Interim Inspection Report

Date of Inspection: 11 August 2010
Length of inspection: 7 hours
Inspectors: Parvez Qureshi
Wil Lenton

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 6 November 2008 and 17 November 2010.

Date of Executive Licensing Panel: 17 November 2010

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the 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 interim 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 make the decision about the continuation of the centre's licence.

Centre details

Centre Name	London Women's Clinic Cardiff
Centre Number	0301
Licence Number	L0301-2-B
Centre Address	Cyncoed Medical Centre Dartington Drive Cardiff CF23 8SQ
Telephone Number	02920 734 008
Person Responsible	Hemlata Thackare
Licence Holder	Kamal Ahuja
Date Licence issued	1 March 2009
Licence expiry date	28 February 2012
Additional conditions applied to this licence	N/A

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Report to Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

The inspectorate considers that overall there is sufficient information on which to recommend the continuation of the centre's licence without additional conditions.

The inspectorate also recommends that the Executive Licensing Panel requires that the Person Responsible (PR) complies with the following recommendations within the prescribed timeframes set out in the inspection report:

- The PR should ensure that all equipment with a critical measuring function is calibrated against a traceable standard, if available.
- The PR should ensure that documented procedures are in place for revalidation of equipment after repair.
- The PR should ensure that documented procedures are established for the operation of each piece of critical equipment. These procedures should include the action to be taken in the event of malfunctions or failure.
- The PR should ensure that audit of the centre's traceability and record keeping and document control procedures are carried against compliance with the approved protocols, the regulatory requirements and quality indicators. These audits must be performed in an independent way, at least every two years. Findings and corrective actions must be documented
- The PR should ensure that Quality Indicators (QIs) relevant to maintaining of confidentiality are established.

Since the inspection, the PR has provided an update on actions taken in response to the recommendations cited above. The inspectorate considers the actions to be a suitable response.

Details of Inspection findings

Brief description of the centre and its licensing history:

The London Women's Clinic (LWC) Cardiff has been licensed since February 2008 and there are no additional conditions on the centre's licence. The unit operates as a satellite centre for other licensed centres within the LWC group (0059 and 0105).

Since the last inspection in November 2008, the premises which are located within the Cyncoed Medical Centre have not undergone any major changes. The business hours at the centre are Monday to Friday from 8.30 am to 4.30 pm.

Data submitted by the centre to the HFEA indicate the centre provided 64 donor inseminations (DI) during the period May 2009 to April 2010 and 37 intra uterine insemination (IUI) treatment cycles for the time period January to December 2009 with success rates in line with the national averages.

The PR is a consultant gynaecologist and obstetrician and is registered with the General Medical Council (GMC). She has extensive experience of working within the reproductive medicine field.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 May 2009 to 30 April 2010*
Donor insemination (DI)	64
Intra uterine insemination (IUI	37 (Note: cycles provided in the period 1 January to 31 December 2009.)

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

*This data was extracted from the HFEA register for the period 1 May 2009 to 30 April 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.

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. Patients are provided with information regarding the cost of their treatment before it commences. The costed treatment plan provides details of the main elements of proposed treatment. However, patients are also informed of other additional costs, such as those for drugs, which they may incur depending on the course of their treatment (Code or Practice (CoP) guidance 4.3). Patients having treatment with donor sperm are informed about parenthood laws verbally and in written format (Licence Condition T60 and T61). Staff interviewed during the course of the inspection were able to demonstrate the requirements of legal parenthood legislation. The centre has established procedures for obtaining written records of consent to parenthood, evidence of which was seen on the day of inspection.
What they could do better. Nothing noted at the time of inspection.

Consent - particularly consent to disclosure to researchers and consent to storage
What the centre does well. Five sets of patient records examined during the inspection contained effective consent, including consent for the disclosure of information to researchers, and consent for the use of gametes (sperm) in the provision of treatment (Licence ConditionT57). The centre has a Standard Operating Procedure (SOP) in place for the process to be followed when obtaining consent (Licence Condition T33(b)). Only DI samples supplied by LWC centre 0105 are stored at the centre prior to use. The PR reported that the relevant supporting information for the DI samples including maximum period of storage and consent to use are sent to the centre with the samples (Act, 14(1) (c) and Act, Schedule 3, 8(1). The centre has established QIs relevant to obtaining consent and regular audits of patient records are conducted by centre staff, to ensure completed consent forms are in place (Licence Condition T35 and T36).
What they could do better. Nothing noted at the time of inspection.

Multiple births

What the centre does well.

Not applicable for this centre.

What they could do better.

Validation of critical equipment and processes

What the centre does well.

Laboratory staff provided documented evidence showing that all critical equipment and processes have been validated (Licence Conditions T24 and T72). Documentation of validation was seen for various equipment including the air flow hood, incubator, microscope and particle counter.

What they could do better.

The centre was not able to provide documented procedure stating the requirements for revalidation of equipment after repair (Licence ConditionT25). However, laboratory staff reported that this will be included in the validation document currently under review and the centre will adopt the Association of Clinical Embryologists (ACE) validation templates.

Witnessing

What the centre does well.

There is a SOP for witnessing in place to double check the identification of samples and the patients to whom they relate at all critical points of the clinical and laboratory processes. Four sets of patients' notes audited at inspection were found to contain a record of the witnessing checks of the person performing the procedure and of the person witnessing the procedure. These records included the respective names, signatures and status (Licence Condition T71).

The centre has established QIs relevant to witnessing and has audited against compliance with the approved protocols, the regulatory requirements and QIs. Evidence of this was made available to the inspection team (Licence Condition T35 and T36).

The centre was able to provide records of staff competence assessment when performing witnessing [T15(a)].

Currently the centre is in the process of validating an electronic witnessing system.

What they could do better.

Nothing noted at the time of inspection.

Gamete and embryo donation – reimbursement, information provision and screening
What the centre does well. Not applicable for this centre as donor samples are supplied by centre 0105.
What they could do better.

Welfare of the Child (in relation to basic partner treatment services only)
What the centre does well. The centre has a policy in place for the process to be followed when carrying out a welfare of the child (WoC) assessment (Licence ConditionT33(b)). Staff reported that prior to any patient being provided with treatment services they take into account the welfare of the child who may be born as a result of the treatment and of any other child who may be affected by that birth. Evidence of this was seen from an audit of five patients' notes which contained WoC forms completed and signed by both partners (Licence ConditionT56). The centre has established QIs relevant to the assessment of WoC. Regular audits of patient records are conducted by centre staff to ensure completed WoC forms are in place (Licence Condition T35 and T36). Staff stated that in cases where further information has been sought, or discussion has taken place regarding WoC, the views of those consulted and the views of the patients are documented in the patient records (CoP guidance 8.18).
What they could do better. Nothing noted at the time of inspection.

Embryo testing (if applicable)
What the centre does well. Not applicable for this centre.
What they could do better.

2. Changes / improvements since the last inspection on 6 November 2008

Area for improvement	Action required	Action taken as evidence during this inspection
A quality policy and a quality manual are in place. However, the centre has not carried out a management review as required by S.4.2.8 and has not established quality objectives or reviewed performance against these objectives as required by S.4.2.4 and S.9.5.1. Some documents have not been reviewed within the last 12 months (S.5.2.5a). CoP 7th Ed. Guidance Note 23 (8th Ed).	The centre should establish documented quality objectives and have plans to achieve and maintain its quality objectives. Centre management should conduct a regular review of the quality management system and all its services and implement procedures for the continual evaluation and improvement of the QMS.	A quality assurance coordinator has been in post since May 2009. The QMS has a centrally managed document control, complaints, non-conformances and adverse incidents systems in place. All the documents seen during the inspection had been reviewed within the last 12 month Quarterly quality management review meetings take place at the centre to review the progress of the QMS. Evidence of recent minutes of these meetings were made available to the inspection team. No further action required.
Air quality in the environment in which gametes are processed has not been demonstrated to meet the required standards. A.10.19, S.6.3.6(b) CoP 7th Ed. Guidance Note 25 (8th Ed).	The processing of gametes while exposed to the environment should take place in an environment of at least Grade C air quality with a background environment of at least Grade D air quality The PR should submit a plan to the HFEA outlining how the requirements of standard licence condition A.10.10 can be met. The PR should monitor the quality of the air in the flow hood immediately. Should it seem likely that the environmental air quality may have dropped below	Air quality is being measured on a regular basis. Evidence of records of air quality measured on 30 June 2010 were seen. Records for 2008 and 2009 were also made available. These were seen to meet the requirements of Licence condition T20. No further action required.

Area for improvement	Action required	Action taken as evidence during this inspection
	grade D in the course of a procedure involving the manipulation of gametes the PR should assess whether there is any additional risk from the use of the gametes to a woman being treated or to any resulting child. The PR should advise the HFEA of the outcome of the monitoring and risk assessment if performed (G.9.4.5).	
Staff competency and training is not documented. S.7.7.2 A.10.11 CoP 7th Ed. Guidance Note 2 (8th Ed).	Personnel must be provided with initial/basic training, updated training as required and adequate opportunity for relevant professional development. The training programme must ensure and document that each individual has demonstrated confidence in the performance of their designed tasks.	A training programme has been implemented and competency framework assessment is in place. Each member of staff has a training folder in place. Evidence of this was seen during the inspection. No further action required.
The protocol for transportation and receipt of gametes and embryos was not fully compliant with HFEA Alert 21 and S.7.7 CoP 7th Ed. Guidance Note 15 (8th Ed).	The transportation protocol should be reviewed and revised as required to ensure compliance with the recommendations of Alert 21.	A transportation protocol is in place which appeared to be compliant with HFEA alert 21. No further action required.
Validation of key processes and procedures has not yet been established S.4.2(a), S 7.8.3 and standard licence condition A.11.11 CoP 7th Ed. Guidance Note 26 (8th Ed).	A plan for validation should be drawn up which takes into account the particular needs of the unit and prioritise the validation of those processes considered to be most likely to impact on the quality of the service.	Validation of key equipment and processes has been undertaken by the centre. Documented evidence of this was made available. No further action required.

Area for improvement	Action required	Action taken as evidence during this inspection
Witnessing is not compliant with guidelines (G.13.1) CoP 7th Ed. Guidance Note 18 (8th Ed).	Review of witnessing procedure to be undertaken.	An amended protocol was seen. This was compliant with Guidance Note 18 (CoP 8th Ed) No further action required.
Information for patients is not fully compliant with all of the requirements of G.5 CoP 7th Ed. Guidance Note 4 (8th Ed).	The centre should review the content of patient information against the requirements of the Cop. Where a decision is made to deviate from the guidance provided in the CoP this should be documented.	Patient information seen during inspection was compliant with requirements of CoP 8th Ed. No further action required.
Low oxygen monitor.	Installation of an audio/visual alarm, outside the laboratory, to enhance its effectiveness.	An audio/visual alarm has been installed outside the laboratory. No further action required.
The centre staff have access to two emergency trolleys which are located on two separate floors, one belonging to the centre and the second one to the Cyncoed Medical Centre. S.6.3.4. CoP 7th Ed.	The PR should review the accessibility of emergency equipment to ensure that the clinical facilities are equipped with backup and emergency clinical facilities equivalent to those which are standard practice in other medical provisions and appropriate to the degree of risk involved in any planned procedure in compliance with S.6.3.4. CoP 7th Ed.	The accessibility and suitability of the emergency equipment from Cyncoed Medical Centre has been confirmed by the PR, to ensure that the clinical facilities are equipped with backup and emergency facilities. No further action required.

3. Areas of concern

The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked at during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
Can all staff provide documented evidence of the assessment of their competence in the performance of their designated tasks? [T12 and T15(a)]. (In the SAQ the centre answered 2 – partially compliant)	Each member of staff has a folder containing training records showing assessment of competence in the performance of their designated tasks.	No further action required.
Is the counsellor employed by the centre accredited under the British Infertility Counselling Association accreditation scheme (BICA) (i.e. not a member	The centre's counsellor is member of BICA and provided evidence of working towards accreditation with BICA.	No further action required.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
only)? If no: can the counsellor provide evidence of working towards accreditation through the British Infertility Counselling Association accreditation scheme (In the SAQ the centre answered no)		
Has the centre provided sperm for home insemination in the last year? If yes Was the sperm supplied thawed or in the process of thawing? (In the SAQ the centre answered no)	The PR reported that the centre does not provide this service.	No further action required.
Does your centre operate a bring-forward system in order to ensure sufficient advance notice of the end of	The centre is supplied with donor sperm by LWC centre 0105 which in conjunction with the centre monitors both the statutory storage period and the outcome of treatments.	No further action required.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
the statutory storage period (or such shorter period as specified by a person who provided the gametes) for gametes or embryos in storage? [17.7] (In the SAQ the centre answered no)	An audit of stored samples is conducted on an annual basis by the centre staff. The findings of an audit dated 21 April 2010 was made available for the inspection team showing that one typographical error was identified and corrective action taken.	
Have traceability procedures been audited against compliance with the approved protocols, the regulatory requirements and quality indicators in the last two years? (In the SAQ the centre answered no)	Audits of traceability and record keeping and document control procedures have not been undertaken yet. However, staff reported that these will be added to the audit schedule.	The PR should ensure that audit of the centre's traceability and record keeping and document control procedures are carried against compliance with the approved protocols, the regulatory requirements and quality indicators. These audits must be performed in an independent way, at least every two years. Findings and corrective actions must be documented.
Does the centre have training and reference manuals? (In the SAQ the centre	Evidence of these being in place was made available by the centre's quality manager.	No further action required.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
answered 3 – partially compliant) Has the centre established quality indicators for all licensed activities and other activities carried out in the course of providing treatment services that do not require a licence? (In the SAQ the centre answered no)	Quality indicators are in place for activities carried out by the centre, with the exception of QIs relevant to confidentiality.	No further action required. The PR should ensure that QIs relevant to maintaining of confidentiality are established.
Can the centre provide documented evidence of actions to be taken in the event of malfunction or failure of equipment]? Is equipment with a critical measuring function calibrated against a traceable standard if	The centre has a documented procedure in place for the operation of all critical equipment. However, the procedure does not outline the actions to be taken in the event of malfunction or failure of equipment. The laboratory staff reported that this will be added to the critical equipment SOP. Calibration of particle counter was not current.	The PR should ensure that documented procedures are established for the operation of each piece of critical equipment. These procedures should include the action to be taken in the event of malfunctions or failure. The PR should ensure that all equipment with a critical measuring function is calibrated against a traceable standard, if available.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
available (e.g. CO2 monitoring devices, particle counting devices, thermometers etc)? (In the SAQ the centre answered 2 – almost compliant) Maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment and premises must be performed regularly and recorded accordingly.	A sample of equipment reviewed on inspection had been maintained in the last year. However a sample of service contracts had expired. Laboratory staff reported that these were in the process of being re-established.	The PR should ensure that all critical equipment is maintained.
Is there an SOP for the process to be followed when submitting data to the HFEA in compliance with the requirements of Directions 0005? Has the centre established quality indicators relevant to submission of data to the HFEA?	The centre has a SOP in place for submitting data to the HFEA and has established QIs for this. In addition the procedures for submission of data to the HFEA have been audited.	No further action required.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
(In the SAQ the centre answered no to the above)		

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 require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are 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
None identified at the time of this 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 or 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
Equipment and Materials Calibration of equipment with a critical measuring function against a traceable standard.	Standard licence condition T24 CoP Guidance Note 26	The PR to ensure that all equipment with a critical measuring function is calibrated against a traceable standard, if available.	By the time the PR responds to this report.	All critical equipment has been serviced or booked for service and has been calibrated against a traceable standard.	The inspectorate considers this to be an acceptable response. Progress to be reviewed at the time of next inspection.
Documented evidence of the revalidation of equipment after repair.	Standard licence condition T25 CoP Guidance Note 26	The PR should ensure that documented procedures are in place for revalidation of equipment after repair.	By the time the PR responds to this report.	The current equipment is validated using previous validation documents. The new validation documents (Validation Master Plan and the Equipment Qualification Review Protocol) contain the process for recording non-conformance generated from equipment failure,	The inspectorate considers this to be an acceptable response. Progress to be reviewed at the time of next inspection.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
				as well as the need for re-validating equipment following repair. These templates will be used at time of re-validation for the current Lab equipment.	
Actions to be taken in the event of malfunction or failure of equipment.	Standard licence condition T27 CoP Guidance Note 26	The PR should ensure that documented procedures are established for the operation of each piece of critical equipment. These procedures should include the action to be taken in the event of malfunctions or failure.	By the time the PR responds to this report.	Each piece of critical equipment has either a Working Instructions Manual or an SOP being finalised now to describe how to operate each item. The non-conformance and Deviations Management SOP describes what to do in the event of a non-conformance, which in these	The inspectorate considers this to be an acceptable response. Progress to be reviewed at the time of next inspection.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
				cases in when a piece of equipment fails.	
Traceability Traceability procedures have not been audited.	Standard licence condition T36 CoP Guidance Note 19	The PR should ensure that audit of the centre's traceability procedures are carried against compliance with the approved protocols, the regulatory requirements and quality indicators. These audits must be performed in an independent way, at least every two years. Findings and corrective actions must be documented.	An action plan to be submitted by the time the PR responds to this report.	The list of the HFEA and ISO 9001 required Quality Indicators for 2011 are being finalised at present. These indicators will again form the basis of the Audit Schedule, for 2011. This includes the audit for traceability compliance. The audits will be carried out and reported by suitably competent staff trained in the Internal Audits Management SOP as before. Each audit will then be discussed at the next quarterly	The inspectorate considers this to be an acceptable response. Progress to be reviewed at the time of next inspection.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
				Quality Management Review meeting with appropriate actions added to the CAPA listings as per the CAPA Management SOP as the previous year's audits were.	
Confidentiality and Privacy The centre has not established quality indicators relevant to maintenance of confidentiality.	Standard licence condition T35 CoP Guidance Note 30	The PR to ensure that QIs relevant to maintaining of confidentiality are established.	By 11 November 2010.	The list of the HFEA and ISO 9001 required Quality Indicators for 2011 are being finalised at present. These indicators will again form the basis of the Audit Schedule, for 2011. This includes the audit for confidentiality compliance. The audits will be carried out and reported by suitably	The inspectorate considers this to be an acceptable response. Progress to be reviewed at the time of next inspection.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
				competent staff trained in the Internal Audits Management SOP as before. Each audit will then be discussed at the next quarterly Quality Management Review meeting with appropriate actions added to the CAPA listings as per the CAPA Management SOP as the previous year's audits were.	

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
None identified at the time of this inspection.					

Additional Information from the Person Responsible

HFEA Executive Licence Panel Meeting
17 November 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 3

Centre 0301 (London Women's Clinic, Cardiff) – Interim Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Nick Jones, Director of Compliance Mark Bennett – Director of Finance & Facilities	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 Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that the centre has been licensed since February 2008, that there are no additional conditions on the centre's licence, and that the Licence Committee on 22 January 2009, granted the centre a three year licence.

2. The Panel noted that the centre operates as a satellite centre for other licensed centres within the London Womens Clinic group (0059 and 0105), offering DI and IUI treatments.

3. The Panel noted that since the last inspection in 2008, the premises which are located within the Cyncoed Medical Centre have not undergone any major changes.

4. The Panel noted that the Inspectorate made five recommendations within the report, and noted the Person Responsible' (PR) response and the progress made since the inspection.

Decision

5. The Panel were satisfied the centre is largely compliant and is making good progress based on the evidence identified within the report. The Panel agreed to the continuation of the centre's licence with no additional conditions and endorsed the Inspectorate's recommendations.

Signed: Peter Thompson Date: 3/12/10.

Peter Thompson (Chair)