Renewal Inspection Report

London Women's Clinic, Cardiff
0301

Date of Inspection: 6 November 2008
Date of Licence Committee: 22 January 2009

Centre Details

Person Responsible	Hemlata Thackare
Nominal Licensee	Kamal Ahuja
Centre name	London Women's Clinic, Cardiff
Centre number	0301
Centre address	Cyncoed Medical Centre Dartington Drive Cardiff CF23 8SQ
Type of inspection	Renewal
Inspector(s)	Parvez Qureshi (Lead)
	Wil Lenton
	Allison Cummings
Fee paid	Yes
Licence expiry date	28 February 2009
NHS/ Private/ Both	Private

Index

About the Inspection:

This inspection visit was carried out on 6 November 2008 and lasted for 7 hours.

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

The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

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

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

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

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

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

Brief Description of the Centre and Person Responsible

The London Women's Clinic Cardiff has been licensed since February 2008 and there are no additional conditions on the centre's licence. The centre was inspected by the Healthcare Inspectorate of Wales in September 2008 and has been operational since then. The unit also operates as a satellite centre for other licensed centres (0059 and 0105) within the London Women's Clinic group.

The premises which are located within the Cyncoed Medical Centre have not undergone any major changes since the initial inspection. An organisational chart is in place indicating key roles and lines of accountability. The business hours at the centre are Monday to Friday from 8.30 am to 4.30 pm.

The Person Responsible (PR) has completed the HFEA PR Entry Programme and she is also registered with the General Medical Council.

Activities of the Centre for the time period from March – October 2008

Donor insemination (DI)	3
Intra uterine insemination (IUI)	3
Storage gametes	Yes

Summary for Licence Committee

The centre has only been fully operational since September 2008 and was considered to be well managed and organised. Since the initial inspection, improvements have been made to the quality of the service being provided. However, improvements are recommended in the following areas of practice:

- Full implementation of quality management system.
- Documentation of staff competency and training.
- Monitoring of background air quality in all areas where key processes take place.
- Review and updating of transportation protocol.
- Review of patient of information.
- Validation of key processes.
- Review of witnessing procedure.

The centre should comply with these recommendations within the suggested timescales. The inspection team supports the renewal of the centre's licence for a period of 3 years.

Evaluations from the inspection

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

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

Breach	Action required	Time scale
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).**	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.	Progress to be monitored at the time of the next inspection.
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)**	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 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).	Submission of a plan to the HFEA by 6 January 2009.
Staff competency and training is not documented. **S.7.7.2 A.10.11**	Personnel must be provided with initial/basic training, updated training as required and adequate opportunity for relevant professional development. The training programme must ensure	Progress to be monitored at the time of the next inspection.

	and document that each individual has demonstrated confidence in the performance of their designed tasks.	
The protocol for transportation and receipt of gametes and embryos was not fully compliant with HFEA Alert 21. and **S.7.7**	The transportation protocol should be reviewed and revised as required to ensure compliance with the recommendations of Alert 21.	Review to be completed and the HFEA to be informed by 6 January 2009.
Validation of key processes and procedures has not yet been established S 6.4.2(a), **S 7.8.3** and standard licence condition **A.11.11**	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.	Progress to be monitored at the time of the next inspection.

Non-Compliance

Area for improvement	Action required	Time scale
Witnessing is not compliant with guidelines **(G.13.1)**	Review of witnessing procedure to be undertaken.	Progress to be monitored at the time of the next inspection.
Information for patients is not fully compliant with all of the requirements of **G.5** of the7th COP.	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.	Information should be reviewed as soon as practicable and the HFEA informed when the review is complete.

Recommendations

Area for improvement	Action required	Time scale
Low oxygen monitor.	Installation of an audio/visual alarm, outside the laboratory, to enhance its effectiveness.	As soon as possible.
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.	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 provision and appropriate to the degree of risk involved in any planned procedure in compliance with S.6.3.4.	Immediately.

Changes/ improvements since last inspection

Recommendations	Action Taken
Further development and implementation of a QMS.	Evidenced during the inspection.
Risk management structure.	Evidence seen of risk assessments being conducted.
Formalising of all third party agreements.	Currently all third party agreements are in place.
Maintenance contracts.	Maintenance contracts are in place for all existing key laboratory equipment, evidenced during the inspection.
Emergency back up power.	In the process of being finalised.
Information for patients on what screening needs to be done.	Information leaflet on screening tests is in place, evidenced during the inspection.
Review of centre's information to ensure that it is both centre and treatment specific.	Evidenced during the inspection.
Review of laboratory protocols to include witnessing requirements.	A witnessing protocol has been developed. However, this requires further review in consideration of COP guidelines at G.13.1.1.

Additional licence conditions and actions taken by centre since last inspection

None.

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
Documentation including an organisational chart showing key responsibilities and lines of accountability were provided to the HFEA pre-inspection. These were reviewed by the inspection team and overall were considered to be in compliance with the requirements of the COP. The centre has been licensed by the HFEA since March 2008. However, it only became fully operational in September 2008 after it was granted a licence by the Healthcare Inspectorate of Wales. Since the previous inspection, additional staff have been recruited to meet an anticipated increase in workload. The PR stated that if required additional staff cover is available through other centres within the London Women's Clinic group. There is a risk management policy in place and evidence of risk assessments conducted in the laboratory and the treatment room were made available for the inspection team. Documented procedures are in place for the identification, notification and investigation of incidents. A review of the centre's incident log showed that since the centre become active no incidents have been reported to the HFEA. The centre has a no blame policy in place. Documented evidence was seen for the management and dissemination of HFEA Alerts and was considered to be appropriate. The centre's complaints log was reviewed during the visit and evidence of actions taken to resolve complaints were noted. The inspection team was informed by the staff that their aim is to resolve any complaints face to face. In the event of an emergency, contingency arrangements are in place with other centres within the London Women's Clinic group for continuation of service. Arrangements are also in place for patients who need to contact staff outside working hours.

Third party agreements are in place and a sample of agreements was reviewed by the inspectorate and was considered to be compliant with HFEA guidelines.

Regular multi-disciplinary team meetings are held at the centre to discuss practice related issues. The minutes of these meetings are made available to all staff and this was confirmed by members of staff who met with the inspection team. A review of minutes of recently held meetings showed that in addition to the centre's business, HFEA related issues were also discussed.

No issues have been raised by the HFEA finance department regarding payment of treatment fees.

Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
No 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]
As the centre only commenced licensed treatments in September 2008 no analysis of live birth rates are available.
Areas of firm compliance
The centre has both a quality policy and a manual in place. A review of documents submitted for the inspection showed that some had recently been updated. There are procedures in place for conducting audits of practice including reviews of patient satisfaction and outcomes. The PR stated that findings of audits are discussed at unit meetings and any areas of concern are subject to corrective action. A total of six patient questionnaires have been returned to the HFEA and the majority of the responses made by the patients were complimentary regarding their experience at the centre. Patients commented that the centre staff are professional and supportive. An effective document control procedure is in place. This was evident from the documents reviewed during the course of inspection and discussions held with staff who met with the inspectorate.
Areas for improvement
Full implementation of the quality management system (QMS) is required to make it more effective. No evidence of the application of the QMS was noted in relation to the following: • Continual improvement of the effectiveness of the QMS. The centre management should have plans to achieve and maintain its quality objectives and these should be regularly reviewed in compliance with S.4.2.4 and S.9.5.1. • The maximum interval between review of documents should be twelve months in compliance with S.5.2.5a • Annual, review of the quality management system should be undertaken in compliance with S.4.2.8.
Areas for consideration
None.

Executive recommendations for Licence Committee
The PR should ensure the continual evaluation and improvement of the QMS, monitoring of performance against quality objectives and that document reviews are performed at twelve month intervals. In addition, an annual review of the QMS should be undertaken.
Evaluation
All areas covered.
Areas not covered on this inspection
Some improvements required.

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
Since the previous inspection no major changes have been made to the premises. All clinical, laboratory and counselling facilities seen during the visit appeared to be clean and well presented. The centre's laboratory which also houses the cryostore appeared to be adequate for the anticipated volume of work. There is controlled access to the facilities. All dewars are fitted with low nitrogen level alarms linked to an auto dial system. In addition, the laboratory is fitted with a low oxygen level monitor. The centre has a procedure in place for responding to alarms. Maintenance contracts are in place for key pieces of equipment and evidence of this was seen during the course of the inspection. Equipment such as incubator, heating block, fridge and liquid nitrogen were being monitored on a daily basis. Logs of these activities are kept and these were reviewed during the course of the inspection and considered to be appropriate. The inspection team considered the current staff facilities to be appropriate. All medical records are stored in a secure area with only members of the staff having access to them.
Areas for improvement
Currently the background air quality in the laboratory is being measured and recorded on a daily basis but it is not being carried out within the class II hood. The PR should ensure that the processing of gametes and embryos while exposed to the environment takes place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality and that it must be demonstrated and documented that the chosen environment achieves the quality and safety required in compliance with A.10.19. 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 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).

Areas for consideration

Overall the men's production room was considered to be appropriate for its intended purpose. However, consideration could be given to making the covering of the chair located in the production room wipeable.

Installation of an audio/visual alarm for the low oxygen monitor, outside the laboratory, to enhance its effectiveness. In addition, a review of the oxygen monitor's current location should take place to ensure that it is easily visible to the staff viewing it from outside of the laboratory.

Executive recommendations for Licence Committee

Monitoring of background air quality should be undertaken in all areas where key processes take place.

Evaluation

Some improvement required.

Areas not covered on this inspection

All areas covered.

4. Information

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

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

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

Areas of firm compliance
The patient information submitted for the inspection was overall considered to be appropriate and included contact details for out of hours emergencies, risks associated with treatment and cost of various treatments. The following information was also seen on display during the course of the inspection:- Counselling information. Centre's treatment licence and complaints procedure. Five patient records were reviewed by the inspection team. The notes were found to be well organised. They contained evidence of completion of a welfare of the child assessment and consent forms which appeared to be compliant with the treatment provided. Patient confidentiality is well maintained. Access to health records is restricted to authorised staff only. The centre has a procedure in place for patients who require a copy of their medical notes. No issues were raised by the HFEA registry regarding quality of data being submitted by the centre.
Areas for improvement
Overall the patient information was considered to be appropriate. However the centre should review the content of patient information against the requirements of the 7th COP. Where a decision is made to deviate from the guidance provided in the COP this should be documented.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
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
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes

Full time equivalent staff

GMC registered doctors	1
NMC registered nurses	4
Non NMC registered clinical staff	0
HPC registered scientists	0.5
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	2.5
Counsellors	0.2

Summary of laboratory audit
Only a few samples have been stored since the centre become operational and this information was seen on a database. Therefore no audit of stored material has been conducted.
Summary of spot check of stored material
Not conducted due to only few samples in storage.
Areas of firm compliance
Continuous professional development (CPD) for staff is well maintained and staff are encouraged to attend seminars and conferences. Staff training files were examined during the course of the inspection and included documentation of participation in induction training as well as mandatory training such as basic life support and manual handling. The centre has policies in place for the assessment of patients seeking treatments and for screening of patients. This was evident from the review of the documentation submitted for inspection and discussions held with staff who met with the inspection team.

The centre will not be running a sperm donor recruitment programme. Donated sperm will be supplied by London Women's Clinic (0105) who will also be responsible for monitoring the use of donated sperm to ensure that the 10 families limit is not exceeded.

Arrangements are in place for laboratory staff to participate in external review of sperm assessment performance through the National External Quality Assessment Service (NEQAS).

There is an effective traceability system in place for materials that come into contact with gametes. A system of unique coding of patients to assist the traceability of gametes is also in place.

Patients are made aware of the counselling service at their initial consultation. The centre's counsellor is a member of the British Infertility Counselling Association (BICA). She confirmed that her CPD is well maintained. Appointments can be booked by staff or patients can contact the counsellor directly. The counsellor receives regular supervision from a mentor and attends the centre's multi-disciplinary meetings.

All counselling sessions take place in comfortable surroundings and notes are kept separate from the patients' treatment notes in a locked cupboard. The counsellor stated that, if required, back up counsellors are available from other centres within the London Women's Clinic group. As there are satellite arrangements in place with centres 0059 and 0105, the counsellor also conducts counselling sessions for those patients who are referred on to centres 0059 and 0105.

Referral data supplied for the inspection showed that support counselling was the most frequently attended followed by implication counselling. However, this information is of limited significance as the centre has only been providing licensed treatments since September 2008.

A procedure is in place to ensure that gametes are not stored beyond the maximum consented storage period.

Areas for improvement

The inspectorate noted that not all staff competency and training has been documented. (S 7.7.2).

The centre's protocol for transportation and receipt of gametes was reviewed against the requirements of HFEA Alert 21 and was found to be not fully compliant.

The validation of key equipment and processes in the laboratory has not been established.

The laboratory staff need to develop a SOP to cover all instances when gametes are added/removed from the cryostore.

A witnessing protocol is in place, but a number of witnessing stages were not being carried out. The protocol does not fully comply with the HFEA guidance and should be reviewed.

Areas for consideration
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. 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 provision and appropriate to the degree of risk involved in any planned procedure in compliance with S.6.3.4.
Executive recommendations for Licence Committee
The PR should ensure that there is a training programme in place to ensure and document that each individual has demonstrated confidence in the performance of their designed tasks in compliance with A.10.11 The centre's protocol for transportation and receipt of gametes should be reviewed to ensure that it meets the requirements of HFEA Alert 21. A plan for validation should be drawn up which takes into account the particular needs of the unit and the PR should prioritise the validation of those processes considered to be most likely to impact on the quality of the service. The witnessing protocol should be reviewed in consideration of the requirements of the HFEA witnessing guidelines at G.13.1.1. Where a decision is made to deviate from the guidance provided in the COP this should be documented.
Evaluation
Some improvements required.
Areas not covered on this inspection
All areas covered.

Report compiled by:

Name……..…Parvez Qureshi……

Designation…...Inspector..…….

Date……4 December 2008……

Appendix A: Centre staff interviewed

PR and five other members of staff.

Appendix B: Licence history for previous 3 years

2008

Licence Committee 13th February 2008
The Committee unanimously decided to grant a 1 year licence with no additional conditions.

Appendix C: Response of Person Responsible to the inspection report

Centre Number……...0301……...

Name of PR…….Hemlata Thackare…….……...

Date of Inspection……..06 November 2008……...

Date of Response……..30.12.2008……

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

Signed……..Hard signed copy received from PR……

Name……Hemlata Thackare …….

Date……..30.12.2008……

1. Correction of factual inaccuracies

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

None.

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

None.

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

(Comments taken from PR response received) Group QMS manager has been appointed and will help us to put QMS in place locally. Regular review of the quality management system and all its services and implement procedures will be conducted for the continual evaluation and improvement of the QMS. Witnessing protocol has been changed to comply with the HFEA standards. Protocol for transportation and receipt of gametes has been reviewed. SOP in place to cover all instances when gametes are added/removed from the cryostore.

Witnessing protocol modified to fully comply with the HFEA guidance.

An audio/visual alarm for the low oxygen monitor has been installed outside the laboratory.

The background air quality within the class II hood is being measured and recorded on a daily basis.

The accessibility of emergency equipment from Cyncoed Medical Centre has been confirmed to ensure that the clinical facilities are equipped with backup and emergency clinical facilities.

Staff training programme now in place and documentation modified to ensure compliance with training requirements and competency assessment.

The validation of key equipment and processes in the laboratory will be completed in the next quarter.

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