Renewal Inspection Report

Assisted Conception Unit Leigh Infirmary 0278

Date of Inspection: 18 March 2008

Date of Licence Committee: 5 June 2008

CENTRE DETAILS

Centre Name	Assisted Conception Unit Leigh Infirmary
Centre Number	0278
Licence Number	E0278/1/a
Centre Address	The Avenue Leigh Lancashire WN7 1HS
Telephone Number	01942 264821
Type of Inspection	First Renewal Inspection
Person Responsible	Phillip Harris
Inspector(s)	Tahir Hussain
	Gill Walsh
Fee Paid – up-to-date	All fees paid to date
Licence expiry date	30/06/08
NHS/Private/Both	NHS

Index

About the Inspection:
This inspection visit was carried out on 18 March 2008, and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between September 2007 and March 2008.

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.

NB: Where there are very minor issues to be addressed these are noted in the "minor issues to be addressed" section for each topic, and this will facilitate the evaluation of 'no improvements required'. 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 Assisted Conception Unit is part of the Obstetric and Gynaecology Directorate of Wrightington, Wigan and Leigh NHS Trust. The unit is located on the first floor of the Women's Unit at Leigh Infirmary.

A Licence Committee of the Authority granted an application for an initial licence, for one year with effect from 5 July 2007.

The unit provides day case surgical treatment, induction of ovulation and intrauterine insemination (IUI). Couples who can only benefit from more complex assisted reproductive therapies, are referred to an appropriate licensed centre.

The unit is open Monday to Friday from 8 am until 5.00 pm.

The Person Responsible is the consultant in charge of the Assisted Conception Unit and has extensive experience in the provision of fertility treatment. He is a Consultant Obstetrician and Gynaecologist.

Summary for Licence Committee

The centre appears to be well managed and offers a good service to the local community and is making good effort in ensuring compliance with EUTD requirements.

The Executive supports the renewal of this Centre's licence for a period of three years.

Evaluations from the inspection

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

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 Centre has not established third party agreements with all suppliers of goods or services which may affect the quality and safety of gametes or embryos	Third party agreements should be established in compliance with (S.4.1.10).	Compliance to be monitored in the course of the next inspection.
The quality management system does not incorporate administration procedures or all of the centre's standard operating procedures. Quality indicators have yet to be established and evaluation procedures have not been implemented.	The Centre should continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, its evaluation activities, corrective and preventive actions and management review. Action plans for improvement should be developed, and documented as appropriate (S.9.5).	Compliance to be monitored in the course of the next inspection.
There is no documented home procurement protocol.	The Centre should establish documented procedures for the home procurement of sperm in compliance with S.7.7.2.(d),	Procedures to be established by 18 July 2008.
Validation of critical equipment and key processes and procedures has not yet been established as required by standards S.6.4.2 and S 7.8.3 of the COP and standard licence condition A.11.11.	A plan for validation should be drawn up. The plan should take into account the particular needs of the unit and prioritise the validation of key equipment and processes considered to be most likely to impact on quality of the service.	Compliance to be monitored in the course of the next inspection.
The PR had judged staff to be competent but the	It should be documented that each individual has	Compliance to be monitored in the course of the next

assessment was not documented.	competence in the performance of their designated tasks in compliance with S.6.2.7 (a),	inspection.

Non-Compliance

Area for improvement	Action required	Time scale
The Centre's incident reporting policy does not reference the HFEA reporting responsibilities and the system in place for monitoring and capturing incident information is laboratory based. (S.9.4.2 (c)).	The Centre's documented procedure relating to adverse incidents should ensure notification of the HFEA within 12 working hours of the identification of the adverse incident and submit an adverse incident report form within 24 working hours. The PR should also ensure that provision is made for the reporting of clinical incidents.	Review to be complete by 18 July 2008.
A witnessing protocol is in place, however, the protocol does not reference the requirement for active identification checks or cross-checking against records	The witnessing protocol should be reviewed in consideration of guidelines at G.13.1. Where the centres practices deviate from the guidelines, the rationale for this and an assessment of the risks of non compliance with guidelines should be documented.	Review to be complete by 18 June 2008.

Recommendations

Recommendations	Time scale

Proposed licence variations

None.

Changes/ improvements since last inspection

Recommendations	Action Taken
No previous Inspection.	N/A

Additional licence conditions and actions taken by centre since last inspection

Date	Action taken
	No previous 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 findings from inspection:

1. Leadership and management
2. Organisation of the centre
3. Resource management
4. Risk management
5. Incident management
6. Contingency arrangements
7. Business planning
8. Clinical governance
9. Payment of treatment fees
10. Third party agreements

Areas of firm compliance
The Person Responsible (PR) for the Centre has successfully completed the HFEA PR entry programme (PREP), and meets HFEA criteria for the role. (S.4.1.4). The PR is in attendance at the centre most working days and can be contacted by the team at other times. The PR satisfied the inspection team that he is conversant with his responsibilities as PR and of his reporting obligations to the HFEA. (S.4.1.7/8/9/11) The PR is supported by the Ward Manager and the Specialist Nurse who manage the day to day running of the service. Both are experienced and knowledgeable about the assisted conception treatment. The centre appeared well organised, with good communication within the team (S.4.1.1). The premises, equipment, facilities and staff skills appeared to be appropriate to conduct the number and type of licensed treatments currently offered. (S.4.2.1 S.5.1.2 S6.1.1 S6.2.1) The PR and Ward Manager both commented that they had the capacity to perform more treatments within their resources but activity is determined by the current PCT contract. There is a clearly defined organisation chart available with clear lines of reporting, and accountability. (S.4.2.5 & S.4.2.6). The clinical staff and laboratory staff have different reporting lines reporting to the clinical and pathology directorates respectively. This did not appear to have a negative impact on the team. The laboratory staff have a documented procedure for the identification, investigation and recoding of incidents. Evidence was seen of laboratory incident reporting, investigation and corrective action. None of the incidents reported related to licensed treatment (S 9.4.1). Any HFEA alerts are circulated via email and communicated at staff meetings. The PR informed the inspectors that the fertility service follows the Trusts risk management policy which was seen by the inspectorate. Evidence was seen of risk assessments having being performed (S.7.8.10 & S.7.8.3).

The service follows the Trusts clinical governance policies which were reviewed by the inspection team.

The centre's annual fee has been paid to the HFEA.

The centre demonstrated a robust Trust incident reporting policy and staff asked were aware of this. There have been no HFEA reportable incidents in the unit to date.

Areas for improvement

The Centre has not established third party agreements with all suppliers of goods or services which may affect the quality and safety of gametes or embryos,

The Centre's incident reporting policy does not reference the HFEA reporting responsibilities and the system in place for monitoring and capturing incident information is laboratory based.

Areas for consideration

Contingency arrangements to accommodate disruption to service were discussed and the PR stated that assistance from other Fertility units was available if required. The PR should ensure that the centre is equipped with backup and emergency clinical facilities equivalent to those which are standard practice in other medical provision and appropriate to the degree of risk involved in any planned procedure and able to cope with predictable emergencies. (S.6.3.4 (b).

Executive recommendations for Licence Committee

Third party agreements should be established in compliance with (S.4.1.10).

The Centre's documented procedure relating to adverse incidents should ensure notification of the HFEA within 12 working hours of the identification of the adverse incident and submission of an adverse incident report form within 24 working hours. The PR should also ensure that provision is made for the reporting of clinical incidents (S.9.4.2 (c)).

Areas not covered on this inspection

Business Planning

Evaluation

Some improvements required.

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

Summary of findings from inspection:

1. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality objectives and plans
5. Quality Management review/evaluation
6. Monitoring and resolution of complaints
7. Staff suggestions
8. Document control
9. Live Birth Rates
10. Counselling (N/A)
11. Welfare of the child (N/A)

Live Birth Rates
In the time period from 1 April 2007 to 31 December 2007 the centre provided 98 cycles of IUI treatment which resulted in 16 clinical pregnancies. These data were provided by the centre.
Areas of firm compliance
The PR and staff within the unit have demonstrated a commitment to the establishment and of a Quality Management System (QMS) by developing policies and procedures for the unit and incorporating a quality policy and objectives. The Quality Manager demonstrated continued development of the quality manual during inspection (S.4.2.1, S.4.2.7, and S.5.11 & S.6.1.1). The nominated Quality Manager is based in the pathology laboratory and is also the health and safety representative. The Ward Manager leads on quality issues for the clinical area and this arrangement was seen to be working well. The policies and procedures reviewed in the course of the inspection were version controlled and dated and available for all staff. (S.5.2.5 / 6). In compliance with the Trust policy, the centre has an effective complaints policy and mechanism for the monitoring and resolution of complaints. Information on how and to whom a complaint should be addressed was available in patient areas. (S.4.2.9, S.9.2.2). No complaints were unresolved on the day of inspection and the inspection team saw evidence of previous complaint investigations and resolutions which were comprehensive and in accordance with the policy. Evidence of staff participation in day to day changes and new developments and consideration of staff suggestions was seen in meeting agendas and minutes (S.6.2.2 (g)). The staff at the unit have carried out a user satisfaction survey and improvements have been made in response to the findings of the survey. (S.9.1.2) An audit programme was reviewed for the current year and was considered sufficient. The PR

stated that he compares outcomes of his unit with local units as part of the audit schedule. (S.9.2.5 S.4.2.8 / 9).

On interview, staff stated that consideration of the welfare of the child is made during consultation and that this is documented

The PR, Specialist Nurse, Ward Manager and Counsellor are aware of their duties under the Trust child protection policy and of the procedure for notifying service users GP of any concerns and the need for the service users to give consent to the disclosure of information.

Areas for improvement

The quality management system does not incorporate administration procedures or all of the centre's standard operating procedures. Quality indicators have yet to be established and evaluation procedures have not yet been implemented.

Areas for consideration

Executive recommendations for Licence Committee

The Centre should continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, its evaluation activities, corrective and preventive actions and management review. Action plans for improvement should be developed, and documented as appropriate (S.9.5).

Areas not covered on this inspection

Live birth rates.

Evaluation

Some small improvement needed.

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

Summary of findings from inspection:

1. General Suitable premises
2. Clinical facilities
3. Counselling facilities
4. Laboratory facilities
5. Air quality
6. Storage facilities for gametes and embryos
7. Staff facilities
8. Management of equipment and materials

Areas of firm compliance
The Assisted Conception Unit (ACU) facilities are located on two levels. The outpatient and treatment area is housed on the 1st floor within a busy area caring for gynaecology outpatient and day patients. Access to the unit is via a dedicated entrance or via the main hospital. There is no lift access to the first floor from the dedicated ACU entrance. It was noted that this is highlighted and an alternative route described on patient information. All areas are accessible by wheelchair. On inspection the premises and clinical facilities were considered by the inspection team to be suitable for the activities for which the centre is licensed. (S.6.3.1/2 /3/4). The facilities were found to be well equipped, maintained and considerate of privacy and dignity for patients and their partners The laboratory is located on a lower floor in a clean air environment, close to the operating theatres, accessed by a dedicated stairwell. Lift access is via another route. Within the unit there is a dedicated waiting room with toilet facilities. There is an ultrasound scan room, IUI treatment room and other clinical and consultation rooms located off the main gynaecology ward. Sensitivity to patient and partner ethnic and religious beliefs was evident in the provision of shower and other facilities provided within the unit (S.6.3.4). There is a staff restroom and secure staff changing facilities on the unit (S.6.3.9 / 10). Equipment and materials observed appeared to be in good order, ‘CE’ marked and appropriate for intended use. Portable Appliance Testing (PAT) and servicing of a sample of equipment was up to date. Regular preventative maintenance is scheduled with the Trust Bio Medical Engineers, who are also responsible for ‘PAT’ testing (S.6.4.1 / 2 (c). It was noted that the centre has a chaperone policy which is rigorously adhered to. The centre encourages both partners to attend all appointments together as a couple wherever possible. Counselling is offered to all patients and partners attending the centre, currently no charge is made for the service. Literature about the counselling service and how it may be accessed was seen to be readily available in patient areas. Counselling is offered throughout the treatment pathway, and also following treatment as required. Appointments may be made

directly.

The counsellor who met with a member of the inspection team was seen to be appropriately qualified and to participate in regular professional supervision and professional development. Trainee counsellors work at the centre on placement under supervision. Counselling takes place in a dedicated room which was seen to be comfortable and private.

Counselling notes are stored securely with restricted access away from the main unit.

The laboratory has a laminar flow hood. Air quality in the laboratory and flow hood has been monitored and it was seen that the requirements of the CoP have been met. The air quality is monitored regularly and achieves a minimum, consistent grade C (CoP S.6.3.6 (b) A.10.19).

Equipment monitoring logs are kept; records of temperatures of the heating block, incubator and fridge were seen.

Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None at this time
Areas not covered on this inspection
All areas covered.

Evaluation
No improvements needed

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

Summary of findings from inspection:

1. General Information
2. Confidentiality and access to health records
3. Information for service users/consents
4. Receipt of gametes / home procurement

Areas of firm compliance
The inspection team reviewed the written patient information on treatment options and implications and found this to be comprehensive (S.7.4). Information on scheduled information sessions, patient support groups and 'drop in' advice sessions was clearly displayed by staff in patient areas. The team has won a local award for a display of fertility treatment information. The centre holds regular staff meetings which are minuted and the minutes made available to all staff. Minutes for a number of meetings were seen by the inspection team and contained referenced discussion of issues such as HFEA alerts and incidents and also clinical and laboratory issues. (S.6.2.2 (g)). The inspection team observed that patient's personal and treatment records are stored at the centre in secure facilities with access limited to authorised personnel. Evidence of traceability of products used in the assisted conception process was seen. (S.7.3.1/2/3/). The lot numbers of media and consumables used are recorded.
Areas for improvement
There is no documented home procurement protocol as required by S.7.7.2(d).
Areas for consideration
None.
Executive recommendations for Licence Committee
The Centre should establish documented procedures for the home procurement of sperm,
Areas not covered on this inspection
All areas relevant to this centre covered.

Evaluation
No improvements required.

5. Laboratory and Clinical Practice
Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

1. Laboratory and clinical processes
2. Selection and Validation of laboratory procedures
3. Storage of gametes and embryos
4. Witnessing
5. Traceability
6. Training and continued professional development

Full time equivalent staff
NB all staff conduct fertility treatment as part of their other duties.

GMC registered doctors	2
NMC registered nurses	4
HPC registered scientists	1
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	3
Counsellors	2

Summary of laboratory audit / Audit of records
Five sets of patient records were audited for completeness. The records were seen to contain welfare of the child assessments, consent to disclosure of information and consent to insemination treatment. The audited records were seen to be well organised and information was easy to locate.
Summary of spot check of stored material
There is no stored material at this unit.
Areas of firm compliance
The laboratory has Clinical Pathology Accreditation (UK) and has recently been inspected: the report of the inspection listed no major citations. The laboratory staff participate in the National External Quality Assessment Scheme and evidence was seen of the results which were in line with the reported averages. All the laboratory policies and procedures are version controlled. Electronic records are kept of the servicing details and maintenance contracts of all equipment. Daily cleaning and general maintenance of key equipment is also logged electronically. The Quality Manager demonstrated a programme of equipment maintenance and calibration. Evidence of traceability of products used in the assisted conception process was seen on inspection (S.7.3.1 / 2 / 3) Lot numbers of media and plastic consumables were seen to be logged. Evidence was seen that the fridge temperature was monitored weekly (log evidenced) and the

PR stated that the ‘hood’ is maintained annually. The incubator temperature is monitored and the thermometer was seen to be calibrated.

The staff interviewed on the day had participated in continuing professional development, mandatory training, appraisals and had training plans (S.6.2.11).

Areas for improvement

A witnessing protocol is in place, however, the protocol does not reference the requirement for active identification checks or cross-checking against records.

Validation of critical equipment and key processes and procedures has not yet been established as required by standards S.6.4.2 and S 7.8.3 of the COP and standard licence condition A.11.11.

The PR had judged staff to be competent but the assessment was not documented.

Areas for consideration

None.

Executive recommendations for Licence Committee

The witnessing protocol should be reviewed in consideration of guidelines at G.13.1. Where the centres practices deviate from the guidelines, the rationale for this and an assessment of the risks of non compliance with guidelines should be documented.

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 key equipment and processes considered to be most likely to impact on quality of the service

It should be documented that each individual has competence in the performance of their designated tasks in compliance with S.6.2.7 (a).

Areas not covered on this inspection

Storage of gametes and embryos – there is no storage at this centre.

Evaluation

Some improvements needed.

Report compiled by:

Name	Tahir Hussain and Debra Bloor
Designation	Inspector /Head of Inspection
Date	20 April 2008

Appendix A: Centre Staff interviewed

Person Responsible
Three members of staff

Appendix B: Licence history for previous 3 years

20 June 2007

Licence Committee - Application for an initial licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (quality and safety) Regulations 2007.

Outcome - The centre's application was approved and a one year licence was issued.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number: 0278

Name of PR: Mr C Philip Harris

Date of Inspection: 18 March 2008

Date of Response: 1 June 2008

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

Signed: (signed hard copy in the post)

Name: Philip Harris

Date: 1 June 2008

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

Section 3 – Premises and equipment
To clarify the comments about the counsellors – we have 2 fully trained counsellors in the unit, with the opportunity for trainees to work at the centre on placement.
Section 5 – Lab and clinical staff – there are 3 GMC registered doctors

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

The home procurement witnessing form is completed. Draft protocol awaiting formal acceptance.

Validation of critical equipment – scan machines have twice yearly maintenance, all laboratory equipment assessed annually for both HFEA and CPA.

As far as staff competencies – the PR will receive the copies of all PDRs of the licensed staff – most of which are performed by the Matron / Ward manager.

Protocol for HFEA reporting of incidents being developed, the special requirements will be inserted into the Trust policy.

Witnessing protocol that cross checks identification against records is completed.

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

Please return Appendix C of the report to:

Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF