Renewal Inspection Report

Hewitt Centre for Reproductive Medicine

Centre 0007

Date of Inspection: 13 March 2008

Date of Licence Committee: 1 September 2008

Centre Details

Person Responsible	Mr Charles Kingsland
Nominal Licensee	Body Corporate of the Liverpool Women's NHS Foundation Trust
Centre name	Hewitt Centre for Reproductive Medicine (Incorporating North West Fertility).
Centre number	0007
Centre address	The Hewitt Centre Liverpool Women's Hospital Crown Street Liverpool L8 7SS
Type of inspection	Licence Renewal – Treatment and Storage
Inspector(s)	Gill Walsh Tony Knox David Gibbons
Licence Number	L0007-14-a
Licence expiry date	31 October 2008
NHS/ Private/ Both	Both
Fees paid	Renewal fee paid

Index

About the Inspection:

This inspection visit was carried out on 13 March 2008 and lasted for 8 hours and was conducted in conjunction with the Healthcare Commission. The report covers the pre-inspection analysis, the visit and information received between April 2007 and February 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.

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 modern, purpose built unit and incorporates The Hewitt Centre for Reproductive Medicine (NHS) and North West Fertility Ltd. which has been registered with the Healthcare Commission as an independent clinic since October 2006 and works in partnership with the Liverpool Women's NHS Foundation Trust.

Collectively, the Centre provides NHS and self funded treatments to patients from a large geographical area covering the North West of England and parts of North Wales, Cheshire and the Isle of Man. The day –to-day operation of North West Fertility Ltd is integrated with the Hewitt Centre, the governance, administrative arrangements for both the NHS funded services, and the privately funded services are closely aligned.

The Centre was last inspected by the HFEA in February 2007 with a three-hour follow up visit in April 2007, following which it was recommended that the Centre's licence be continued without additional condition.

The Centre was awarded ISO:9001,2000 Certification in September 2006 and was subject to an ISO Surveillance Audit in November 2007 during which no non-conformities were noted.

The Centre reports that non conformities noted in the Centre's Clinical Pathology Accreditation (CPA) assessment of their semenology service have been addressed and are now awaiting imminent award of non conditional accreditation status.

The Centre has transport centre arrangements with Centre 0279 The Fertility Unit, Leighton Hospital, Crewe and Centre 0280 Chester Fertility Centre, Countess of Chester Hospital. The Centre has recently entered into a Satellite arrangement with the Linden Medical Centre, Altrincham.

The Centre has informed the HFEA of plans to significantly expand and refurbish facilities within the curtilage of the Centre. Architect loaded drawings have been submitted to illustrate this. It is anticipated that the extension to existing premises and refurbishment will have minimal impact on patient services until completion which is planned for Spring 2009. It is anticipated that this extension to existing facilities will enable the Centre to conduct up to 2000 treatment cycles per year.

The Person Responsible has been in post since 1998 and has stated that he wishes to relinquish the post and become Nominal Licensee and has proposed the Scientific Director for the Centre as Person Responsible. This application is currently in process.

Activities of the Centre[1] for the time period from 1 Jan 2007 to 31 Dec 2007

In vitro fertilisation (IVF)	652
Intracytoplasmic sperm injection (ICSI)	845
Frozen embryo transfer (FET)	596
Intra uterine insemination (IUI) Donor	21
Research	No
Storage gametes/embryos	Yes

Summary for Licence Committee

At the time of the last inspection, the Centre was considered to be working to absolute capacity. An independent review of staffing, equipment and practice was conducted on behalf of the Centre to facilitate resource planning to accommodate this and further expansion of the service. Since that time, significant work has been undertaken by the Centre to improve on the regulatory issues noted on that inspection and to achieve a good standard of regulatory compliance and in ensuring safety and quality in their practice.

The Executive supports the renewal of this Centre's licence for the period of five (5) years.

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement 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
Validation of equipment and procedures is not yet being done. This is a breach of	Validation of equipment and procedures should be undertaken. The centre staff explained that they are waiting	By the next inspection.

[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.

licence condition A.11.11 and standards S.6.4.2 and S.7.8.3.	for documentation on this to become available from ACE/HFEA.	
Verification of identity The Centre does not currently have a system in place to verify the identity of patients or partners attending for treatment or donation. S.7.5.2. CH (99) 07	The Centre should ensure there is a documented procedure communicated to all staff to ensure that reasonable steps are taken to verify the identity of patients, partners or those wishing to donate by asking for proof of identification. (G.3.4.1 G.4.6.2 G.6.1.1/2 G.13.7)	With immediate effect.

Non-Compliance

Area for improvement	Action required	Time scale
Information Outcome data posted on the Centre's website and in written patient information does not have any comparative data drawn from national statistics displayed alongside. This is in non-conformance with S.7.4 Guidance G.5.3.1 (e).	Data provided in all relevant patient resources should include the centre's own most recent live birth rate per treatment cycle as verified by the HFEA, and the national live birth rate per treatment cycle S.7.4 G5.3 (e)	December 2008
Quality Management Review The Quality Management System has not undergone an initial management review**.** (S.4.2.8)	The PR should work with the Quality Manager to conduct a scheduled review the Quality Management System and all its services. The review should be used to assess the need for change and identify opportunities for improvement. NB This should be done as a minimum every 12 months but at shorter intervals while the Quality Management System is being established or when there are significant changes to the premises and processes.	December 08

Recommendations

Area for improvement	Action required	Time scale
Validation of key	It is recommended that a plan for validation be	

equipment and processes.	drawn up. The plan should take into account the particular needs of the unit and prioritise the validation of key equipment and processes considered most likely to impact on quality of the service.	December 08
The Quality Management System has not undergone an initial management review	The PR should work with the Quality Manager to conduct a scheduled regular review the Quality Management System and all it's services. The review should assess the need for change and identify opportunities for improvement. NB This should be done as a minimum every 12 months but at shorter intervals while the Quality Management System is being established or when there are significant changes to the premises and processes.	December 08
The Centre does not have a documented procedure for verifying the identity of patients, partners or donors.	The Centre should ensure that documented systems are in place to demonstrate all reasonable steps have been taken to verify the identity of donors and patients seeking treatment, including partners who might not often be seen in the Centre during treatment and, to avoid possible misinterpretation or mistake, were patients attend for treatment with a new partner.	December 08
Timely incident reporting	The PR should consider how best to ensure that incidents are reported to the HFEA in a timely manner.	September 08
The Centre's website does not offer national data in comparison to Centre treatment outcome data.	The Centre should review the information displayed on it's website to reflect guidance.	December 08

Changes/ improvements since last inspection

Recommendations	Action Taken
PR was to review adverse incident reporting procedures following failure to report a number of incidents to the HFEA in addition to the Trust Adverse Incident reporting mechanism.	Action in relation to reporting of adverse incidents was taken immediately following the inspection.
PR to review witnessing procedures to ensure compliance with current witnessing guidance.	Changes to witnessing procedures were reported immediately post inspection.
Written agreements with Transport treatment	Copies of the required agreements were

centres were to be established.	provided to the HFEA.
The PR was to assess all areas of practice that give rise to risk.	The Centre confirmed that the Trust has now established a risk register and the Centre now actively participates in Trust risk management agenda and the QM now sits on the Trust Risk Management Committee. Evidence of risk assessment has been provided.
The PR was to investigate obstacles to staff attending scheduled mandatory training.	Attendance was reviewed on inspection. Training records seen were up to date and mandatory training had been conducted where due.
Patient information packs to be reviewed to ensure patient are provided with appropriate information as outlined in guidance provided in the 7th Code of Practice.	Patient information submitted to the HFEA and viewed on inspection appeared clear and in line with HFEA guidance.

Additional licence conditions and actions taken by centre since last inspection

No additional licence conditions have been imposed.

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

Leadership and management

Activities at the Centre are lead by the Person Responsible (PR) who is also the nominated medical practitioner and the HCC Registered Manager who is also the Scientific Director and is nominated to assume the role of PR going forward. (S.4.1.1 A.10.2)

The Person Responsible is based at the centre throughout the working week and has satisfied the Executive that he is fully conversant with the scope of his responsibilities as PR and reporting obligations to the HFEA. (S.4.1.4 / 5 /7 / 8 / 9 / 11).

Organisation

An up to date organisation chart was seen to be in place, demonstrating accountabilities and reporting relationships. (S.4.2.5 & S.4.2.6).

The centre appears well organised, with good communication within this large team at all levels. (S.4.1.1) (S.4.1.1) Evidence of effective communication was seen in minutes of meetings. (S6.2.13)

Resource management

The PR stated that staffing was to establishment and that he felt confident the Centre had sufficient staff of the appropriate skill mix to fulfil the current activity.

Clinical Governance

Both the Hewitt Centre and North West Fertility Ltd. feed into the Trust Clinical Governance Agenda. The Centre also has a nominated Clinical Governance Lead.

Risk management
The Quality Manager oversees the process for risk assessment at the Centre and attends both the Trust wide Risk Management Committee and the Gynaecology Risk Forum. The Executive saw a number of completed risk assessments for the laboratory and clinical areas and some evidence of positive action in changing and monitoring practice following risk assessment, including that for witnessing. Recent risk assessments include a Heath & Safety Workplace Audit, manual handling (patient transfers during treatment, movement of medical records) and a full review of witnessing procedures. (S.7.8.10 S.9.4.3).

Incident management
The Centre has reviewed its incident management process in line with recommendations made in the last inspection report. Incidents are managed through the Trust Incident Reporting policy. Staff were aware of the incident reporting policy and of HFEA requirements but one member of staff was unsure about the time frames in which the HFEA must be notified. (S.4.1.8, S.4.2.9, S.6.4.3, S.7.7.1 S.7.7.8, S.9.4 and A.4). Two incidents have been reported to the HFEA since the last inspection, which are now closed. The Centre has presented evidence of how these were investigated and corrective measures applied.

Alerts
The PR was able to describe an appropriate method of disseminating this information as required to the appropriate team members. Evidence of review, risk assessment and a consequent action were required in response to HFEA Alerts was seen on inspection. It was also noted that HFEA alerts appear as a regular item on Centre meetings.

Complaints Management
There is a Trust wide complaints management policy in place and a one individual has been nominated as the person to whom complaints should be directed. The Centre complaints log was seen which illustrated the process by which these complaints were managed. Two complaints have been received by the Centre since last inspection, both of which are now resolved. No complaints have been received by the HFEA.
(S.4.2.9 S.9.5.4)

Contingency Arrangements
The centre demonstrated that they have considered their best options in the event of disruption to service and have some back- up equipment available and can relocate patients within the Trust . The Centre also has an agreement with another licensed centre in the region. A written procedure was seen to be in place. (S.6.3.4 (b)).

An on call arrangement is manned by members of the clinical and senior laboratory team to advise on out of hours on urgent calls from patients, or respond to alarm activation or other laboratory alarms. It is anticipated that the laboratory on call rota will be expanded to include other members of the team from April 2008 to coinside with the new financial year.

The Centre is supported by the Trust emergency generator back up system and an uninterrupted power supply to key equipment (S,6,3,4 (b).

Clinical Governance
The Centre, comprising both Hewitt Centre and North West Fertility, subscribe to the Trust Clinical Governance Agenda.

Third Party Agreements
A list of third party agreements was seen and sample agreements viewed appeared to be appropriate. (S.4.2.10)

Meetings and staff suggestions
There appears to be good, open communication within the team whereby staff comments and suggestions are valued and encouraged. The Centre holds regular operational meetings, the minutes of which are circulated to all staff. Evidence of this was seen on interview with team members and in reported exchange in the minutes of team meetings. Other staff members attend work-stream specific meetings regularly, evidence for which was also seen.

HFEA Fees
The Finance Dept. of the HFEA has reported that payments of fees are up to date.

Areas for improvement

Incident management
Whilst is it is recognised that the Centre has made great progress with ensuring that the Centre's Incident Management process is compliant with that required by the HFEA, the Centre should consider how best the reporting timeframes and to whom incidents for HFEA attention should be addressed in the absence of the PR.

Areas for consideration

Executive recommendations for Licence Committee

The PR should ensure that there is an effective method of ensuring that incidents and adverse events are reported to the HFEA in a timely manner in the absence of the PR.

Evaluation

Some improvement 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]
The Centre conducted 1497 IVF / ICSI procedures and 596 previously frozen embryo transfers in 2007 which is comparable with the number of procedures conducted in 2006. Figures for intra uterine insemination using donor sperm have fallen from 99 in 2006 to 21 in 2007. Analysis of outcome data extracted from the HFEA register for the period 1st April 2004 to 31st March 2007 for this Centre indicate that IVF / ICSI success rates for women below 35 is 19.73% and Frozen Embryo Transfer (FET) is 10.16%. The success rates for women aged 35 to 37 for IVF / ICSI is 13.42% and FET is 8.87 and for women aged 38 – 39 is 10.62%, all of which are significantly below the national average. Success rates for intrauterine insemination with donor sperm (IUI D) for women aged 38 – 39 is 21.05%, which is significantly above national average. All other outcome date for this period is in line with national average.
Areas of firm compliance
Quality Management System There is a Quality Management System (QMS) in place and the Quality Manager has been working hard to develop the scope of the QMS to fully reflect all key elements of the Centre's service. (S.4.2.1, S.4.2.7, S.5.11 & S.6.1.1), evidence for which was seen on inspection. **Policy** A quality policy has been developed and is in place and is available to all staff. (S.4.2.2/3 S.5.2.2 / 6) It was noted that the policy was also displayed in the Centre's main waiting area. **Feedback** Both the Centre and the Trust conduct regular, Centre specific audits of patient satisfaction questionnaires. The results of the last Trust audit and the Centre's own internal audit (October 2007 for both) was seen. In addition, the Centre also conducts a targeted survey of

the people who attend their open information evenings. The report on the most resent survey conducted in June 2007 was seen.

A small number of patient questionnaires were returned to the HFEA prior to inspection. Comments made were overwhelmingly positive about the staff and service provided by the Centre some of note were:

'the staff are thorough and compassionate. I know they see hundreds of people but I always felt like an individual and that they truly cared about the outcome of my treatment'

and after a number of treatment cycles one couple commented

''we have found all staff, from the receptionist to the Consultants helpful, informative, sympathetic and professional…no complaints only praise!.

One respondent commented on having problems getting through to the Centre by telephone and one other said they had been unable to take counselling as the distance to travel was too great.

It was reported that a confidential staff survey is conducted annually, the results for which were not seen.

Document control
A comprehensive number of Centre policy documents were submitted prior to and were available on inspection. Documents seen appeared appropriate, were version controlled and were within their specified review date. (S.5.2.5).

The Quality Manager stated that the Centre is moving to an electronic document management system which will facilitate accurate version control and monitoring of document review dates.

There is also a system in place to ensure any change in policy or procedure is communicated to relevant personnel and is confirmed and acted upon as required.

Areas for improvement

The Centre has not yet conducted an initial Quality Management Review.(S.4.2.9)

Areas for consideration

Executive recommendations for Licence Committee

The Centre should conduct a review a Management review of the Centre's Quality Management System (QMS) to assess the need for changes to the QMS and opportunities for improvement.

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

General suitability of premises

In the opinion of the Executive, the general premises, clinical and laboratory facilities are suitable for the activities for which the Centre is licensed and provide a physically safe working environment for patients, staff and visitors. (S.6.3)

Trust wide facilities contracts for waste management and cleaning are in place, evidence of which was seen. The Centre is covered by the Trust wide emergency power supply contingency plan. Key electrical equipment is connected to an uninterrupted power supply (UPS) S.6.3.1 / 2).

The Centre is housed in a modern, purpose built unit, which is part of the Liverpool Women's Hospital. Access to the Centre is from the main hospital corridor on the second floor of the building. Once through the main doors to the Centre, which are locked where the Centre is not staffed, there is a reception desk to which patients report on arrival and the main waiting area. The waiting area is of good size and had adequate seating, there is access to patient toilet facilities (including disabled) and drinking water available.

It was noted that the Centre's current HFEA and Healthcare Commission licence were clearly displayed, alongside the Centre's quality policy. Patient information regarding treatment, patient support groups and counselling was available to those waiting. There was also a notice board which displayed pictures of the Centre's team members, their names and details of their role within the Centre.

Information on how to complain or comment was displayed and included information on how to contact the HFEA. There were several boxes placed about the area in which patient questionnaires and Trust satisfaction cards are collected.

Access to the administrative and clinical areas of the Centre is via double doors, which are

locked when the Centre is unmanned.

The administration office is open plan with areas subdivided by screens. Patients required to settle treatment accounts are seen in this area, during which time they are accompanied by Centre staff.

Clinical facilities
Within this area there was seen to be a staff rest room, Sister's office and the PR's office. There are two ultrasound scanning rooms, a phlebotomy room and two other rooms which could be used for this purpose or for quiet discussion / medicines training or similar. There is a dedicated examination room and two treatment rooms. Adjacent to this is a Nurses Station. Health records for patients actively in treatment are held in lockable filing cabinets in this area. Staff state that these files are locked at the end of the day or when this Nurses Station is unmanned.

There are two clinical rooms in which procedures such as egg collection, embryo transfers are conducted, and a 5 trolley bay recovery bay to which patients are transferred following their procedure. This area is overlooked by a nurses station which is manned at all times whilst patients are in recovery. All areas appeared to be well equipped for their intended use. It was noted that there is a emergency call system in place in the recovery area and equipment for or post procedure monitoring, the administration of oxygen and emergency equipment in this area.

The PR stated that some patients elect to have or require intravenous sedation of varying depth, which is only administered by, or in the presence of a Consultant Anaesthetist who will then oversee the recovery of the patient until they are fully alert and mobile.

There is an emergency resuscitation trolley sited in the corridor. It was noted that the trolley was reported to be checked daily. This was confirmed by observation of the attached record sheet. (S.6.3.4 (b)).

Counselling facilities
There is a designated room for counselling which was seen to be both quiet and private, there is also an office for the use of the Centre's Counsellors. (S.3.5)

Laboratory facilities
There are two laboratories situated on the 2nd floor of the building alongside the Centre's clinical treatment areas and a semenology laboratory on the floor below. The laboratories on the 2nd floor are used for ICSI and IVF. The laboratories appeared to be appropriately equipped for the type and number of treatments currently offered. They also appeared to be clean and well maintained. (S.6.3.6) Access to all laboratory areas was seem to be controlled and limited to licensed personnel only

There is a semenology laboratory, a small waiting room and two small rooms designated as men's rooms and a laboratory office located on the floor below, Access to this entire area is restricted. (S.6.3.4 (iii).

N.B It is intended that this entire area, which includes the separate provision for gamete and embryo storage will be absorbed back in to the main footprint of the Centre with the intended

expansion and refurbishment.

Air Quality
Assessment of background and critical work space air quality is currently conducted monthly by an external monitoring company. Recorded Air quality of grade A in flow hood working areas and background grade D was seen on inspection. (S6.3.6 (b), evidence of biological testing was also seen. (S.7.8.5)

Management of equipment and materials
Evidence of scheduled, preventative maintenance of laboratory and other equipment was provided in the course of the inspection. Equipment seen, including consumable items were seen to be 'CE' marked. (S.6.4.1/2). A schedule of preventative maintenance was also seen.

Portable Appliance Test (PAT) was current on all but a small number of items. When asked, Centre staff stated that once commissioned, new equipment was not tested for one year. Validation of equipment has not yet begun. It is understood that guidelines for validation from the Professional body ACE (Association of Clinical Embryologists) are to due for publication shortly and that the Centre is waiting is to begin the process in earnest.

It was noted that all critical equipment is also linked to a computerised monitoring system which logs calibration parameters and will alert nominated staff to changes out of set range by telephone text message. (S.6.4.2 (b)).

Storage facilities for gametes and embryos
Facilities for the storage of gametes and embryos is currently split, embryos and eggs are currently stored within a designated store on the second floor of the Centre alongside the embryology laboratories. Semen is stored on the floor below in the semenology laboratory, Both areas were seen to be secure and to be appropriate for use. (S.6.3.7 / 8)

Appropriate alarm and monitoring mechanisms were seen to be in place, as was a policy directing action in the event of an alarm being activated.

It was noted that a low level extraction system is in place in both storage areas.

Large cylinders containing Carbon dioxide (CO_2) supply piped CO_2 to equipment requiring it in the laboratories. Liquid nitrogen (LN_2) is delivered to the storage areas by Hospital maintenance department. There is a protocol in place for safe working systems during the transport and 'topping up' of Liquid Nitrogen, including the prohibition of staff travelling in the lift when transporting Liquid Nitrogen.

Staff facilities
There is a separate staff rest room where staff may take breaks and store personal effects securely and a staff changing area. Access to this area is restricted to Centre personnel. (S.6.3.9/ 10)

Storage of records
Medical records for patients currently attending the Centre are held in room behind the main reception desk. This room is always manned during Centre opening times and access to this

room is controlled by key pad. A lockable roller shutter seals the reception desk area when the Centre is closed. Another room off this area is also used for medical records storage, access is controlled by keypad lock. Both areas were seen to be appropriately secure. (S.5.2.7 G.10.2.1). Staff described that patient medical records are held on site for up to two years following treatment and are then archived off site with a secure data storage facility.
Areas for improvement
The process of validation of laboratory equipment has not commenced. It was also noted that a number of pieces o f equipment had not been 'PAT' tested S.7.8.3
Areas for consideration
Executive recommendations for Licence Committee
Validation of key equipment should be undertaken.
Evaluation
Some improvement required.
Areas not covered on this inspection

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

Information for service users

Comprehensive patient information is available both on the Centre's website to download or print and in hard copy available at the Centre, a list of which was made available to the Executive. Patient information reviewed was seen to be appropriate and easily understood.

It was noted that in response to recommendations made in the previous report that the Centre has prepared information for young people who are considering the storage of gametes prior to treatment that may impair their fertility. The Executive viewed this information.

In addition to generic treatment and information about the Centre, each patient is given a specific Patient Treatment Booklet according to their treatment pathway. It was noted that this booklet also contains, were appropriate, information on Ovarian Hyper Simulation Syndrome (OHSS) and what to do if the patient feels unwell. Patients are advised to attend the Liverpool Women's Hospital Emergency Room (same campus as the Centre) out of Centre hours.

Consent

It was stated that Nursing and Embryology staff at key points make routine checks of valid consent during the treatment cycle. Staff when asked to describe their practice affirmed this. There is a documented procedure in place to ensure consent is sought by authorised personnel and that valid consent is in place prior to the commencement of treatment or manipulation of gametes by both clinical and scientific staff. Evidence for this was seen and was appropriately described by staff when asked about their practice. (S.7.5 S.7.8.4).

Welfare of the Child

Comprehensive consideration for welfare of the child was seen in policy documentation was described by staff the their practice. The Centre has access to an ethics committee to which a small number of referrals have been made in the last year. Patients are informed of this process throughout and are given the opportunity to address the ethics committee in writing should they wish. Patients are given written information about the process and about the role of the ethics committee and remain in contact with Counsellor throughout and following the outcome any decision process.

Evidence was seen of regular communication regarding welfare of the child issues during which cases are rendered anonymous and discussed.

Areas for improvement
Information for service users Outcome data posted on the Centre's website refers to clinical pregnancy rates and not live births nor has comparative data drawn from national statistics displayed alongside. This is in non-conformance with S.7.4 G.5.3.1(e). **Provision of information to the HFEA register** Prior to the inspection in was noted that there had been some delays in the transfer of data form the Centre to the HFEA. At inspection, staff explained that following an electronic 'update' certain operating system files had been corrupted, making the transfer of data to the HFEA incomplete. Centre staff state that this has now been resolved.
Areas for consideration
Executive recommendations for Licence Committee
Data provided in all relevant patient resources should include the centre's own most recent live birth rate per treatment cycle as verified by the HFEA, and the national live birth rate per treatment cycle S.7.4 G5.3 (e).
Evaluation
Some improvement required.
Areas not covered on this inspection
All areas 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

Full time equivalent staff *

GMC registered doctors + Consultant Anaesthetist	4.59 0.40
NMC registered nurses	14.86
Non NMC registered clinical staff	4
HPC registered scientists	6.9
Scientists pre registration	7
Scientists in training	3
Support staff (receptionists, record managers, quality and risk managers etc)	17.04
Counsellors	1.67

- At the time of PIQ submission and may have subsequently changed.

Summary of laboratory audit
A randomly selected set of five (5) patient records with gametes or embryos in storage were reviewed by the Executive, appropriate consents were seen to be in place in all case. (S.7.5.4) There was seen to be a protocol and procedure in place to ensure that gametes and embryos are not stored beyond the maximum period consented by the patient or statute. (S.7.8.11) Results of the most recent (within the previous six (6) months) Audit of stored gametes and embryos were seen both on the Centre's data base and in submission to the HFEA prior to inspection. No samples were seen to be stored beyond their consented or statutory storage period. (S.7.8.12)
Summary of spot check of stored material
As a recent audit of stored material had been conducted a spot cross check was not conducted.

Areas of firm compliance

Staff training and competence

A comprehensive induction programme is in place for both the Trust and specific to the Centre. Evidence for this was observed by viewing the programme underway for two recently recruited nurses. (S.6.2.7) Participants in the programme are allocated a mentor and as part of the programme spend time in each of the composite departments to gain insight into the overall working of the Centre.

There is good evidence of competency assessment both verbally in discussion with staff and in review of documentation provided. Training is provided on a Matrix modular system, the plans for and records for which are held on computer. Information detailing training opportunities available, training planned and training already undertaken for all staff is held on the system and was seen on inspection.

All staff members have a Professional Development and training record and competency assessments are included in that record. Evidence was seen of competency assessment for the Counsellor, members of the nursing and laboratory team. Review of sample staff mandatory training record demonstrated that mandatory training was conducted within the prescribed period.

Staff stated that, whilst not part of the training matrix system yet, Child Protection training had recently been expanded and was to be conducted annually. It was noted that persons under 18 are treated for the storage of gametes for the preservation of fertility only under the NHS. Appropriate policy in consideration of this was seen to be in place.

Clinical Practice

As part of the Fertility Nurse Specialist role staff will co – ordinate patient treatment cycles, perform intra – uterine insemination and embryo transfers. Egg collection and nurse prescribing is also undertaken by certain members of the nursing team, Both external body and in house training has been given, especially for egg collection, ultrasound scanning and nurse prescribing, evidence for which was seen.

Documented measures were seen to be in place to ensure that donated gametes are screened appropriately but was not audited specifically. (S.7.8.12)

There was seen to be an embryo transfer policy in place. Three embryo transfers were conducted on a total of 22 occasions in 2007. A report on all three embryo transfers was available on inspection. All transfers were deemed to be appropriate in accordance with guidance.

Laboratory Practice

Procurement, distribution and receipt of gametes and embryos

The Scientific Inspector was able to witness the receipt of gametes transferred from another centre and was satisfied that the procedure in place was appropriate. (S.7.7.15 / 16)

Evidence of appropriate donor records being maintained was seen on the Centre's data base. (S.7.7.4 / 5)

Documented procedures were seen to be in place to ensure the use of donor gametes does

not exceed the 10 family limit. A designated Gamete Donation Coordinator is responsible for tracking live birth events form donor gametes. (S.7.8.12)

A documented procedure was also seen to be in place for the receipt and verification of semen samples produced away from the Centre. (S.7.7.9)

Traceability
Evidence was seen in patient records and in the laboratory that there is a documented procedure in place and that practice is in compliance of this, to assure the traceability of gametes and embryos and of the equipment and consumables used in the assisted conception process. (S7.3.1/2)

Coding / identification of samples / witnessing
Following the report of the last inspection the Centre has conducted a comprehensive review and risk assessment of the witnessing procedures. An audit of patient / sample identification has been conducted. On the samples audited by the Centre using the HFEA Audit tool showed one signature to be absent in the final sperm preparation process for one patient.

Samples were observed to be identified using a bar coding system and are also witnessed electronically. Samples observed to be witnessed manually were being conducted in accordance with HFEA guidance. (S.7.3.3 S.7.8.12 G.13)

An audit was conducted on a random sample of 5 patient records on inspection. Appropriate consent was seen to be in place in all cases and no discrepancies were seen. One alteration was noted but had been initialled by the patient. (S.5.2.7)

On inspection, an audit of witnessing processes was conducted on five (5) randomly selected patient records. All records were seen to be compliant with current witnessing guidelines with the exception of one patient file when treatment was conducted in 2003.

Counselling practice
The Centre has two Counsellors both of which are appropriately qualified and undertake regular professional supervision. Each Counsellor has a mandatory and professional training log. Mandatory training had been conducted in date and there was evidence of comprehensive competency assessment. A random selection of counselling policies and procedures viewed were seen to be version controlled and reviewed within date. When asked, the Counsellor interviewed was able to describe good communication with the Centre team and evidence of attendance at unit meetings was seen. Welfare of the Child consideration appears to be robust. Evidence was seen of anonymous case conferences and referral to the Ethics Committee on occasion. The Counselling team were seen to work proactively in support of patients throughout this process.

Areas for improvement

Validation of laboratory processes has not yet begun.
The Centre does not currently have a system in place to verify or positively confirm the identity of patients and partners attending the Centre, especially men attending the semenology laboratory alone. (S.7.5.2 / G.4.6.2)

Areas for consideration

Executive recommendations for Licence Committee
The Centre should review their process for the positive identification of patients and partners attending the Centre for treatment or donation.
Evaluation
Some improvement required.
Areas not covered on this inspection

Report compiled by:

Name Gill Walsh

Designation HFEA Executive - Inspector

Date 27 July 2008

Appendix A: Centre staff interviewed

The Person Responsible and six members of the Centre team.

2 patients in treatment.

Appendix B: Licence history for previous 3 years

L0007-14-a Treatment and Storage - current
Licence Variation pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007).

08/03/07
Licence Variation to include storage of eggs.

L0007-12-a
Replaced by new version.

Appendix C: Response of Person Responsible to the inspection report

Centre Number 0007

Name of PR Mr Charles Kingsland

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

Signed……

Name…….

Date……

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.

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

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

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

Licence Committee Meeting

1 September 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 6

Hewitt Centre for Reproductive Medicine (0007)
Licence Renewal

Members of the Committee:	In Attendance:
Walter Merricks, Lay Member – Chair	Debra Bloor, Head of Inspection
Sally Cheshire, Lay Member	Claudia Lally, Committee Secretary
David Archard, Lay Member	
Jennifer Hunt, Senior Infertility Counsellor, IVF Hammersmith	Providing Legal Advice to the Committee: Graham Miles, Morgan Cole

Conflicts of Interest: Sally Cheshire informed the Committee that she is Deputy Chair of the NHS North West Strategic Health Authority with responsibility for 63 Trusts one of which is the Liverpool Women's NHS Foundation Trust with which this centre works in partnership. The Committee agreed that this is not an interest that gives rise to a conflict but asked that this interest be recorded in the minutes. Other 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 (37 pages)
- no papers were tabled.

1. The papers for this item were presented by Gill Walsh, HFEA Inspector. Mrs Walsh informed the Committee that this centre is a modern, purpose built unit incorporating the Hewitt Centre for Reproductive Medicine and North West Fertility Ltd. Collectively, the centre provides treatments to self-funded and NHS patients from a large geographical area covering the North West of England and parts of North Wales, Cheshire and the Isle of Man. Mrs Walsh reported that the renewal inspection visit took place on 13 March 2008. The inspection found that significant work has been undertaken to address the areas for improvement noted at the previous inspection of the centre and to achieve a good standard of regulatory compliance and ensure safety and quality.

2. Mrs Walsh referred to the areas for improvement listed at pages 6 to 8 of the report. These were as follows:
   - equipment and procedures have not yet been validated
   - the centre does not have a system in place to verify the identity of patients or partners attending for treatment or donation
   - outcome data posted on the centre's website and in written patient information does not have comparative data drawn from national statistics displayed along-side
   - the Quality Management System has not undergone an initial management review
   - the Person Responsible should consider how best to ensure that incidents are reported to the HFEA in a timely manner.

3. Mrs Walsh discussed the response to these findings from the Person Responsible. She reported that the centre is waiting to hear back from ACE and the HFEA for further information with respect to validation. The centre is in the process of reviewing the issue of verification of patients and the Person Responsible anticipates that a system of photo-ID will be implemented. Mrs Walsh recommended that the centre's licence be renewed for a period of five years.

The Committee's Decision

4. The Committee decided to renew the centre's licence for a period of five years.

Signed…… … Date……..
Walter Merricks (Chair)