Renewal Inspection Report

London Women's Clinic
0105

Date of Inspection: 25 September 2008
Date of Licence Committee: 12 January 2009

Centre Details

Person Responsible	Geetha Venkat
Nominal Licensee	Kamal Ahuja
Centre name	London women's Clinic
Centre number	0105
Centre address	113-115 Harley Street London W1G 6AP
Type of inspection	Renewal
Inspector(s)	Parvez Qureshi
	Andy Leonard
	Carmel Dodson-Brown
	Angela Sutherland
Fee paid	Paid
Licence expiry date	28 February 2009
NHS/ Private/ Both	Private

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About the Inspection:

This inspection visit was carried out on 25 September 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 is privately owned and has been licensed since 1992. There are no additional conditions on its licence. Currently around 1300 treatment cycles per year are carried at the unit.

Since the previous inspection further improvements have been made to the premises. An organisational chart is in place indicating key roles and lines of accountability. The business hours at the centre are Monday to Friday from 8.00 am to 5.30 pm and Saturday 8.00 am to 4.00 pm.

The Person Responsible (PR) has completed the HFEA PR Entry Programme. She is registered with the General Medical Council (GMC).

Activities of the Centre[1] for the time period from 01/01/2007 – 31/12/2007

In vitro fertilisation (IVF)	151
Intracytoplasmic sperm injection (ICSI)	332
Frozen embryo transfer (FET)	11
Egg donor	65
Egg recipient	48
Donor insemination (DI)	663
Intra uterine insemination (IUI)	69
Storage gametes/embryos	Yes

Summary for Licence Committee

Since the last inspection the centre's premises have been further improved and were considered to be appropriate for their intended purpose. Recently additional staff have been recruited to meet an increase in workload. Feedback from patients was complimentary regarding the quality of service they had received at the centre.

Improvements are recommended to the following areas of practice:

- Payment of invoices.
- Full implementation of the quality management system.
- Maintenance of all critical equipment.
- Validation of key processes.
- Review of witnessing procedures.
- Review of patient of information.

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 5 years.

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

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
During the current financial year the centre has taken an average of 60 days to pay HFEA invoices. This is potentially a breach of standard licence condition **A.16.3.**	The PR should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.	Progress to be monitored at the time of the next inspection.
Nursing staff meetings to be documented, S.6.2.13.	Consideration should be given to documenting of all departmental meetings.	On going.
A quality policy and a quality manual are in place. However, implementation of the quality management system is not fully compliant with the requirements of **S.4.2.3b, S.4.2.4, S.4.2.8, & 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.	Progress to be monitored at the time of the next inspection.
Air quality in the Andrology laboratory has not been demonstrated to meet the required standards. **A.10.19, S.6.3.6(b), S.7.8.5, G 9.4.3.**	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.	Immediately.
Storage of embryos beyond consented storage limit **S.7.8.11**	The PR needs to put measures in place to ensure that gametes or embryos are not stored beyond the maximum period consented for by	Immediately.

	the patient or statute.	
Validation of key processes and procedures has not yet been established **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
Information for patients is not fully compliant with all of the requirements of **G.4.11.1** & **G.5**	The centre should review the content of patient information against the requirements of the COP.7th Where a decision is made to deviate from the guidance provided in the COP 7th this should be documented.	Information should be reviewed as soon as practicable and the HFEA informed when the review is complete.
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.

Recommendations

Area for improvement	Action required	Time scale
Information on payments made to sperm donors is not compliant with the SEED review.G.4.11.1) and Chair's letter CH(06)01. However, no evidence of donors being paid in excess of the limits of the SEED recommendations was found.	The PR needs to review the payments made to donors to ensure that they are compliant with the requirements of the SEED review.	Immediately.
Reporting of incidents.	The PR should review the centre's incident reporting policy to ensure that all staff are able to both identify and report any incidents.	Immediately.
The HFEA registry reported that the centre was not addressing their error reports on a regular basis.	The PR needs to put measures in place to ensure that this issue is resolved.	Immediately.

Checking of emergency trolley.	Updating of log at the time of checking.	Immediately.

Changes/ improvements since last inspection

Recommendations	Action Taken
Departmental meetings.	Regular departmental meetings are held. Evidence of this was seen during the course of the inspection.
Review of security for the room housing the medical notes.	A key pad lock has been installed.
Review of out of hours on call system.	Since the last inspection an out of hours procedure has been implemented which was considered to be appropriate.

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
The inspection team considered the centre to be well organised and managed. There is an organisational chart in place showing key responsibilities and lines of accountability and this was further demonstrated by staff who were interviewed during the visit. Since the previous inspection additional staff have been recruited in almost all departments to meet an increase in workload The PR informed the inspection team that further appointments are pending. There is a risk management policy in place. Documented procedures are in place for the identification, notification and investigation of incidents. Review of the centre's incident log showed that, since the last inspection, only one incident had occurred at the centre and it was reported to the HFEA within prescribed timeframes and had been investigated effectively. There are arrangements in place for the management and dissemination of HFEA Alerts and any necessary recommendations are implemented by the appropriate personnel. The centre's complaints log was reviewed by the inspection team and evidence of actions taken to resolve complaints were noted. In addition to other centres within the London Women's Clinic group, contingency arrangements are in place with CRM London (centre 0199) and London Fertility Centre (centre 0088) for continuation of service. Discussions held with staff confirmed that arrangements are also in place for patients who need to contact staff outside working hours.

Third party agreements are in place which were reviewed and considered to be compliant with HFEA guidelines.

Documented evidence of multi-disciplinary team meetings held at the centre to discuss practice related issues was made available for the inspectorate. The minutes of these meetings are circulated to all staff. A review of minutes of recently held meetings showed that in addition to centre's practice HFEA related issues were also discussed.

Areas for improvement

During the current financial year the centre has taken over 60 days to pay HFEA invoices. This is a breach of standard licence condition A.16.3.

Nursing staff meetings are not being documented. Consideration should be given to documenting of all departmental meetings, S.6.2.13.

Areas for consideration

With reference to the number of treatment cycles carried out at the centre and the number of incidents reported, The PR should review the centre's incident reporting policy to ensure that all staff are able to both identify and report any incidents.

Executive recommendations for Licence Committee

The PR should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices with progress to be monitored at the time of the next inspection.

Documentation of departmental meetings.

Evaluation

Some improvement required.

Areas not covered on this inspection

All areas covered.

2. Quality of service

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

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

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates
For the time period from 1 April 2004 to 31 March 2007 the centre's live birth rates were in line with national averages for all treatment types and in all age bands. In the time period from 5 July 2007 to 31 December 2007 the centre provided 30 cycles of IUI and report that 3 clinical pregnancies resulted from the treatments.
Areas of firm compliance
Since the last inspection a Quality Manager has been appointed to further develop the centre's quality management system (QMS) A quality policy and a quality manual are in place. A review of documents submitted for the inspection showed that some had recently been updated. The centre has arrangements in place for conducting audits of practice including reviews of patient satisfaction; pregnancy rates and audit of consent forms The outcome of audits are discussed at quality management meetings and any areas of concern are subject to corrective action. Evidence of this was provided in the course of the inspection. The HFEA has received feedback from 11 patients who have received treatment at the centre in the time since the last inspection. The majority of the responses made by the patients were complimentary regarding the quality of service they had received. Patients commented on the centre being well organised and staff being supportive. Two patients interviewed during the course of the inspection also made complimentary comments about their experience at the centre including staff being helpful and friendly. The centre has an effective document control procedure in place. This was evident from the documents reviewed during the course of inspection and discussions held with staff who met with the inspection team.
Areas for improvement
There is a quality policy and a quality manual in place. However, 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 by the inspection team in relation to the following areas of

practice:

- 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, S.4.2.3 & S.4.2.8.
- The maximum interval between reviews of documents should be twelve months S.5.2.5a
- Annual, review of the quality management system, S.4.2.8.

Areas for consideration
None.
Executive recommendations for Licence Committee
The PR should ensure that appropriate procedures are implemented to ensure the continual improvement of the QMS and that the maximum time between reviews of documents is twelve months. In addition, an annual review of the QMS is undertaken.
Evaluation
Some improvement required.
Areas not covered on this inspection
All areas covered.

3. Premises and Equipment

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

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

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
Further refurbishment of the premises has taken place since the last inspection. The centre's management team informed the inspectorate that, in the near future, they are expecting to re-organise the premises which will result in expansion of the laboratory and the cryostore areas. There is a controlled access to both the IVF and the donor bank facilities. The clinical, counselling and laboratory facilities seen during the course of the inspection appeared to be clean and well presented. The men's production rooms were considered to be appropriate for their intended purpose The current cryostore facilities appeared to be adequate for the volume of work being carried out. Access to the cryostore is restricted and all dewars are fitted with low nitrogen level alarms linked to an auto dial out system. The cryostore is also fitted with a low oxygen monitoring system. There are adequate procedures in place, with laboratory staff being on a rota system, for responding to alarms. The laboratory staff confirmed that since the last inspection, no significant changes have been made to the equipment. Maintenance contracts are in place for key pieces of equipment and evidence of this was made available for the inspectorate. Logs of incubator temperature and carbon dioxide level check are kept and evidence of this was seen during the course of the inspection. In the event of a power failure the centre has access to a back up generator. Processes in the IVF laboratory take place in an environment of at least Grade C air quality with the background air quality being of at least Grade D. The current staff changing facilities appeared to be adequate. Patient treatment records are stored securely with only members of the staff having access to them.

Areas for improvement
The air quality is not monitored in the andrology laboratory.
Areas for consideration
A large number of dewars are stored in the cryostore. Although the centre is considering alternative cryostorage methods, a risk assessment should be conducted for the existing cryostore facility to ensure that it is not hazardous due to the large numbers of dewars held there.
Executive recommendations for Licence Committee
Monitoring of air quality should be should be performed according to a defined monitoring protocol which should be validated.
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
Comprehensive patient information was submitted for the inspection, which was considered appropriate except for the specific issues raised in the improvements section. In addition to counselling service information, the centre's treatment licence, complaints procedure and details of a variety of treatments available at the centre were also seen on display Five patient records were reviewed by the inspection team. The notes were found to be well organised and all contained consents which were compatible with the treatment provided. Evidence of welfare of the child assessment being conducted at the centre was also noted in the patient records and this was further confirmed by discussions held with the staff. If required, staff can raise any concerns regarding welfare of the child at clinical meetings. Patient confidentiality is well maintained. The centre has a procedure in place through which patients can obtain a copy of medical notes.
Areas for improvement
The patient information was considered to be appropriate. However, the following areas for improvement were identified: • The centre's sperm donor information sheet quotes a fixed payment for each donation. On this basis a donor who completes a whole donation cycle would receive total payments which far exceed those stipulated in the Sperm, Egg and Embryo Donation (SEED) review. Therefore, the PR needs to review the payments made to donors to ensure that they are compliant with the requirements of the (SEED) review (G.4.11.1) and Chair's letter CH(06)01. Payments made to donors were reviewed in the course of the inspection however, and no evidence of donors being paid in excess of the limits of the SEED recommendations was found. The centre's protocol for donor screening needs to be re-titled to reflect that it is for blood tests only. The inspectorate noted that embryos from 10 patients have been stored beyond their consented storage limit. The PR needs to put measures in place to ensure that gametes or embryos are not stored beyond the maximum period consented for by the patient or by

statute (S.7.8.11). The Human Fertilisation and Embryology Act 1990 14 (1)(c) states the following shall be conditions of every licence authorising the storage of gametes or embryos: that no gametes or embryos shall be kept in storage for longer than the statutory storage period. Schedule 3 of the Act at section 8 states that (2) An embryo the creation of which was brought about *in vitro* must not be kept in storage unless there is an effective consent, by each person whose gametes were used to bring about the creation of the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents. Section 1 of schedule 3 of the Act requires that consent under this Schedule must be given in writing.
Areas for consideration
The HFEA registry reported that the centre was not addressing their error reports on a regular basis. The PR needs to put measures in place to ensure that this issue is resolved .
Executive recommendations for Licence Committee
The PR should review information on payments made to sperm donors to ensure those payments are compliant with the requirement of the SEED review. The PR needs to put measures in place to ensure that gametes or embryos are not stored beyond the maximum period consented for by the patient or statute.
Evaluation
Significant improvement required.
Areas not covered on this inspection
All areas covered.

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	5
NMC registered nurses	5
Non NMC registered clinical staff	3
HPC registered scientists	2
Scientists working towards registration	1
Support staff (receptionists, record managers, quality and risk managers etc)	21
Counsellors	2

Summary of laboratory audit
An audit of cryopreserved samples was conducted recently. No discrepancies were identified.
Summary of spot check of stored material
As an audit of stored samples was conducted recently without any discrepancies. No spot check was conducted during the inspection.
Areas of firm compliance
Evidence of continuous professional development (CPD) for staff was made available for the inspectorate. Staff training files examined during the course of the inspection and discussions held with staff confirmed that both orientation and induction courses had been completed. In addition, where appropriate, staff competencies have been documented. Mandatory training such as basic life support and manual handling is addressed on a regular basis. There are policies in place for the assessment of patients seeking treatments and for screening of patients and donors. This was evident from the documentation submitted for inspection and discussions held with staff.

Andrology laboratory staff participate in the National External Quality Assessment Service (NEQAS).

The centre's 3 embryo transfer (3ET) log showed that, since the last inspection, 27 patients had 3 embryo transferred and all of them were above 40 years of age. In order to address the risk of multiple pregnancy an elective single embryo transfer policy has been developed for consultation within the London Women's Clinic group.

The centre has 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 samples is also in place and was considered to be appropriate.

The counselling service is well promoted at the centre and patients are made aware of the service at their initial consultation. The counsellor is member of the British Infertility Counselling Association (BICA). Her CPD is well maintained and she receives regular supervision from a mentor. She stated that, if required, a backup counsellor is available. All counselling sessions take place in comfortable surroundings and notes are kept a secure place. Patients can book appointments via the administration staff or by contacting the counsellor directly. The counsellor attends centre's multi disciplinary team meetings and is able to discuss any difficult cases with rest of the team.

The counselling audit supplied for the inspection confirmed that there were a total of 213 referrals between January and July 2008 showing that implication counselling was the most frequently attended.

Areas for improvement

The validation of key equipment and processes such as the flow hood in the andrology laboratory has not been conducted (S.6.4.2).

A witnessing protocol is in place. However, it was noted in the andrology laboratory that a number of witnessing stages were not being carried out. These included time and, date of signature.

Areas for consideration

The centre's protocol for screening of potential donors needs to be re-titled to reflect that it is for blood tests only and not for all screening conducted.

The emergency trolley located in the recovery area is checked on a daily basis. However, the log is updated every two to three days. The PR needs to ensure that the log for the trolley is updated on the same day as it is checked.

Executive recommendations for Licence Committee

Validation of all key equipment and processes to be conducted (S.6.4.2).

The witnessing procedures require review to ensure full compliance with COP 7th Guidance G.13 1.

Evaluation
Some improvements required.
Areas not covered on this inspection
Procurement, distribution and receipt of gametes and embryos.

Report compiled by:

Name……Parvez Qureshi…….

Designation…..Inspector…….

Date……29.10.2008……

Appendix A: Centre staff interviewed

PR and eight other members of staff.

Appendix B: Licence history for previous 3 years

2008

Licence Committee 6th March 2008
The Committee agreed that the centre's licence should continue with no additional conditions.

2007

Licence Committee 23rd May 2007
The Committee agreed that the centre's licence should continue with no additional conditions.

Licence Committee 26th April 2007
The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

2006

Licence Committee 22nd November 2006
The Committee was satisfied that the premises were suitable for IVF and ICSI and agreed to vary the centre's licence to add IVF and ICSI, subject to a follow up visit being undertaken before any such treatment commences.

Licence Committee 27th February 2006
The Committee decided to grant the centre a licence to store embryos and sperm and to carry out donor insemination. This licence is for three years and with no additional conditions.

Appendix C: Response of Person Responsible to the inspection report

Centre Number……0105……..…

Name of PR……..Geetha Venkat..…….

Date of Inspection……25 September 2008……..…..

Date of Response…….21 November 2008……

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

Signed……Hard signed copy received from PR……

Name……..Geetha Venkat……

Date……21 November 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.

Factual corrections have been made where required.

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) **Breaches** Payment of HFEA invoices were delayed due to duplication. This has been put in order and we will endeavour to make payments within 30 days of invoicing (A.16.3). Nursing staff meetings minutes are taken and are available to view (S.6.2.13). The centre QMS is in development since appointment of a quality manager. The sections of the code quoted in the report as not being compliant are either in place or in development. Specifically there are quality objectives (contained within the quality policy of the

unit)(S.4.2.3b). Management review of the quality objectives and whole QMS has not been possible due to the work in progress on developing the QMS but is scheduled within 6 months of full implementation (S.4.2.4; S.4.2.8). A SOP for document control has been established and all current documentation is under review (S.5.2.5a).

Air quality monitoring in the donor bank is now conducted (SOP, manual for use of device and log completed) (A.10.19, S.6.3.6b, S.7.8.5, G.9.4.3).

The PR has reviewed donor payments and introduced donors providing proof of expenses and tick box confirmation of time lost and expenses incurred (G.4.11.1).

All embryos stored beyond consented period have been discarded. Measures have been introduced to ensure this does not occur in the future (S.7.8.11).

Validation of key processes is planned following ACE guidelines. This is an ongoing process (S.7.8.3; A.11.11.

Non-compliance
All patient information is currently under review (G.4.11.1; G.5).

Witnessing steps in the Donor bank are being reviewed and a new witnessing sheet is to be produced (G.13.1).

Recommendations
The policies for reporting an incident has been reviewed by the PR. Staff have been made aware of the requirements of the reporting and three incidents have been reported.

The issue of HFEA registry reporting has been discussed and staff trained in performing EDI in a timely fashion.

The emergency trolley is checked at regular intervals and a log completed.

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

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

12 January 2009
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 3

London Women's Clinic, 0105
Licence Renewal

Members of the Committee:

David Archard, Lay Member – Chair
Sally Cheshire, Lay Member Jennifer Hunt, Senior Infertility Counsellor, IVF Hammersmith
Hossam Abdulla, Director, Lister Fertility Clinic

In Attendance:

Debra Bloor, Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice to the Committee:

Graham Miles, Morgan Cole Solicitors

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

The following papers were considered by the Committee:

- papers for Licence Committee (32 pages)
- no papers were tabled.

1. The papers for this item were presented by Parvez Qureshi, HFEA Inspector. Mr Qureshi informed the Committee that this centre is privately owned and has been licensed since 1992. Currently, around 1,300 treatment cycles are carried out per year. He also highlighted the fact that the inspection team identified a number of further improvements to the centre since the last inspection. He reported that the centre is in the process of recruiting additional staff to meet an increase in workload and complimentary feedback has been received by the HFEA from patients at the centre.

2. Mr Qureshi drew the Committee's attention to the findings of the inspection, summarised at pages 6 and 7 of the report. Improvements were recommended in relation to the following areas:

    - payment of invoices
    - full implementation of a quality management system

- maintenance of critical equipment
- validation of key processes
- review of witnessing procedures, and
- review of patient information.

3. Mr Qureshi then drew the Committee's attention to the response to the report by the Person Responsible, appended at page 21 to 22 of the report. He reported that the Person Responsible has now addressed most, if not all, of the issues identified in the report and is working to address the remainder. In particular, all improvements to have been implemented immediately have now been addressed.

The Committee's Decision

4. The Committee noted the areas for improvement identified in the inspection report and welcomed the fact that the Person Responsible is implementing all the recommendations from the inspection team.

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

Signed……. … Date……..
David Archard (Chair)