Renewal Inspection Report

Date of Inspection: 12 & 13 October 2010
Length of inspection: 7.5 hours
Inspectors: Mim Glenn (Lead)
Dr Vicki Lamb
David Gibbon
Chris Hall
Gladys Dye
Dr Debra Bloor (Observer)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between 15 October 2009 and 14 January 2011

Date of Licence Executive Licensing Panel: 14 January 2011

Purpose of the Inspection report

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

Centre details

Centre Name	London Women's Clinic, Darlington
Centre Number	0075
Licence Number	L0075/13/d
Centre Address	Woodlands Hospital, Morton Park Darlington County Durham, DL1 4PL
Telephone Number	01325 371 070
Person Responsible	Mrs Shailaja Nair
Licence Holder	Dr Kamal Ahuja
Date Licence issued	01/10/2009
Licence expiry date	31/03/2011
Additional conditions applied to this licence	No additional conditions imposed

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

London Women's Clinic, Darlington, is one of four licensed centres owned by JD Healthcare Limited. The centre has held an uninterrupted Human Fertilisation & Embryology Authority (HFEA) licence since 1996, during which time no additional conditions have been imposed on their treatment and storage licence.

The centre is a stand-alone unit, located within the BMI Woodlands Hospital, Darlington and offers a comprehensive range of licensed assisted conception treatments to self funding patients. Opening hours at the centre are Monday - Friday 8.30am – 4.30pm and Saturday 8.30am – 12.00.

The centre informed the inspection team that they are in the process of applying for ISO 9001:2008 accreditation, with an inspection planned for November 2010.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 01/07/2009 – 30/07/2010*
Intra Cytoplasmic Sperm Injection ICSI	80
In Vitro Fertilisation IVF	126
Frozen Embryo Transfer (FET)	55
Insemination (Partner) 01/01/2009 – 31/12/2009	5
Insemination (Donor)	35

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

*These data were extracted from the HFEA register for the period 01/07/2009 – 30/07/2010. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

Summary for licensing decision:

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

- the Person Responsible (PR) is suitable and she has discharged her duty under section 17 of the Human Fertilisation & Embryology Act 1990 (as amended). She has completed the PR Entry Programme (PREP) certificate number T/1158/8 (January 2010)
- the premises are considered to be suitable for the range of services provided
- the practices were found to be suitable, except for those specified below, which should be addressed within the timeframes specified in pages of this report
- the PR has submitted appropriately completed documentation in accordance with General Directions 0008 in application for the renewal of its licence
- the PR has submitted an application fee to the HFEA in accordance with requirements

Summary for licensing decision

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including 1 critical area of non-compliance, 6 major areas of non-compliance and 5 other areas of non-compliance or areas of poor practice.

Since the inspection visit on 13 October 2010 the PR has provided information / evidence that, in the view of the inspection team, provides sufficient information to conclude that the centre is now compliant with, or has given a commitment to implement, the following recommendations.

- Witnessing: the PR confirmed that witnessing is now recorded contemporaneously when performed on a Sunday and that a full and complete record of witnessing is maintained by staff at all times
- Adverse Incidents: the PR has confirmed that all required adverse incidents and near misses will be reported to the HFEA as required by Directions
- Procurement, processing and transporting of gametes and embryos: the PR has confirmed that validation of critical processes will be completed by March 2011
- Staff: the PR has confirmed that the laboratory staff member has been assessed as competent to perform ICSI and medical staff will be assessed as competent to perform their designated tasks by 31 December 2010
- Premises and Facilities: the PR confirmed with the external laboratory that provides screening test is perusing Clinical Pathology Accreditation (CPA)
- Equipment and materials: the PR has confirmed that arrangements have been made to ensure that all laboratory consumables are CE marked
- Legal parenthood: the PR has confirmed that the centres patient information relating to legal parenthood provisions is being amended.
- Third party agreements: the PR has confirmed that they intend to assess the ability of their third parties to meet the required standards as part of 2011 audit plan
- Record keeping and document control: the PR has confirmed that there is a system in place to ensure that all the centres documents will be compliant with licence condition T34

Recommendation to the Executive Licensing Panel

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

Details of Inspection findings

1. Risk to patients and children born as a result of treatment services

Focus

- **Welfare of the Child** – all assisted conception processes should only be conducted in a manner that takes into account the welfare of any child that may be born as a result of treatment services

- **Ensuring patients receive treatment using the correct gametes or embryos** – patients should have confidence that the gametes or embryos used in their treatment are either their genetic gametes or embryos created with their gametes (or in the case of donor gametes that the gametes used are from the correct donor)

- **Ensuring donor gametes are only used where appropriate screening has taken place** – the health of patients and children, born as a result of treatment services, could be at risk if gametes from unscreened donors are used in the provision of treatment services

▶ Take account of the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth (Principle 4).
What the centre does well **Welfare of the Child** (Guidance Note 8) During the inspection four sets of patient records were audited and appropriate Welfare of the Child documentation found in all, demonstrating that before providing treatment services the centre takes into account the welfare of the child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth (Licence Condition (LC) T56). During discussions with staff they described how they can access further information about the patient and their partners from the general practitioner, social services or other support services including referral to the centre's qualified counsellor should the need arise.
What the centre could do better. Nothing noted at the time of inspection.

▶ Conduct all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring (Principle 7).
What the centre does well **Reimbursement of donors** - Guidance Note 13 The centre does not recruit sperm donors. If a patient requires donor sperm the centre obtains stock from a HFEA licensed sperm bank. The centre does have an active egg share programme carrying out treatment with eggs donated from patients undergoing egg sharing arrangements.

Quality Management System – Guidance Note 23
The centre has access to a Quality Manager who is employed at the company's head office and oversees the activities in quality management on all four sites with local 'link' personnel at each centre in the group. Minutes of the quality management meeting were seen for April 2010 and included a review of the quality management system. It was also noted that at this meeting results of audits were discussed and corrective actions were agreed and documented on the centre's Corrective and Preventive Action (CAPA) forms (LC T32).

The Quality Manager presented evidence which demonstrated that there are Standard Operational Procedures (SOP~~s~~) in place for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence (LC T33), unless otherwise stated in the body of this report. The centre has developed a number of quality indicators (LC T35) and a schedule of audits, which for the coming year also include targets. The inspectors saw evidence of audits having been undertaken on a regular basis and where applicable corrective actions were documented on CAPA forms. The Quality Manager stated that at the time of auditing the SOP is also reviewed (LC T36).

What the centre could do better.

Procuring, processing and transporting of gametes and embryos – Guidance Note 15
The PR is aware that not all of the centre's critical processes have been validated (LC T72 & T73). Evidence presented on the day of inspection confirmed that validation of all critical processes is due to be completed by December 2010 (LC T72).

Intra-cytoplasmic sperm injection (ICSI) – Guidance Note 21
No evidence was presented to confirm that the embryologist who performs ICSI had been assessed as to their competency to perform this procedure (LC T15 (a)).

▶ Ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose (Principle 8).

What the centre does well

Import and Export – Guidance Note16
Laboratory staff confirmed that since the last inspection in October 2009 no gametes or embryos have been exported and they have only imported two sperm samples; evidence presented demonstrated that the imports were compliant with Direction 0006.

Storage of gametes and embryos – Guidance Note 17
The cryostore facilities were observed to be adequate for the volume of work being carried out. The facilities are fitted with a low oxygen monitoring system. All dewars are alarmed and linked to an auto dialler system (LC T72). A spare dewar is kept for emergency use. There is an 'on-call' system in place and staff are contactable by mobile phone. In the event of a power failure the centre has access to an uninterrupted power supply from the main hospital and if this fails, the centre has its own generator (LC T27).

Witnessing – Guidance Note 18
The centre's SOPs specify the witnessing steps to be carried out, both for clinical and laboratory practice (LC T71). An audit of six sets of patient records indicated that

witnessing is undertaken by two members of staff at all critical points for all gametes and embryos from procurement to use (LC T71), with the exception of those occasions documented below.

A training and competency assessment programme for witnessing has been developed and implemented. A review of one staff member's training record provided at the inspection included assessment of their competency in carrying out witnessing (LC T15).

Traceability – Guidance Note 19
The scientific inspector saw evidence which demonstrated that batch data is recorded on laboratory forms for all equipment and medium that comes into contact with gametes and embryos from procurement of the gametes to use in patient treatment and disposal (LC T99 to T104). A traceability audit of one patient's records confirmed this.

Third party agreements – Guidance Note 24
The centre's company head office oversee all third party agreements with third parties who provide goods and services that influence the quality and safety of gametes (LC T111 & LC T115). Copies of all agreements seen were signed and dated by both parties, and contained the core requirements described in licence condition T114.

Premises and Facilities – Guidance Note 25
The PR confirmed that all licence activities are carried out on licensed premises which were found on the day of the inspection to be fit for their intended purpose (LC T17).

The laboratory staff provided documented evidence that the processing of gametes and embryos takes place in an environment of Grade C air quality, within a background environment of Grade D air quality (LC T20).

Equipment and materials – Guidance Note 26
Laboratory staff provided evidence demonstrating that all equipment and materials used in the course of procurement and processing are traceable (LC T22), and are being maintained and regularly inspected in accordance with manufacturer's instructions (LC T23). Laboratory staff provided documented evidence which demonstrated that all critical equipment has been validated (LC T24). Laboratory staff confirmed that other than the equipment documented below, all equipment is CE marked (LC T30).

Laboratory staff were able to provided written evidence in the form of a validation report by an external company to demonstrate that critical measuring functions, such as the monitoring of CO_2 in incubators, are being calibrated. There are procedures in place for staff to follow in the event of malfunction or failure (LC T24) and relevant staff were aware of the need for equipment to be revalidated following repair (LC T25).

What the centre could do better.

Witnessing – Guidance Note 18
Laboratory staff stated that when material is frozen on a Sunday, it is not witnessed by a second member of staff until the following Monday (LC T71).

During an audit of six sets of patient records the following was noted as not being documented

- The name of the person performing the procedure and the name of the person who witnesses the procedure.

- Witnessing the disposal of fresh material, no longer needed for treatment or storage (LC T71).

Third party agreements – Guidance Note 24
The centre's company head office has not as yet evaluated the ability of their third parties to meet the required standards. The Quality Manager stated that they are intending to audit suppliers next year (LC T36).

Premises and Facilities – Guidance Note 25
Laboratory staff confirmed that regular cleaning and decontamination of equipment is undertaken in accordance with manufacturer's instructions, but the actual cleaning is not being documented (LC T26).

The external laboratory the centre uses to carry out screening tests is not accredited with ~~Clinical Pathology Accreditation (CPA)~~ the CPA. However, a letter dated October 2009 indicates that the laboratory has applied for CPA accreditation. The letter also indicated that they were awaiting an audit date (LCs T21 & T51).

Equipment and materials – Guidance Note 26
It was noted on the day of the inspection that the petri dishes and specimen tubes in use in the laboratory are not CE marked (LC T30).

▶ Ensure that all staff engaged in licensed activity are competent and recruited in sufficient numbers to guarantee safe clinical and laboratory practice (Principle 9).

What the centre does well

Staff – Guidance Note 2
The PR reported that currently they are operating with a full staff complement and she considered that the number of staff is adequate for the current volume of work being undertaken by the centre (LC T12). An organisation chart is in place which defines accountability and reporting relationships (LC T11).

Training files for three members of staff were reviewed by the inspection team. Two contained evidence of appraisals, mandatory training (including fire and life support training) and continuing professional development and assessment of competency to perform their designated tasks (LC T15). With the exception of the trainee embryologist all staff, where applicable, are registered in accordance with the appropriate professional and/or statutory bodies (LC T14).

What the centre could do better

Staff – Guidance Note 2
The training file for one of the consultants appeared to contain a statement made by him some time ago as to his competency to perform tasks. There was no other evidence to indicate that the PR had assured herself as to his competence to perform these tasks in his current setting (LC T15).

▶ Report all adverse incidents (including serious adverse events and reactions) to the HFEA, investigate all complaints properly, and share lessons learned appropriately (Principle 11).
What the centre does well **Complaints** – Guidance Note 28 The centre has, and adheres to, a complaints procedure. The centre's electronic complaints log seen during the inspection, demonstrated that complaints reported to the centre were being investigated and managed in line with the National Health Service (Complaints) Regulations 2004 and the Private and Voluntary Health Care (England) Regulations 2001.
What the centre could do better. **Adverse Incidents** – Guidance Note 27 During a post inspection review of the minutes of a meeting held in April 2010 it was noted that an incident had not been reported as required by HFEA Direction 0011. The PR was contacted and has since submitted an incident report form (LC T118).

2. Patient Experience

Focus

- **Ensuring patients and donors are treated fairly and that any treatment is conducted in suitable premises by trained competent staff** – treatment should only be carried out in licensed premises and staff must been trained and competent to perform their jobs. All patients and donors should be treated fairly and without discrimination

- **Guaranteeing patients, donors and partners' independent decision making** – this should be done through the careful giving of appropriate and accurate information and the offering of counselling, and the subsequent taking and recording of effective consents

- **Outcome data** – variation in quality of practice and subsequent treatment results

▶ Treat prospective and current patients and donors fairly, and ensure that all licensed activities are conducted in a non-discriminatory way (Principle 1).
What the centre does well **Procuring, processing and transport of gametes and embryos** – Guidance Note 15 The inspection team saw evidence which demonstrated that the clinician responsible for the patient documents the justification for the use of patient's gametes and/or embryos created with gametes in treatment, based on the patient's medical history and therapeutic indications (LC T49).
What the centre could do better. Nothing noted at the time of inspection.

▶ Have respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors (Principle 2).
What the centre does well **Counselling** - Guidance Note 3 The counsellor stated that all patients/partners and donors are offered counselling prior to providing consent to treatment or donation. The counsellor can be contacted via a referral from centre staff. A telephone number is available for self referral if the patient prefers. This information was seen in a number of patient information leaflets (Schedule 3 HFE Act). The centre has access to a second accredited counsellor to ensure that when assessments are required as to a patient or partner's suitability to receive treatment, it is separate from the normal relationship between the centre's resident accredited counsellor and clinical staff. **Confidentiality**– Guidance Note 30 Discussions with staff, and a tour of the premises indicated that patient privacy, dignity, comfort and confidentiality are accommodated. There are key pad locks to all doors, both internal and external.

The inspection team observed that patient records are stored appropriately within cabinets that are locked after hours in an office that is locked when no staff are present The staff were aware of when information could and could not be disclosed (LC T43). All members of staff have their own password and electronic pin number for the centre's electronic database which holds all patients records (LC T45). The quality manager was able to confirm that all staff have undergone confidentiality training, as evidenced in one nurse training file (LC T15 (a)).

Consent to disclosure of identifying information was seen to be present in four sets of patient records. The requirement for consent to disclosure is explained in the centre's initial patient information pack.

What the centre could do better.

Nothing noted at the time of inspection.

▶ Give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions (Principle 5).

What the centre does well

Information to be provided prior to consent – Guidance Note 4

A number of the centre's patient information such as counselling and donor insemination was audited against HFEA Guidance in the CoP and was found to be compliant, with exceptions detailed below (LC T58). Patient information leaflets are distributed by staff when required (CoP Guidance 4.2).

A "schedule of fees" is sent to patients prior to their first appointment and gives comprehensive details of charges. The cost of treatment is discussed with patients at their initial consultation. During the information session with the nurse the specific costs of their treatment is discussed (CoP guidance 4.3).

On the day of the inspection three patients agreed to be interviewed by the inspection team and although it is acknowledged that the experience of those patients interviewed may not be representative of the centres other patients' experiences, they were all satisfied with the level of information they had received.

Legal parenthood – Guidance Note 6

Through discussions with staff and a review of information provided, the centre was able to demonstrate that patients are provided with information about varying or withdrawing any consent given regarding legal parenthood (LC T64 and T65). An audit of four patients' medical records confirmed that the correct consents were in place when donor gametes were used. Staff confirmed that where applicable, information regarding legal parenthood is included in the nurse's talk before such consents are taken.

Egg sharing arrangements – Guidance Note 12

Staff responsible for the egg sharing programme confirmed that treatment is provided to the egg share donor during the course of the donation cycle. If there was a medical reason why treatment could not be provided at that time, it would be documented in the patient's records. Patient information also informs both the donor and the recipient about the screening required, options if the egg donor produces fewer follicles than the minimum

needed for sharing and the costs involved.

Storage of Eggs – Guidance Note 17
Evidence presented on the day of the inspection demonstrates that the centre ensures that patients seeking to store their eggs are provided with oral and written information about the risks associated with the cryopreservation and thawing of eggs (LC T84).

Donor assisted conception – Guidance Note 20
Through discussions with staff, the counsellor and a review of information provided, the centre ensures that the patient/couple are aware of the importance of informing any resulting child at an early age that they were born as a result of such treatment, and suitable methods of informing such a child of that fact (LC T63). The patient information sheet for egg donors also states the type of information that can be given to the recipient and any resulting child by the centre and the HFEA (LC T54).

What the centre could do better.

Legal parenthood – Guidance Note 6
Although it appeared that staff interviewed during the inspection understood the new legal parenthood provisions, the centre's patient information leaflet – 'Donor insemination', did not reflect the new provisions in relation to treatment using donor sperm in which the patient couple are not married or in a civil partnership (LC T64 & LC T65).

▶ Ensure that patients and donors have provided all relevant consents before carrying out any licensed activity (Principle 6).

What the centre does well

Consent – Guidance Note 5
Verbal and written evidence presented demonstrated that staff have had training covering the new HFEA consents forms.

An audit of four patients records demonstrated that all appropriate consents are completed prior to treatment commencing. The treatment-specific nurses' consent checklist requires a nurse to confirm that the correct consent forms are completed. Three patients interviewed on the day of the inspection confirmed that they had all received sufficient information and had been given the opportunity to discuss it, before signing consents.

The scientific inspector saw evidence of the procedures to be followed when a patient or their partner withdraws their consent to parenthood (LC T64 and T65).

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

Live Birth Rates

Relative live birth success rates from the HFEA register data for 1 January 2007 to 31 December 2009 show that the centre's success rates are in line with the national averages for all treatment types.

Multiple Births – Guidance Note 7

What the centre does well

Data extracted from the HFEA register for 2008 and 2009 show multiple clinical pregnancy rates of 19.2% and 22.1% respectively.

In compliance with Directions 0003, the centre has a documented record of their multiple birth minimisation strategy (MBMS) including:

- How the centre identifies suitable cases for single embryo transfer (SET), including criteria in relation to embryo assessment and patient selection criteria (Directions 0003 (5(a)).
- How the centre aims to reduce the multiple birth rate and how to ensure that the rate does not exceed the maximum specified rate of 20% (Directions 0003 5 (b)).

The centre maintains a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer as set out in the strategy (Directions 0003). Where more than one embryo has been transferred, the centre has recorded in the patient record an explanation of the reasons for transferring more than one embryo in that particular case.

One hundred and forty seven patients have had two embryos transferred in 2010, the PR confirmed that this was due to patient demand and that all had signed a disclaimer, confirming that information regarding risks had been given and that they wished to have two embryos transferred against the centre's recommendation, copies of this disclaimer were seen in the patient notes. The PR stated that only one patient has had three embryos transferred in the last year. This was confirmed by reviewing the centre's three embryo transfer log.

The PR stated that following an audit of their Multiple Birth Minimisation Strategy (MBMS) in September 2010 they have identified patient acceptance as an issue and have introduced measures to encourage patients to participate in their MBMS. The measures include introducing the patients to the policy at the first consultation, raising staff awareness and not charging patients who have a blastocyst transfer.

What the centre could better

Nothing noted at the time of inspection.

3. Protection of embryos

Focus

- **Safe procurement, processing, storage, application and disposal of gametes and embryos** – gametes and embryos must only be procured, processed, used, stored and disposed off in accordance with the law

▶ Have respect for the special status of the embryo when conducting licensed activities (Principle 3).
What the centre does well **Guidance Note 22 - Research and training** The centre is not involved with any research projects and does not use embryos in training. As a result there is no information or consent process for these activities.
What the centre could do better. Nothing noted at the time of inspection.

▶ Ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose (Principle 8).
What the centre does well **Storage of gametes and embryos** – Guidance Note 17 The laboratory staff demonstrated the centres bring forward system for the management of stored gametes and embryos. The centre's database showed that all gametes and embryos in storage were within their consented storage period (Licence Condition T79).
What the centre could do better. Nothing noted at the time of inspection.

4. Good governance and record keeping

Focus

- **Where gametes or embryos are used complete and accurate information should be recorded and reported to the HFEA in a timely manner** – incomplete and / or inaccurate information may lead to the wrong information being provided to offspring and / or researchers
- **Ensuring gametes and embryos are only stored in accordance with effective consent and within the statutory timeframe**
- **Ensuring identifying information is only disclosed in accordance with consent**

Maintain accurate records and information about all licensed activities (Principle 10).

What the centre does well

Record keeping and document control – Guidance Note 31
The company has introduced a document control procedure that records the history of document reviews and ensures that only current versions of documents are in use (LC T34). All quality documents are referenced in an electronic database accessible to all staff.

Licensed Treatment Reporting
On the basis of the audit described below the inspection team concluded that HFEA register submissions are completed to a good standard.

To determine whether all licensed treatments are reported to the Authority as required by Direction 0005, a sample of licensed treatments undertaken by the centre between 01/09/09 and 31/08/10 was reviewed. The sample was drawn from the centres records and was reviewed against an extract of the Authority's statutory register.

Of 141 treatments reviewed, all were reported to the HFEA by the time of the inspection139 (99%) of the 141 treatment cycles in the audit sample had been reported to the HFEA within 5 working days of treatment as required by Direction 0005.

To ascertain the quality of the data submitted by the Centre for inclusion on the HFEA register, 91 sets of assorted form data submitted to the Authority between 01/09/09 and 31/08/10 were reviewed against data held on the centre's electronic patient records system (EPRS). Although 13 (14%) of the forms were found to contain an error or omission, no errors were found in critical fields (e.g. a donor reference) that could affect the Authority's ability to fulfil obligations to offspring. Additionally, no systemic or systematic errors were found.

Discrepancies were noted between consents to the use of register data for research recorded on disclosure consents in the patient's records and the consents recorded on the registration form submitted by the centre to the HFEA in 3 instances. In each case the patient/partner had given consent to disclosure but this was not reflected on the register.

At the moment the centre is in the process of transferring all patient records to an electronic patient records system (EPRS). The EPRS was used as the primary data source for data quality testing at this inspection. The assessment found that the EPRS in use did not always to hold a complete audit trail, which is a reflection of the ongoing

population of the centres EPRS.

The centre has been provided with a list of the errors and omissions found at the time of the inspection to enable appropriate corrections to be made

What the centre could do better.

Record keeping and document control – Guidance Note 31

It was noted during the course of the inspection that not all the centre's documents are in line with the company's document control procedure, particularly the patient information leaflets. Those seen did not record the history of the document, such as version and review dates (LC T34).

Some documents appeared to be past their review dates, such as the SOP for staff to follow when recruiting, assessing and screening donors, which should have been reviewed in December 2009 (CoP 31.6). The Quality Manager reported that she is aware of this and is currently working towards addressing it.

▶ Conduct all licensed activities with regard for the regulatory framework governing treatment and research involving gametes or embryos within the UK, including: maintaining up-to-date awareness and understanding of legal obligations responding promptly to requests for information and documents from the HFEA, co-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare (Principle 13).

What the centre does well

Obligations and reporting requirements of centres – Guidance Note 32

The PR and centre staff interviewed during the inspection demonstrated awareness and understanding of the legal obligations and recent changes to the CoP. Staff cooperated fully during the inspection and made all documents and records available to the inspection team (LC T3).

What the centre could do better.

Nothing noted at the time of inspection.

5. Changes / improvements since the last inspection on 15 October 2009

Area for improvement	Action required	Action taken as evidenced during this inspection
Third Party Agreements HFEA Act 1990 (as amended) Section 2(A)(2) Licence Conditions T111 to T117	The centre must establish written agreements with all third parties who provide goods and services that influence the quality and safety of gametes and embryos and ensure compliance with the licence conditions.	The Purchasing Department is based in the LWC London offices and a third party agreement is in place for all supplies that LWC London purchases for LWC Darlington. The agreements with the individual suppliers have been reviewed and are being pursued by the LWC Purchasing Manager. No further action required
Validation of equipment and processes HFE Act 1990 (as amended) 17(1)(b) Schedule 3A Licensing conditions T24 & T25	The PR should ensure that all critical equipment and technical devices are identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions.	The centre was able to provide comprehensive written evidence to demonstrate that all critical equipment has been validated, regularly inspected and maintained in accordance with the manufacturer's instructions. No further action required
Legal Parenthood Licence condition T15(d) T60, T61, T62, T63, T64, T65	The PR must ensure that staff have been trained and assessed as to their understanding of the broader ethical, legal and regulatory context of their work, to ensure they provide the correct information in relation to legal parenthood to patients to ensure compliance with licence conditions.	Staff were able to demonstrate through verbal and written evidence that they had received training and been assessed as to their competence to provide information to patients in relation to legal parenthood. No further action required Patient information in relation to legal parenthood does require further action, as reported in the body of this report.
Disclosure of information held on the HFEA register, for use in research HFEA Act 1990 (as amended) Section 15 (2); 12 (1) (d) and (g)	The PR must ensure that staff have been trained and assessed as to their competencies in providing information to patients, as to the patients right to decide what identifying information, held on the HFEA register, is use in research, and to whom it should be disclosed, when obtaining their consent in accordance with	Staff were able to demonstrate through verbal and written evidence that they had received training and had been assessed as to their competence to provide information to patients in relation to disclosure of information held on the HFEA register for the use of researchers.

GN5.27 (d)	guidance 5. 27 (d).	No further action required
Consent in relation to the storage of embryos (including cooling off period) HFEA Act 1990 (as amended) Schedule 3 4A GN5 (h)	The PR must ensure that all staff involved with obtaining consent have been trained and assessed as to their competencies in providing information to patients as to consent issues in relation to the storage of embryos (including cooling off period) in accordance with Guidance 5 (h)	Evidence seen in two members of staff training records demonstrates that staff have been trained and assessed as to their competence in providing information to patients to consent issues in relation to the storage of embryos (including cooling off period) in accordance with Guidance 5 (h). No further action required
Staff: Basic/initial and mandatory training HFEA Act 1990 (as amended) Schedule 3A 5 Licence Condition T15	The PR must ensure that all staff are provided with initial/basic and mandatory training in accordance with licence conditions.	Evidence seen in two members of staff training records demonstrates that initial/basic and mandatory training is now in place for all staff in accordance with licence condition LC T15. No further action required
Staff - Annual joint review, with their line manager HFEA Act 1990 (as amended) Schedule 3A 5 Licensing condition T15 Staff (2) 2.1(c) & 2.2(j) 2.3 of the 8th CoP	The PR must ensure that all staff have participated in an annual performance review, with a manager and a plan for CPD established in accordance with licence conditions.	Evidence was presented that demonstrates that a schedule for annual staff appraisal has been implemented. No further action required
Staff – Assessment of competencies HFEA Act 1990 (as amended) Schedule 3A 5 Licence Conditions T12 & T15(a) 2.2(e) of the 8th COP	The PR must ensure that all personnel have demonstrated competence in the performance of their designed tasks. Assessments undertaken should be documented in each individual staff members training records.	Evidence seen in two members of staff training records demonstrates that staff are being assessed as to their competence to perform their designed tasks. However, the training records of one medical member of staff did not demonstrate that they had been assessed as to their competence in the performance of their designed tasks. Please see further comments in the body of the report as further action is required.

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Witnessing – Staff stated that when material is frozen on a Sunday, it is not witnessed by a second member of staff until the following Monday.	LC T71	The PR must ensure that all witness checks are completed and recorded at the time the relevant clinical or laboratory process/procedure takes place.	Written confirmation that this requirement has been instigated by the time the PR responds to this report.	I can confirm that witnessing is now recorded contemporaneously	The lead inspector accepts the PR assurances that all witness checks are completed and recorded at the time the relevant clinical or laboratory process/procedure takes place this will be reviewed again at the next inspection

Major area of non compliance

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

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage distribution of gametes and embryos, which do not comply with the centre's licence;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non compliance.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Adverse Incident During a post inspection review of the minutes of the quality management review meeting in April 2010 it was noted that an incident had not been reported to the HFEA.	Directions 0011 LC T118 & LC T119	The PR was contacted and informed that this was something that should have been brought to the attention of the HFEA and was asked to complete a HFEA incident form retrospectively. The PR should ensure that all incidents are reported as required by Directions 0011 and LC T118 & LC119.	Immediately	PR submitted an incident form to the HFEA clinical governance team on 20 October 2010.	The HFEA clinical governance team reviewed the evidence and the actions taken by the centre following the incident. The incident was closed on 20 October 2010. No further action required.

Procuring, processing and transporting of gametes and embryos The centre has not undertaken validation of critical processes.	LC T72 & T73	The PR must ensure that all critical processes have been validated.	The PR should submit a detailed plan including a list of all critical processes to be validated and timeframes for completion of validation by the 17 December 2010. The PR should submit quarterly reports to the centre's inspector regarding the progress of implementation of this plan until it is completed.	Attached is plan for the process validation, which sets the date for completion as March 2011 due to awaiting the arrival of the new Senior Embryologist, as well as the Process Validation Protocol outlining the processes to be validated. Quarterly reports will be submitted until the plan is completed - the first will be dated 31 Mar 2011.	The inspector is satisfied with the plan submitted and the PR's commitment to provide quarterly reports until the plan is completed. This will be monitored via the compliance cycle.

Intra-cytoplasmic sperm injection (ICSI) No evidence was available to demonstrate that the embryologist who performs ICSI had been assessed as competent to perform this procedure.	LC T15 (a)	The PR must confirm that the embryologist who performs ICSI has been assessed as to their competence to perform this task.	By the 17 December 2010.	The Embryologist concerned was assessed as competent by the HFEA in 1998 and submitted her ICSI data until the HFEA no longer required it. ICSI results are examined as part of our Quality Indicator audits and have been shown to be at least in line with national benchmarks. The Embryologist was also assessed as competent during in-house competency assessments.	The inspector is satisfied with the assurances provided by the PR confirming that the Embryologist has been assessed as to their competency to perform this task. No further action required.

Premises and Facilities The external laboratory the centre uses to carry out screening tests is not accredited with CPA.	LC T21 & T53	The PR must provide written evidence including timeframes as to when the external laboratory used for screening tests will obtained accreditation by CPA (UK). The PR should submit quarterly reports to the centre's inspector regarding the progress of implementation of this plan until it is completed.	By the 17 December 2010.	As discussed, we had obtained confirmation that the lab had an equivalent accreditation and had been assured that the lab was perusing CPA accreditation. This has now been followed up and the Lab has since been taken over by another Lab which is registered with UKAS for 15189. This lab is due an inspection in Dec 2010 and we will follow this up. We will submit quarterly reports until this issue is resolved - the first report will be due 31 Mar 2011.	At the present time the inspector believes that the PR has taken all reasonable practicable steps to ensure that the external laboratory used for screening tests will obtained accreditation by CPA (UK) and the PR's commitment to provide quarterly reports until the plan is completed. This will be monitored via the compliance cycle.
Equipment and materials It was noted on the day of the inspection that the petri dishes and specimen tubes in use in the laboratory are not CE marked.	LC T30	The PR must confirm that wherever possible the centre will only use CE marked equipment.	By the 17 December 2010.	Arrangements have been made to ensure that all lab consummables are now CE marked	To be reviewed at the next inspection

Legal parenthood Although it appeared that staff interviewed during the inspection understood the new legal parenthood provisions, the centre's patient information leaflet – 'Donor insemination, did not reflect the new provisions in relation to patients receiving treatment with donor sperm where the patients are not married or in a civil partnership (LC T64 & LC T65).	LC T64 & LC T65	The PR must review the centre's patient information leaflets to ensure that they reflect the new legal parenthood provisions.	Written confirmation by the 17 December 2010.	The patient information leaflet has been submitted into our document control process for ammending as required	The information provided did not satisfied the inspector that the centre's patient information leaflets had been reviewed to ensure that it reflect the new legal parenthood provisions The centre was contacted on the 8 December 2010 for further clarity. The Quality Manager confirmed immediately that 'it will do once it has finished the review process. It will be reflected in not only the Company-wide information sheet but also the local Darlington one'. The inspector is satisfied with this response and the patient information relating to legal parenthood provisions will be reviewed at the next inspection.

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from good practice.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Witnessing During an audit of six sets of patients' records the following was noted as not being documented in patients records • the name of the person performing the procedure and the name of the person who witnesses the procedure • witnessing the disposal of fresh material, no longer needed for treatment or storage	LC T71	The PR must ensure that a full and completed record is maintained of all actions undertaken by staff from procurement to completion of treatment and storage of a patient treatment cycle.	Written confirmation that information is recorded in the patient's notes by the 17 December 2010.	The new Witnessing Record and the Sperm Sample Witnessing Record allows for all of the requirements as per LC T71	The lead inspector accepts the PR assurances that the new witnessing documentation allows for all the requirements of LC T71 have now been met. This will be reviewed again at the next inspection

Third party agreements The company has not as yet evaluated the ability of their third parties to assess whether they meet the required standards. The quality manager stated that they are intending to assess their suppliers next year.	LC T36	The PR must evaluate the ability of their third parties to assess whether they meet the required standards.	A plan showing timelines for completion of assessment of all third party agreements by the 17 December 2010. The PR should submit quarterly reports to the centre's inspector regarding the progress of implementation of this plan until it is completed.	See attached plan and verification of the system for Third Party assessments. A quarterly report will be submitted - the first of which will be dated 31 Mar 2011.	The inspector is satisfied with the plan submitted and the PR's commitment to provide quarterly reports until the plan is completed. This will be monitored via the compliance cycle.
Premises and Facilities Laboratory staff confirmed that regular cleaning and decontamination of equipment is undertaken in accordance with manufacturer's instructions, but it is not documented.	LC T26	The PR must ensure that there is documented evidence of regular cleaning and decontamination of equipment in accordance with manufacturer's instructions.	Written confirmation that regular cleaning and decontamination of equipment in accordance with manufacturer's instructions is being documented by the 17 December 2010.	New laboratory cleaning logs have been reinstated and are in use to ensure compliance with LC T26	The lead inspector accepts the PR assurances that the laboratory staff will document when cleaning and decontamination of equipment is undertaken. This will be reviewed again at the next inspection

Staff The training file for one of the consultants appeared to contain a statement made by him some time ago as to his competency to perform tasks. There was no other evidence to indicate that the PR had assured herself as to his competency to perform these tasks in his current setting (LC T15).	LC T13, T14 and T15	The PR should ensure there is written evidence that the requirements of the licence conditions have been met for everyone working at the centre, and available on request.	Written confirmation that individual training files are available for all staff onsite, by the 17 December 2010.	All training files are available on site for all staff as per requirements. By 31 Dec 2010 the consultant concerned will have had independent assessment of his competencies formally recorded	The inspector is satisfied with the information provided by the PR confirming that the requirements of the licence conditions have been met for everyone working at the centre.. To be reviewed at the next inspection

Record keeping and document control It was noted during the course of the inspection that not all the centre's documents are in line with the company's document control procedure, particularly the patient information leaflets. Those seen did not record the history of the document, such as version and review dates. Some documents appeared to be past their review dates, such as the SOP for staff to follow when recruitment, assessment and screening donors due December 2009 The quality manager reported that she is aware of this and is currently working towards addressing.	LC T34 & CoP 31.6	The PR must ensure that all documents conform to licence condition T34 and are reviewed, revised and reapproved at a frequency that ensures they remain fit for purpose. The maximum interval between reviews should be 12 months.	The PR should submit a schedule, including timeframes as to when all documents will be reviewed and conform to the companies document control procedure by the 17 December 2010. The PR should submit quarterly reports to the centre's inspector regarding the progress of implementation of this plan until it is completed.	The documents have since been submitted to the document control process and staff re-informed of the need to comply with the SOP. Please see the attached management plan to resolve this issue. The first quarterly report will be dated 31 Mar 2011	The inspector is satisfied with the plan submitted and the PR's commitment to provide quarterly reports until the plan is completed. This will be monitored via the compliance cycle.

Additional information from the Person Responsible
I wish to thank the inspecting team for their constructive comments and would like to reassure the Executive Licesning Committee that we intend to fully complete the required actions. Since the inspection we have gained ISO 9001:2008 certification of our Clinic which will help us monitor and implement further continual improvements.

HFEA Executive Licence Panel Meeting

14 January 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0075 (London Women's Clinic, Darlington) - Renewal Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Helen Richens – Policy Manager	Joanne McAlpine

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

The Panel also had before it:

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

Consideration of Application

1. The Panel noted that the London Women's Clinic, Darlington is one of four licensed centres owned by JD Healthcare Limited.

2. The Panel noted that the centre has held an HFEA licence since 1996, and that no additional conditions have been imposed on its licence during that time.

3. The Panel noted that the centre is a stand-alone unit, located within the BMI Woodlands Hospital Darlington and offers a comprehensive range of licensed assisted conception treatment to self funding patients.

4. The Panel noted that the centre is in the process of applying for ISO 9001:2008 accreditation and that an inspection was planned for November 2010.

5. The Panel noted that at the time of the inspection (13 October 2010) there was one critical area of non-compliance in relation to witnessing, 6 major areas of non-compliance and 5 other areas of non-compliance or poor practice.

6. The Panel noted that since the inspection, the Person Responsible (PR) has provided evidence to the Inspectorate and given assurances that the centre is now compliant with, or has given a commitment to implement the recommendations made in the report.

7. The Panel noted that in the critical area of non-compliance relating to witnessing the PR has now addressed this and put measures in place to the satisfaction of the Inspectorate to prevent this from happening again.

8. The Panel noted the Inspectorate's recommendation to renew the centre's licence for a period four years without any additional conditions.

9. The Panel had regard to its decision tree. It was satisfied that the application was submitted in the form required, and contained the supporting information required by General Direction 0008. It was also satisfied that the appropriate fee had been paid.

10. The Panel was satisfied that the application designated an individual to act as the Person Responsible (PR) and that the PR had consented to act as such.

11. The Panel was satisfied the character of the PR is such as is required for supervision of the licensed activities and that the PR will discharge

the duties under Section 17 of the Act. The Panel also noted that the PR has successfully completed the PR Entry Programme.

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

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

14. The Panel was satisfied that the application does not involve the use of embryos for training purposes, nor does it involve the testing of embryos.

Decision

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

16. The Panel considered whether to grant a two year licence in light of the critical area of non compliance highlighted within the report. However, recognising that this has now been addressed and the general progress made, the Panel agreed to renew the centre's licence for a period of four years with no additional conditions. In order to ensure continued improvement the Panel request that the PR submits quarterly reports following the centre's Quality Management meetings to the Inspectorate.

17. If the Inspectorate then has concerns regarding the evidence of the reports submitted by the centre, or the centre fails to provide the reports, the Panel asks the Inspectorate to consider a management review meeting with the centre.

18. The Panel endorsed all recommendations that the Inspectorate has made within the report.

Signed: Peter Thompson Date: 25/1/11.
Peter Thompson (Chair)