A.10.15 and A.10.23.	To be implemented before the provision of IUI services.
It has not been demonstrated or	The PR should implement an air	To be

documented that the air quality in the environment where gametes will be processed is compliant with the requirements of A.10.19.	quality monitoring programme, that documents that the air quality in the laboratory and in the critical work area is compliant with the requirements of Licence.Conditions A.10.19 and A.11.11.	implemented before the provision of IUI services..
Validation of critical equipment and key processes and procedures has not yet been established. This is in breach of Code of practice (Standards S.6.4.2 and S 7.8.3) Standard licence condition A.10.13, 11.11.	It is recommended that a plan for validation is drawn up. The plan should take into account the particular needs of the unit and prioritise the validation of those processes and equipment considered to be most likely to impact on the quality of the service and ensure compliance with Standards 7.8.3, S.6.4.2.	Progress to be monitored in the course of the next inspection.
Standard operating procedures (SOPs) for procurement or preparation of gametes have not been established, contrary to Standard Licence Conditions A.6.4 and A.11.1.	The PR should ensure procedures are documented describing the centre's sperm procurement and preparation processes, to comply with Standard Licence Conditions A.6.4 and A.11.1.	To be implemented before the provision of IUI services..
The laboratory staff member did not appear to be included in the centre's competency assessment programme contrary to Licence condition A.10.9.	The PR should ensure that all personnel are provided with initial/basic training, updated training as required when procedures change or scientific knowledge develops, and adequate opportunity for relevant professional development. The training programme must ensure and document that each individual has demonstrated confidence in the performance of their designed tasks in compliance with A.10.11.	Progress to be monitored before next inspection.

Non-Compliance

Area for improvement	Action required	Time scale
Not all the required witnessing steps are captured in the laboratory witnessing protocol. G. 13.1.2	Witnessing procedures should be reviewed in consideration of the Code of Practice guidelines G 13	Before starting IUI procedures.

Recommendations

Area for improvement	Action required	Time scale
The centre did not appear to have considered the need to verify the identity of patients attending the centre for treatment.	The PR should consider the requirement to verify patient identity at the start of treatment using a photographic form of identification, such as a passport or driving licence, to ensure compliance with Code of Practice, Standards S.7.3.1, S.7.3.2 and S.7.7.1 and Guidance G.6.1.1.	Progress to be monitored before next inspection.

Report of inspection findings

1. Organisation

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
The Person Responsible (PR) has completed the HFEA PR entry programme. The PR ensured that all IUI activity at the North Middlesex University Hospital (NMUH) was stopped when the EUTCD amendments to the HFE Act (1990) were introduced in July 2007. Centre activities will be led by the PR, assisted by three consultant gynaecologists. A small clinical, nursing and administrative team facilitate the day to day management of the Centre. The centre appears well organised with good communication within the team at all levels. Evidence of effective communication was seen in minutes of meetings. The centre has an andrologist who had been in post for approximately 6 weeks at the time of inspection and who attends for only one day per week, on secondment from the Microbiology Department. Thus progress in the laboratory with regard to methods selection and validation, and development of laboratory standard operating procedures has been limited. The PR recognised that the laboratory staffing level is limited, and plans to employ an embryologist/andrologist. Finance is required for this however and the PR is negotiating with NMUH management to facilitate this. The PR considered that the centre will be well equipped when equipment is all delivered. A time-line for this was presented to the Executive. The PR reported that there have been resource management discussions and confirmed that a management review of proposed activity levels and resources, including personnel, facilities, equipment, materials and data/information systems had been performed, though minutes of this meeting were in preparation. Area risk assessment of the renovated premises has been performed and will be updated when the centre is fully equipped and furnished in 'operational mode' by the hospital risk

manager. The Centre feeds into the NMUH Trust-wide Clinical Governance system.

The PR was able to describe an appropriate method of disseminating HFEA Alerts to appropriate team members. It was stated that HFEA Alerts, amongst other matters will be a regular agenda item at team meetings.

There is a Trust wide complaints management policy in place.

The Centre's electrical supply is supported by the Trust emergency back up generator .

The centre has formalised a contingency arrangement with another licensed centre to provide clinical and scientific facilities in case of an emergency. Procedures are in place for patients to contact staff out of working hours.

The Finance Department of the HFEA confirm that this Centre has paid the licence application fee.

The inspectorate was satisfied that the mechanisms for dissemination information to staff are effective. Copies of minutes of meetings are available in a file stored in the staff room. Staff interviewed during the inspection stated that they receive information and document updates via email.

Staff reported that they are encouraged to make suggestions to improve the service and that these are considered during team meetings. Members of the staff confirmed that they were aware of the HFEA alerts.

Areas for improvement

The organisational chart reflected the structure and some lines of responsibility, however lines of responsibility were considered unclear for the clinical staff as the chart does not indicate to whom they report. In addition the laboratory staff were not included on the chart.

Assessments to ensure that any hazard to patients and/or staff are minimised and that the risks inherent in handling gametes and embryos are identified and minimised have not yet been carried out as laboratory standard operating procedures have not yet been developed.,. This is non compliant with the requirements of S.6.3.6.

The Centre has not established, documented procedures to report, investigate, register and transmit information about adverse incidents in compliance with standard licence condition A.4.1.

The centre has not established a documented procedure for recording complaints, their investigation or corrective action taken to effect resolution in compliance with Code of Practice, Standard S.9.2.2.
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The PR stated that Third Party Agreements (TPAs) are in place with clinical suppliers. It was found that no TPAs have been established with laboratory suppliers. The Centre are directed to the HFEA 'Third Party Guidance Note' for advice regarding the content of Third Party Agreements and should ensure that TPAs are developed as soon as laboratory processes

have been decided and documented to ensure compliance with Licence Conditions A.5.1 – A.5.7.

Areas for consideration

The PR should consider modifying his application to include a Nominal Licensee. This is recommended as a risk control measure in response to several incidents which have occurred in HFEA licensed IUI centres.

The PR should ensure that regular resource management review is performed to ensure that proposed activity levels can be supported by the personnel, facilities, equipment/material and data/information systems available, to ensure compliance with Code of Practice, standards S.6.1 – S.6.5. It is recommended that the outcomes of such reviews are documented.

It is recommended that the PR ensures that patient complaints are reviewed to ascertain whether they also constitute HFEA reportable incidents, and consider including patient complaints within their patient satisfaction survey.

Executive recommendations for Licence Committee

To require the centre to ensure:-

The accuracy of the organisational chart to be compliant with Code of Practice, Standards S.4.2.5 and S.4.2.6.

That assessments are carried out to ensure that any hazard to patients and/or staff are minimised and that the risks inherent in handling gametes and embryos are identified and minimised to be compliant with Code of Practice, Standard S.6.3.6.

That documented procedures to report, investigate, register and transmit information about adverse incidents are established to ensure compliance with Standard Licence Condition A.4.1 and an incident log be kept to ensure compliance with Code of Practice, Standards, S.9.4.2.

Documented procedures to record patient complaints and actions taken to effect their resolution should be established to comply with Code of Practice, Standards, S.9.2.2.

That TPAs are established with clinical and laboratory suppliers.

Evaluation

Some improvements are required.

Areas not covered on this inspection

All areas covered.

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
Not applicable
Areas of firm compliance
The centre has a designated Quality Manager (QM). There is a Quality Management System (QMS) in place and the QM has been working hard to develop the scope of the QMS to fully reflect all key elements of the Centre's service, evidence for which was seen on inspection. A quality policy has been developed and is available to all staff. The Quality Manual was submitted with the Centre's licence application and was seen to be compliant with the exception of items detailed below. Documentation indicating the scope and detail of a proposed review was discussed. The Centre's protocols and procedures were submitted with the Licence Application and were available on inspection. The documents described procedures in most areas though it was seen that a sperm preparation protocol had not been written. The laboratory scientist explained that this was because the method to be used had not been confirmed. The scientist will be liaising with a local IVF unit to be trained in the application of an appropriate method and will write a procedure. Some of the documents were found to be non-compliant, as discussed below.
Areas for improvement
An outline for the processes and documentation required to establish the QMS was not present in the quality manual in breach of Code of Practice, Standards, S.5.4.2 (d) Systems for the continual evaluation and improvement of the quality of service have not been yet established, contrary to Code of Practice, Standards S 4.2.9 and S.9.1. For example a procedure and programme for centre audit and service review needs to be prepared to ensure future compliance with Code of Practice, Standards, S 9.2.5. The centre has not identified and established quality indicators (S.9.5.2), developed a system for monitoring and assessing laboratory and clinical practice (S.9.5.3.) The quality policy does not clearly state commitments to providing services which meet user

needs and requirements, continual improvement of the effectiveness of the QMS, good professional practice, or the health safety and welfare of staff and visitors to the centre, as required within Code of Practice, Standards, S.4.2.3. The quality policy needs to be revised, signed by the PR and displayed within the centre for patients to ensure compliance with the requirements in Code of Practice, Standards S.4.2.3. A copy should also be held, or referred to, within the quality manual to ensure compliance with Code of Practice, Standards S.5.2.4 (b).

Some documents reviewed did not contain appropriate document control information, e.g. a unique identifier, the edition or current revision date, or revision number, the number of page/total number of pages (where applicable), authority for issue, and author identification, within headers or footers, in breach of Code of Practice, Standards S.5.2.6 (b).

Some documents exhibited review dates which indicated annual review had not been performed. In addition, examples of documents imported from other centres still contained information from those centres. The PR should ensure that centre documents are reviewed at least annually, to ensure future compliance with Code of Practice, Standards, S.5.2.5 (b), and are accurate and appropriate to the centre's needs.

Areas for consideration

None

Executive recommendations for Licence Committee

That the PR consider Code of Practice, Standards, S.5.4.2 (d) and ensure an outline for the processes and documentation required to establish the QMS is described within the QM.

That the PR reviews the requirements of Code of Practice, Standards, S.9 'Evaluation and Improvement', and ensures that procedures for the evaluation and improvement of the quality of the service are developed and implemented. The PR should also ensure that a management review of the quality of the service is planned to ensure future compliance with with the requirements of S.4.2.9.

That the quality policy is revised, signed by the PR, displayed within the centre, and included or referred to in the QM, to ensure compliance with the requirements in Code of Practice, Standards S.4.2.3 and S.5.2.4 (b).

That the PR reviews documents to ensure they contain appropriate document control information compliant with Code of Practice, Standards S.5.2.6 (b), and are scheduled for annual review to ensure accuracy and appropriateness, and future compliance with Code of Practice, Standards, S.5.2.5 (b),

Evaluation

Some improvement required

Areas not covered on this inspection

All areas covered.

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
The new premises consist of:- • A reception area, with IT facilities for staff to carry out administrative work;. • Patient waiting area; • An ultrasound room;. • Two consultation rooms; • A dedicated room for nursing consultations and also to store treatment records in lockable filing cabinets;. • A laboratory for sperm processing. There is controlled access to every room and the centre is locked out of working hours. The reception desk overlooks the entry to the centre, providing controlled access during opening hours. General patient information is displayed in the waiting area and information on how to make comment or complaint, including to the HFEA directly, was displayed. Clinical facilities were unequipped on the day of inspection however the PR described the equipment to be fitted and these plans appeared to be appropriate for the proposed use. There is a semen production room which needs to be furnished but was secure. Laboratory facilities are for sperm preparation for IUI though some equipment was not in place. A class II air flow cabinet had however been fitted and commissioned by the suppliers. The laboratory appeared to be clean and well maintained. Access to all laboratory areas was seen to be strictly controlled and limited to licensed personnel only. On the day of inspection the premises and facilities appeared basic, due to most areas being unequipped, but well maintained and clean. All equipment is due to arrive at the centre by 12th of January 2009. The centre is covered by the Trust wide emergency power supply. In the opinion of the Executive, the general premises, clinical and laboratory facilities are suitable for current activities and for the proposed licensed treatments and will ensure patient's privacy and dignity are maintained. The Centre's ability to provide a physically safe working environment for patients, staff and visitors has been evaluated through risk assessment of the centre premises and equipment.

Staff facilities were reviewed on inspection and seen to comply with Code of Practice Standards S. 6.3.9 and S.6.3.10.

The patients' notes will be stored in lockable cabinets in the lockable administration room with access restricted to licensed personnel. Computer records are maintained on a secure server administered by the NMUH IT department and only accessible to centre staff.

The inspectorate agreed that the clinical and laboratory facilities including the sperm production rooms ensure that patient's privacy and dignity are maintained.

Areas for improvement

A procedure for cleaning the laboratory and key items of equipment has not been written contrary to Code of Practice, Standards S.6.3.1 and Standard Licence Conditions A.10.15 and A.10.23. Actions to take in the event of their malfunction or re-validation after repair have not been documents, contrary to Licence Conditions A.10.12 – A.10.16

The laboratory has a positive pressure purified air supply designed to meet the EUTD requirements for air quality, however, at the time of inspection an air quality monitoring programme had yet to start,. Furthermore, the air quality assessment procedure has not been documented or validated, contrary to Licence condition A.10.19 and A.11.11.

All equipment to be used has yet to be validated, contrary to Licence Condition A.10.13.

Areas for consideration

Laboratory staff have yet to decide what consumables will be used in sperm processing. The PR is advised to ensure that only CE marked equipment is used in this activity to ensure compliance with Licence Condition A.10.17 and Code of Practice, Standards, S.6.4.1. In the absence of a CE marked product, the PR should ensure appropriate tests (e.g. sperm motility and survival assays) are performed on the consumables to be used to ensure the quality and safety of processed gametes is maintained.

The laboratory is only 5 metres from the patient waiting area. It is recommended that the PR ensure that if the laboratory is vacated by the scientist during gamete processing for any reason, that the room is secured at all times and the security of gametes is protected.

Executive recommendations for Licence Committee

That the PR prepare a procedure for cleaning the laboratory and key items of equipment within, to comply with Code of Practice, Standards S.6.3.1 and Standard Licence Conditions A.10.15 and A.10.23.

That the PR prepare and validate an air quality monitoring programme, and implement that programme to ensure air quality in the laboratory and in the critical work area is compliant with Licence.Conditions A.10.19 and A.11.11.

That the PR ensures all equipment to be used is validated before use, as required by Licence Condition A.10.13.

Evaluation

Some improvement required

Areas not covered on this inspection
Counselling facilities (basic partner services are exempt from the requirements of schedule 3 consent)

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance
The information management system, both computerised and paper-based, was seen during the visit and was considered to be well organised. There are Trust procedures in place for patients who require a copy of their medical notes. Systems and procedures are in place to ensure that patients will be provided with oral and written information and that consents for treatment will be collected in a manner compliant with the requirements of the HFE Act (1990). Evidence of this was seen in documentation submitted for the inspection and from discussions held with staff. Patient information submitted for inspection was reviewed by the inspectorate and considered appropriate and included the following:- • Contact details for out of hours emergencies. • Risks associated with treatment. • Contact details for queries, treatment costs and what screening needs to be done. The centre has chosen to perform Welfare of the Child assessment for all patients. The PR stated that he was aware of the procedure for notifying the HFEA of all treatments that will be carried out at the centre.
Areas for improvement
None
Areas for consideration
The inspectorate discussed with the PR the need to verify patient identity at the start of treatment using a photographic form of identification, such as a passport or driving licence, to ensure compliance with Code of Practice, Standards S.7.3.1, S.7.3.2 and S.7.7.1 and Guidance G.6.1.1. The PR said that he would implement effective patient identification in the Centre's procedures
Executive recommendations for Licence Committee
None
Evaluation
No improvement required

Areas not covered on this inspection
All areas are covered.

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	0.6
NMC registered nurses	1.0
Non NMC registered clinical staff	0.1
HPC registered scientists	0.3
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	0.5
Counsellors	Tbc

Summary of laboratory audit
No activity since July 2007
Summary of spot check of stored material
No storage at this centre
Areas of firm compliance
The PR reported that all staff have a job description and are engaged in a programme of continuous professional development (CPD). This was confirmed by the clinical and laboratory staff who were interviewed. All nursing staff participating in licensable activity are registered with the Nursing and Midwifery Council. The job description and training record of a randomly selected member of the nursing team were seen on inspection. The senior nurse has also undertaken formal ultrasound scanning training and hopes to extend this to other members of the nursing team over the next year. A senior ultrasonographer supervises ultrasound practice and training in the centre. Recent training included all Trust mandatory training in fire, manual handling, resuscitation,

COSHH and also risk assessment, incident reporting and complaints, infection control, child protection and data protection.

A competency framework and supervision log for a number of clinical practices was seen. Staff asked stated that they were also subject to new starter then annual appraisal.

Clinical procedures and protocols appeared satisfactory. The centre has documented clinical procedures for insemination and management of ovarian hyperstimulation syndrome (OHSS).

The laboratory will initiate participation in the NEQAS scheme for inter centre comparison of sperm assessment when operational. The PR said the centre as a whole will compare quality indicators with IVF and IUI centres in its locale.

Areas for improvement

The laboratory staff member described a situation regarding competency assessment in which it appeared she was not included in the centre's competency assessment procedure, contrary to Licence Condition A.10.9.

A procedure was provided for sperm quality assessment, however, no procedures were available describing the centre's sperm procurement or preparation processes, contrary to Standard Licence Conditions A.6.4 and A.11.1.

Critical laboratory procedures have not yet been validated. This is a breach of Standard Licence Condition A.11.11. Equipment validation has been discussed in Section 3.

Areas for consideration

The competency of one staff member was found to have not been signed off at the appropriate interval specified in the quality system.

The centre's written protocols for witnessing were reviewed prior to inspection. Although the protocols specify that patient documentation should be present at the time of witnessing, the requirements to cross check information against the documentation at every stage was not recorded. It is recommended that a revision of witnessing forms is carried out to ensure that the protocols are compliant with HFEA witnessing guidelines at, G.13.1.1.

The inspectorate discussed with the PR the need to verify patient identity at the start of treatment using a photographic form of identification, such as a passport or driving licence, to ensure compliance with Code of Practice, Standards S.7.3.1, S.7.3.2 and S.7.7.1 and Guidance G.6.1.1. The PR said that he would implement effective patient identification in the Centre's documented procedures

The laboratory have yet to decide which consumables are to be used in sperm processing or the method to be used. The PR is advised to ensure that all consumables should maintain the quality and safety of the patient gametes (Standards S.7.7.11), that all consumables which could influence the quality and safety of gametes should be traceable (Standards S.7.3.1), and that all patient samples should be clearly labelled at all times (Standards S.7.3.3 and S.7.7.13).

Executive recommendations for Licence Committee

The PR should ensure that all personnel are provided with initial/basic training, updated training as required when procedures change or scientific knowledge develops, and adequate opportunity for relevant professional development. The training programme must ensure and document that each individual has demonstrated confidence in the performance of their designed tasks in compliance with A.10.11. The PR should ensure procedures are documented describing the centre's sperm procurement and preparation processes, to comply with Standard Licence Conditions A.6.4 and A.11.1. The PR should ensure that a plan for key procedure validation should be drawn up to comply with Standard Licence Condition A.11.11. The centre may wish to consider referencing Association of Clinical Embryologists (ACE) professional body guidelines on validation and associated templates. Process validation should take into account the particular needs of the unit and validation of processes and equipment considered to be the most likely to impact on the quality of service should be prioritised.
Evaluation
Some improvements required.
Areas not covered on this inspection
Counselling practice

Report compiled by:

Name……Dr. Neelam Sood

Designation……Inspector…….

Date……22/01/2009……

Appendix A: Centre staff interviewed

Five members of the staff interviewed.

Appendix B: Licence history for previous 3 years

The centre was granted a licence in July 2007 but did not carry out any licensable activity because of resource issues. Prior to recommencement of activity the unit has applied for a licence for a newly built facility, the North Middlesex Fertility Unit.

The report has been presented after five months of inspection due to the delayed response by the unit.

Appendix C: Response of Person Responsible to the inspection report

Centre Number……0289……

Name of PR……Mr. Stanley Okolo……

Date of Inspection……11/01/2009……

Date of Response……28/04/2009……

I have read the inspection report and agree to meet the requirements of the

I have read the inspection report and agree to meet the requirements of the report.

Signed … A signed copy sent by the PR.

Name……Stanley Okolo……

Date……28/04/2009…….

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

None

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

We have completed most actions as in attached Action Plan (see 3 below).

3. Please state any actions you have taken or are planning to take following the inspection with time scales.

The unit will follow the trust's complaints policy - Air quality monitoring programme was established. - Standard operating procedures for procurement or preparation of gametes have been established. - Laboratory witnessing protocol has been established. - Patients identity verification system has been started.

- An embryologist has been employed for 4 sessions a week (in liaise with the Homerton Hospital

- Organisation chart has been reviewed to define accountability and relationships.

- Risk Assessment pathway has been completed
- Serious adverse incident management procedure has been established

- Third party agreement policies have been established

We welcome comments about the inspection on the inspection feedback form, a copy of which should have been provided at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

HFEA Licence Committee Meeting

28 May 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

The North Middlesex University Hospital Fertility Unit (0289) – Initial Inspection

Members of the Committee:	Committee Secretary:
Clare Lewis-Jones (Lay) – Chair Ruth Fasht (lay) Sue Price (clinical geneticist)	Kristen Veblen Legal Adviser: Graham Miles, Morgan Cole Observers: Ian Peacock, HFEA Hannah Darby, HFEA

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

The following papers were considered by the Committee:

- papers for licence committee (40 pages)
- no tabled papers.

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009.

1. The Committee noted that this Centre had previously been licensed by the HFEA to perform intra uterine insemination (IUI). However, this licence had lapsed. Therefore the present application was for a new licence to perform IUI treatment to NHS funded patients.

2. The Committee noted that the inspection of the Centre took place on 11 December 2008 and that some improvements were required in the following areas:
   - Revision of the organisation chart to accurately reflect reporting relationships;
   - Assessments to ensure that any hazard to patients and/or staff were minimised;
   - Development of a documented complaints process;
   - Establishment of third party agreements with clinical laboratory suppliers;
   - Further development of the quality management system to ensure current and future compliance with Code of Practice requirements;
   - Validation of laboratory equipment and processes;
   - Monitoring air quality;
   - Assessment of staff competency and provision of training;
   - Development of standard operating procedures for laboratory activities.

3. The Committee noted the response of the Person Responsible (PR) outlining progress made in relation to the areas for improvement identified at the inspection and stating that most actions had been completed.

The Committee's Decision

4. The Committee noted that the PR had completed PREP training and that there were no issues regarding the character, qualifications or experience of the PR to perform his duties under Section 17 of the HFE Act 1990 (as amended). The Committee therefore agreed that it was satisfied that the Person Responsible was suitable. On the basis of the information provided the Committee agreed that it was also satisfied of the suitability of the premises.

5. The Committee agreed that it was satisfied that it had sufficient and satisfactory information on which to make a determination, was in receipt of a signed application and that the relevant fee had been paid.

6. In accordance with the recommendation of the inspection team, the Committee decided to grant a licence for a period of 12 months. The

Committee agreed that the Centre should be inspected again prior to the renewal of the licence in 12 months time.

7. The Committee agreed that the granting of this licence should be subject to the PR providing written confirmation that treatment would not commence until the PR had provided documentary evidence of completion of the following to the Executive and the Executive had acknowledged receipt of that evidence.
   - Assessments should be carried out to ensure that any hazards to patients and/or staff were minimised and that the risks inherent in handling gametes and embryos were identified and minimised to be compliant with Code of Practice, Standard S.6.3.6.
   - The Centre should establish, implement and comply with documented procedures to report, investigate, register and transmit information about serious adverse events and serious adverse reactions which occurred on any premises to which a licence related and any relevant third party premises in compliance with Standard Licence Conditions A.4 and standard S.9.4.2.
   - A documented procedure for cleaning of laboratory and key items of equipment should be established, to comply with Code of Practice Standards S.6.3.1 and Standard Licence Conditions A.10.15 and A.10.23.
   - The PR should implement an air quality monitoring programme, that documented that the air quality in the laboratory and in the critical work area was compliant with the requirements of Licence Conditions A.10.19 and A.11.11.
   - The PR should ensure procedures were documented describing the Centre's sperm procurement and preparation processes, to comply with Standard Licence Conditions A.6.4 and A.11.1.
   - Witnessing procedures should be reviewed in line with the Code of Practice guidelines G.13.

Signed..... Date.....
Clare Lewis-Jones (Chair)