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Renewal Inspection Report

Lister Fertility Clinic

Centre 0006

Date of Inspection: 24 September 2009

Date of Executive Licensing Panel
27 January 2010

Centre Details

Person Responsible	Mr Hossam Abdalla
Nominal Licensee	Ms Mary Power
Centre name	The Lister Fertility Clinic
Centre number	Centre 0006
Centre address	The Lister Fertility Clinic The Lister Hospital Chelsea Bridge Road London SW1 W 8RH
Type of inspection	Treatment Licence Renewal
Inspector(s)	Gill Walsh – Lead Inspector Janet Kirkland – Clinical Inspector Lynne Nice – Scientific Inspector
Fee paid	Renewal fee paid
Licence expiry date	28 February 2010
NHS/ Private/ Both	Private

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About the Inspection:

This inspection visit was carried out on 24 September 2009 and lasted approximately 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 Lister Fertility Centre has been licensed with the HFEA since 1993. The centre is housed within the Lister Hospital, an acute, independent hospital which is part of the HCA group of 6 hospitals in London.

The centre offers a comprehensive range of assisted conception therapies including, IVF, ICSI, insemination with partner / donor sperm and the storage of gametes and embryos. The centre recruits sperm and egg donors and runs an egg share programme.

Application by the centre to vary their licence to include pre-implantation genetic diagnosis for the avoidance of chromosomal rearrangement was granted by licence committee in February 2009 and a further application to vary was granted in May 2009 to reflect different pre-implantation genetic screening methodologies, namely 2 modified FISH methodologies and testing for Comparative Genomic Hybridisation (CGH).

The centre is considered large, conducting over 2000 cycles of licensed treatment per year. The centre is open routinely for consultation and treatment from 8:00am to 6:00pm Monday to Friday and at weekend according to need.

The centre was briefly inspected by the HFEA in February 2009 following refurbishment to the laboratory which was found to be compliant with the relevant professional society and regulatory requirements. Refurbishment to other patient consultation areas had recently been completed prior to this inspection. The last full inspection of this centre was and interim inspection conducted in October 2007.

Since last inspection (September 2008) the centre has voluntarily relinquished its research licence.

The centre has be held ISO 9001 certification since 2005, certification was upheld following a successful audit in March 2009.

The centre has satellite arrangements with;
The Agora Clinic, Brighton
Thames Valley Nuffield Hospital, Slough (Mrs Watson)
Spire Murrayfield Hospital, Edinburgh (Dr Thong)
BMI Winterbourne Hospital, Dorchester (Mr Dooley)
and also conducts consultations and ultra sound scanning appointments off site in the Old Street area of London.

The Person Responsible (PR) is an a independent Consultant Gynaecologist and has been on the specialist register of the General Medical Council (GMC) for Obstetrics and Gynaecology since January 1997. The PR has been Medical Director of the Lister Fertility Clinic since 1988 and has successfully completed the HFEA Person Responsible Entry Programme (PREP) and has held the post for many years.

Please note that this inspection was conducted prior to the 8th Code of Practice being implemented. References to findings on the day of inspection are to the 7th Code of Practice whilst recommendations going forward are referenced to the 8th Code of Practice.

Activities of the Centre from the period 1 Jan 08 to 31 Dec 08*

Licensed Treatments	
IVF (cycles)	1038
ICSI (cycles)	1161
Frozen embryo transfer (FET)	370
Donor Insemination (DI)	21
Storage o f gametes / embryos	Yes
Research	No

Summary for Licence Committee

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

- the PR has discharged his duties under Section 17 of the HFE Act. and that those acting under the supervision of the PR are suitably trained and qualified for their designated roles.
- The executive believes that the existing and refurbished premises and equipment inspected are suitable for the treatment procedures for which the centre is licensed
- the executive believes that the premises and equipment inspected are suitable for the treatment procedures for which the centre is licensed
- the centre has been proactive in the development and implementation of a quality management system
- the executive is satisfied that, overall the centre demonstrates suitable practices in respect of air quality, laboratory, clinical and administrative procedures conducted in relation to licensed treatments.
- the centre has submitted appropriately completed documentation in application for renewal of their licence and has submitted fees to the HFEA in accordance with requirements.
- some improvements should however be considered relating to the following aspects of the centre's practice:
    - Demonstration and assessment of staff competency
    - Documentation of Welfare of the Child assessments having been conducted
    - Validation of some laboratory equipment, practices and processes

The executive considers that, overall there is sufficient information available to recommend the renewal of this centre's licence for a period of four years without additional condition. Compliance with the recommendations proposed in this report should be within the prescribed timeframes.

Evaluations from the inspection

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

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

Breach	Action required	Time scale
Validation Validation of some critical equipment and key processes and procedures is not in place, Ref: S.6.4.2 and S.7.8.3 of the COP and standard licence condition A.11.11.	It is recommended that a plan for validation is drawn up. The plan should take into account the particular needs of the unit and prioritise the validation of key equipment and processes considered to be most likely to impact on the quality of the service. CoP 8 T24 T25 T28 T29 T30 T31	Validation of all critical equipment should be completed by April 2010 Progress towards full implementation of the plan to be monitored in the course of the next inspection
Competence Assessment Whist staff training logs and the framework for competency assessment is in some instances for laboratory staff are in place, nursing staff competency assessments have not being documented. A.10.11	The centre should establish documented procedures for staff management that ensure that all staff have competence assessment. The competency of the personnel must be evaluated at appropriate intervals specified in the quality system. The PR must ensure and document that each individual has demonstrated confidence and competence in their designated	March 2010

	tasks. CoP 8 T12 & T15 (a) G 2.1 (b)	
Evidence of welfare of the child assessment The centre has a documented SOP in place for the assessment of welfare of the child. Documented evidence that this had taken place was absent in a number of patient records observed on inspection and in the centre's own patient records audit findings. CoP S.7.6.4	. The centre should ensure that a record of an appropriate welfare of the child assessment having been conducted should be retained in the patients health record and be available for consideration prior to any treatment being conducted. T56 G.8.18 T46(e)	Immediately.
Document Control Not all documents viewed were appropriately controlled and reviewed within an appropriate time scale. CoP S.5.2.5	The centre should ensure that all documents generated, stored and released for use in accordance with the requirements of the Quality Management System. Such documents are to be regularly reviewed, revised, dated and re-approved for release T34 G 31.4/5/6	February 2010
Donor or potential donor screening Two patients who had consented to the posthumous use of their embryos in the treatment of others had not been screened as donors. S.7.4 G.5.4	The centre should ensure compliance with the selection criteria for donors and the requirements for laboratory tests and storage and that documentary evidence of which is available in the potential donor's health record. T52	With immediate effect.

Non-Compliance

Area for improvement	Action required	Time scale
Assess to the medical records store was unprotected at the time of inspection when the room was unmanned. A.10.31	The centre should ensure that access to patient health records is protected at all times. T45	Immediate – corrected at the time of inspection

Other Recommendations

Area for improvement	Action required	Time scale

Changes/ improvements since last inspection

Recommendations – Potential Breaches	Action Taken
The downstairs laboratory was left unattended / insecure CoP 7 – S.6.3.1	Resolved All laboratory areas were seen to be secure when unmanned on inspection. A digital lock has been fitted which locks automatically on closure.
A sperm tank audit had not be completed within appropriate time scales. CoP 7 S.7.8.12(b)	Resolved This was conducted on 21 December 2007 documented evidence was seen on this inspection.

Recommendations – Non Compliance	Action Taken
Three embryos replaced in a woman < 40 years G.8.5.1	No further 3 embryo transfers have been undertaken.
A sperm tank audit had not be completed within appropriate time scales.	This has been conducted since last inspection.

Additional licence conditions and actions taken by centre since last inspection

No licence conditions in place

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
This large centre's activities are lead by the PR who is also Medical Director. He is supported by the Unit Manager, who is also the Quality Manager and department Heads respectively. In the opinion of the executive, evidence drawn from the inspection demonstrates that the PR provides the required leadership and management skills to fulfil his responsibilities. During the inspection this busy centre appeared to be operationally well organised. All pre-inspection material was submitted to the HFEA complete and on time. All required members of staff were present for the inspection and provided information, written and verbal, as requested An organisational chart was seen to be in place which clearly demonstrated current responsibility and reporting lines. Evidence of regular management communication and review of centre activities was seen in the minutes of management group meetings. Staff asked stated that meeting minutes were emailed to all associated staff and were for all to view on the centre's intranet. The centre participates in the HCA wide clinical governance agenda. Staff asked were able to demonstrate effective risk awareness. Key areas of the centre's activities were seen to have been risk assessed, including risk assessment of the radio frequency witnessing system. The centre states their most recent annual HCA Health and Safety inspection was conducted in February 2009 and that no non-conformities were noted. The centre manages incidents and complaints in accordance with the HCA Corporate policy and HFEA requirements. There is a nominated complaints officer and all complaints /

incidents were seen to be discussed at team meetings. All incidents / adverse events and complaints are logged within the centre an on the HCA electronic database for clinical governance and trend analysis. Staff stated that indentifying patient information is redacted prior to entry onto the data base. Information regarding how and to whom a complaint should be made is available in patient information. . Local trend analysis of verbal and written complaints lodged with the centre indicate problems with patients being able to access staff by telephone during busy times and also appointments overrunning and so delaying patients. The centre is actively trying to implement measures to improve these issues, evidence of which was seen in the minutes of the quality management review.

Staff asked were aware of the HFEA Alert system. 3 incidents have been reported to the HFEA since last inspection. Local investigation of each incident was evident and corrective action / change to practice documented and implemented where required.

The PR stated that contingency measures are in place to manage the following eventualities and disruption to service:

- Power 'outage' – the centre is part of the hospital's emergency back up generator network and uninterrupted power supply for critical equipment.
- Significant absence of the PR – there is a Nominal Licensee in place and appropriate clinical cover available
- Significant disruption to clinical service on site –contingency arrangement with the licensed treatment centre at Guys Hospital.
- Patients requiring admission to hospital under emergency conditions may be admitted to the Lister Hospital or to their local hospital for which a telephone clinical handover with be provided by the Lister Fertility Clinic as required.
- Instructions for emergency contact with the centre (including out of hours) are contained in the patient information leaflets.
- Equipment for use in the resuscitation of a patient who may collapse is available for use in the centre and was seen to be appropriately equipped and checked.
- The centre has appropriate alarms in place to monitor oxygen and nitrous levels in the cryo store, laboratory staff participate in an on call rota to manage any out of hours response required.
- The centre has spare dewar capacity to accommodate continued staff storage of gametes and embryos in the event of a dewar failure.

Details of all third party agreements in place were seen on inspection.

The finance department of the HFEA report routine payments from this centre are made within HFEA required timescales and prompt payment of the licence renewal fee has been received.

Areas for improvement

None

Areas for consideration

At the time of inspection it was noted that there were a number of posts vacant, four of which are nursing and three members of the team are currently on maternity leave, one of which is in the laboratory. It was recognised that the centre is actively recruiting to these posts. Staff asked stated that there is good communication between the PR and the nursing team to

ensure that the level of centre activity is moderated to ensure that sufficient resources are available.
Executive recommendations for Licence Committee
The PR should ensure that until such time as the posts are filled and staff appropriately inducted and at the competency level required for their designated duties is assured, the level of activity within the centre should be monitored to ensure it does not exceed a level commensurate with the resources available.
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]
Figures drawn from data submitted to the HFEA by this centre for the full year 2007 for IVF and ICSI in women whose age ranges from under 35 to 42 years give the following (predicted) live birth rates per cycle of treatment completed: < 35 years = an average 35% which is above the national average of 32.3% 37 -37 years = an average of 35.2% which is above the national average of 27.7% 38 – 39 years = an average of 25.8% which is above the national average of 19.2% 40 -42 years = an average of 18.8% * ***** National averages for ages 40 and above are not represented as cycle numbers are smaller and success rates are significantly reduced making meaningful national comparisons difficult to demonstrate.
Areas of firm compliance
The Unit Manager also has the role of quality manager and leads the development of the QMS. She is supported by a Quality Co-ordinator (currently on maternity leave) and designated members of each department as quality 'link' persons. There is a comprehensive quality management system in place. The centre's commitment to quality is outlined in a policy within the quality manual and incorporates all elements required by the 7th Code of Practice. In compliance with HFEA Standards, the quality manual clearly outlines: (a) a description of the centre, including its legal identity, and the scope of the services provided, (b) a quality policy (c) an organisational chart and a definition of the centre's place in any parent organisation,

(d) an outline of the processes and documentation established for the quality management system.

A list of measurable quality objectives for the year 2008/09 were seen and were said by staff to be under review for the period 2009/10. A full quality management review was held on 19 December 2008, the report for which was seen on inspection.

The centre to date has conducted a number of internal audits, namely egg sharing, scheduling, document control, sharps, patient admission times, transport of gametes, witnessing and welfare of the child. The centre states that a series of 10 laboratory process outcomes are monitored quarterly as are individual laboratory and clinical personnel procedure outcomes.

Patient satisfaction data is analysed by an external organisation and a report submitted to the centre quarterly. These reports are discussed at Management Review meetings and required actions agreed. The most recent report was available to view on inspection.

Staff are encouraged to contribute ideas and comment during staff meetings, evidence for which was seen in team meeting minutes and in the quality management review.

There is a document control policy in place. The centre holds a master document list which denotes all documents currently approved for use within the centre which denotes the current version and review date. Overall the documents received prior to and seen during the course of inspection proved compliant with HFEA Standards in that they are uniquely identified, version controlled , had an operative and review date and authority for issue and author identification.

When asked, staff stated that records held electronically are 'backed up' daily and are only accessible to centre staff with allocated user access. These records are held on a server separately from those of the rest of the hospital.

Archived records are held off site with records management company in compliance with HFEA requirement, evidence for which was seen.

Areas for improvement

It was noted that a number of documents viewed had varying review periods from one to three years and / or it was unclear if they had been reviewed and a new review date set. On other documents data fields were blank.

When asked a staff member was unable to access the centre's multiple birth minimisation strategy from the master document index as it was not listed.

Areas for consideration

Executive recommendations for Licence Committee

The centre should ensure that all documents in use at the centre are appropriately authorised and released as part of the quality management system. Review periods should not exceed 12 months and it should be clear when this is due or has been conducted.

Evaluation
Some small 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

Brief description of premises
The centre is a largely stand alone unit within the Lister Hospital. All reception, consultation and some treatment areas are housed separately from the main hospital, some clinical facilities for patient treatment and recovery are shared with the hospital's day unit. The centre has recently undergone a substantial programme of redecoration and refurbishment to common areas, consultation rooms and some treatment areas. The laboratory has also undergone some refurbishment which includes the introduction of radio frequency identification of samples (RNID).
Areas of firm compliance
Overall the premises and facilities available appear to be suitable for the activities for which the centre is licensed. The clinical facilities appeared to be appropriately equipped and provide for the privacy, dignity and comfort of (i) those seeking treatment and (ii) those undergoing examination and treatment and (iii) providing semen samples for therapeutic use. Counselling facilities were seen to be private and quiet. The laboratory facilities appeared to be appropriately equipped for the treatments provided. Recent refurbishment has improved security with the introduction of person specific swipe card access to the laboratory. Background air quality is supported by positive pressure high efficiency particulate air (HEPA) filtration. Air quality in the laboratory areas is currently monitored quarterly for particulates and every six months for microbial contamination. Results for the most resent air quality tests were seen on inspection and considered to be compliant with air quality requirements.

Scheduled maintenance logs and portable appliance testing (PAT) for clinical and laboratory equipment seen was in date. Sample maintenance agreements for equipment in the centre were available to view on the day of inspection.

Patient treatment records were seen to be stored in a fully equipped, designated medical records room. There is a designated records officer in post who occupies this area the majority of the time during normal working hours. It was noted that this room is secured by means of swipe card lock.

Areas for improvement

Areas for consideration

It was noted that the medical records store room was unlocked and briefly unmanned when inspectors entered to view this area.

It was noted that room signage was limited at the time of inspection as the centre had only very recently completed the refurbishment process in some areas. Centre staff stated that new signage had been delivered and scheduled to be in place the following week.

Executive recommendations for Licence Committee

The centre should ensure that access to the medical records store is controlled at all times.

Evaluation

No real improvement required.

Areas not covered on this inspection

4. Information

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

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

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

Areas of firm compliance
Information for service users submitted prior to inspection and seen on the day was found to be current, clearly presented and relevant to the treatments for which the centre is licensed. Staff state that treatment options are discussed in the clinical consultations. Written information regarding their proposed treatment is given at this time. Patients will then attend a nurse leg consultation at which point patients are asked if they require any clarification or additional information regarding their treatment pathway or treatment options. It was noted that an 'booking' checklist is used to ensure patients have received and understood all the information they require to give valid consent. Consent is currently only sought by a member of the medical team. Staff stated that the welfare of the child is assessed at consultation and thereafter if required. A 5 randomly patient records were audited on inspection. All consents were seen to be in place for the proposed treatment / storage. There is a policy in place for the controlled access to health records which is in compliance with HFEA requirements. The registration department of the HFEA report that overall there are no issues with the timeliness and accuracy of the data submitted to the register by this centre.
Areas for improvement
On auditing the patient records it was noted that a documented record of a welfare of the child assessment having been conducted was missing from all but one set of patient notes.
Executive recommendations for Licence Committee
The centre must ensure that a record of the a welfare of the child assessment having been conducted should be retained with the patients treatment record.
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
- Laboratory practice
  - Procurement, distribution and receipt of gametes
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Witnessing

Full time equivalent staff

GMC registered doctors	9
NMC registered nurses	11
Non NMC registered clinical staff	2
HPC registered scientists	3
Scientists working towards registration	3
Laboratory support staff	3
Support staff (receptionists, admin, records etc)	9
Counsellors	1

Summary of audit
An audit of witnessing was conducted by the centre in 2008, minor changes to the SOP resulted. A spot audit of 5 sets of patient / egg share / donor patient notes was conducted on inspection. Evidence of a welfare of the child assessment was absent in two sets of notes and also evidence of screening as per donor whereby the patient had consented to use of her embryos in the treatment of others posthumously The centre stated that sperm and egg / embryo tanks were audited alternately. The most recent embryo storage audit was submitted to the HFEA ahead of the inspection (December 2006) Minor date entry discrepancies were noted and were corrected. Staff asked state that the cryo preserved sperm storage audit had been delayed pending the completion of refurbishment works and so could not be seen.
Summary of spot check of stored material
A spot check on stored material was not conducted on this occasion.
Areas of firm compliance
Staff asked were able to show that the centre has an agreed competency framework and documentation in place for the assessment of competency across three levels for both nursing and laboratory staff. Staff asked said that they were afforded a good level of clinical professional development and were supported by the centre in achieving this. Staff also stated that they participate in an annual Professional Development and Appraisal process in accordance with HCA policy. Evidence for this was not seen.

The centre utilizes an electronic booking management system for mandatory training. This system books and records attendance for each staff member.

On discussion with and by observations made by the clinical and scientific inspectors, clinical and laboratory staff were able to demonstrate that they were appropriately qualified and registered to perform their assigned tasks, including for laboratory staff, the procurement, distribution and receipt of gametes

Laboratory staff have recently begun to participate in the National External Quality Assurance Service (NEQAS) for andrology. The centre also has an intra laboratory comparison relationship with Guys Hospital whereby they meet twice per year to compare and review outcome and other data.

An SOP for the traceability of materials and equipment which in contact may influence the safety of gametes and embryos was seen. Practice in the laboratory was observed, both of which were considered to be compliant with HFEA requirements.

The centre has recently introduced a radio frequency identification system (RFID) for the witnessing of the manipulation of gametes and embryos in the assisted reproduction process. The centre conducted full risk assessments reflecting the change to witnessing practice (seen) and conducted three days parallel testing of the new system. SOP's to reflect new practices were seen to be place.

Areas for improvement

Whilst it is acknowledged that staff are competent to perform designated tasks, the centre has not begun the process of documenting competency in all areas using the template framework seen on inspection.

Areas for consideration

Executive recommendations for Licence Committee

The centre should establish documented procedures for staff management that ensure that all staff have competence assessment.

The competency of the personnel must be evaluated at appropriate intervals specified in the quality system. The PR must ensure and document that each individual: has demonstrated confidence in the performance of their designed tasks,

A continuing education and professional education programme should be available to staff at all levels.

Evaluation

Some improvement required

Areas not covered on this inspection

Report compiled by:

Name Gillian Walsh

Designation Inspector

Date 2 November 2009

Appendix A: Centre staff interviewed

The Person Responsible, Quality Manager and members of the centre team

Appendix B: Licence history for previous 3 years

Appended

Appendix C: Response of Person Responsible to the inspection report

Centre Number 0006

Name of PR Mr Hossam Abdalla

Date of Inspection 24 September 2009

Date of Response 23 December 2009

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

Signed comments submitted separately signed on email. (Trim)

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.

No comment made

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

I am writing in the first instance to contest your first assertion that validation of critical equipment and key processes and procedures are not in place. Validation of key equipment has been performed and documentary evidence was shown on the day of the inspection to the inspector. Validation documents consist of Commissioning documents, Warranty, temperature calibration documents, Verification of product record and lab culture validation documents. Together with these documents annual or biannual service reports are kept. The Inspector seemed satisfied that this was carried out to the required standard. Validation documents are available for key pieces of equipment on request. With regards to the processes and procedures, they have been in place in our department and we have SOPs and clear processes for all laboratory procedures. I personally believe that I do not need to provide any further validation given the results, the fertilisation rate, implantation rate and pregnancy rate for the clinic. Each individual embryologist is being assessed and the processes we are adopting are standard and have been verified though our own results. It is not good enough to reinvent to the wheel or to validate what you have been continuously doing successfully. I can understand that this should be performed for new procedures being introduced but not for standard procedures that have been carried out for more than 20 years utilising time and effort of the staff of the highest calibre and validated by all our results. We did provide you with the ICSI fertilisation rate for all our embryologists and also generate internally, so we know the incidence of damage of eggs, fertilisation rate, cleavage rate, implantation rate for each

individual embryologist for each different procedure in our department. I do not think it is fair to ask us to do more than that. I therefore refuse these assertions and do not accept that “some improvements are required” for laboratory and clinical processes.

Furthermore, I do not understand at all what further improvements are required to our premises or equipment. We have just finished full refurbishment of our unit and we believe that it stands alone as one of the best premises providing IVF in this country, the same
goes for the equipment. All our colleagues and practising fertility specialist who attended the re launch of our department (including some members of the authority) can attest for that. I therefore refuse and contest your tic that some improvements are required to our premises and equipments.

As far as competency assessment, although this might be true in general it is not practical for all of it to finish before March 2010. Furthermore all staff carrying out critical procedures are regularly assessed as there is documented evidence of this. As I did outline the rate of egg collection per doctor, the rate of success for embryo transfer per doctor, the rate of ICSI treatment and the outcome for each individual embryologist – all critical procedures to do with IVF are regularly assessed and documented. There is however a number of aspects within the department whereby we rely on patient feedback, potential complaints and other things to look at our processes and procedures.

I am afraid; the way the Code of Practice is written is such that it forces one way of management and one method of assessing quality is rather cumbersome for clinics and individuals. I have noted that in the Self Assessment Questionnaire whereby for every single step along the way we need to have targets, assessments and corrective action and documentation of all of that. Although we may have to comply with all of this I personally believe that there is over-regulation here. What you really need is to assess is as to whether you have any evidence that the staff are not doing their jobs competently and appropriately, something that I contest given the level of service we provide and the relatively low rate of complaints related to the number of procedures we perform and also our success rate.

With regards to the Welfare of Child assessment I agree with you that there were some that were not filled by some of the consultants at the time of the procedure, but that of course does not mean that the Welfare of the Child was not performed, but I am afraid that it was not signed. We are undergoing an audit of all the patients that will be consulted as of January with clear instructions to all the doctors and nurses to follow this and the operating procedures.
As far as the document control, as you are aware we are reviewing our quality management system and updating the document control within our systems. I accept your point about carrying out a screening and measures are being carried out according to your suggestions.
As far as the patient records room is concerned, I am not sure how this happened, but this room has a digi-lock and is always manned by two members of staff. It is just simply ‘sod’s law’ that this has happened, but of course we will tighten up the procedure, but we have clear policies in place that the room should never be left open with no one manning it but we will ensure that this will not happen again.

Yours sincerely

Hossam Abdalla FRCOG
Director

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

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

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

HFEA Executive Licensing Panel Meeting

27th January 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – item 2

The Lister Fertility Centre (0006), Licence Renewal

Members of the Panel:	
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Trish Davies, Director of Compliance	Committee Administrator: Joanne McAlpine

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 (46 pages)
- no papers were tabled for this item

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 21 October 2009
- Indicative sanctions guidance approved by the Authority on 18 March 2009
- Licence application and any relevant documentation

1. The Panel noted that this application is for a renewal of a treatment and storage licence and noted that the Person Responsible at the centre is also a member of the Authority.

2. The Panel noted that the papers for this item consisted of a renewal inspection report, an application for renewal of licence and the last three years of previous Licence Committee minutes.

3. The Panel noted that this centre has been licensed since 1993, and the centre is housed within the Lister Hospital.

4. The Panel noted that this is a large centre conducting over 2000 cycles of licensed treatment per year.

5. The Panel noted that the centre was briefly inspected in February 2009 following the refurbishment of the laboratory, which was found to be compliant with the relevant professional society and regulatory requirements.

6. The Panel noted that since September 2008 the centre has voluntary relinquished its research licence.

7. The Panel noted that the Person Responsible is an independent Consultant Gynaecologist and has been on the specialist register of the General Medical Council (GMC) for Obstetrics and Gynaecology since January 1997. The PR has been in post at the centre since 1988 and has successfully completed the PR Entry Programme.

8. The Panel noted that the inspectorate identified some areas of improvement required to the following aspects of the centre's practice:

    - Demonstration and assessment of staff competency
    - Documentation of Welfare of the Child assessments having been conducted
    - Validation of some laboratory equipment, practices and processes.

9. The Panel noted the inspectorate's recommendation that the centre's licence should be renewed for a period of four years without additional conditions, and that the outstanding recommendations in the report should be delivered within the prescribed timeframes.

10. The Panel noted the breaches highlighted within the report and in particular the evidence of the welfare of the child assessment in accordance with the CoP S.7.6.4. The Panel supported the immediate action and noted the PR's response that it was being rectified in January 2010.

11. The Panel noted and welcomed the PR's response to the report and the areas of improvement required. Nevertheless, the inspectorate's recommendations and timescales were considered broadly proportionate.

12. The Panel noted that there is a concern over the numbers of staff at the centre, and noted that there were some posts vacant. The Panel recognises that the PR is actively recruiting for these posts and encourages the PR to monitor the levels of activity and available resources

13. The Panel noted on page 13 of the report that the live birth rates for this centre are significantly above the national average.

14. The Panel noted that the PR has completed the PR Entry Programme and that there are no issues regarding the character, qualifications, experience or ability to discharge the necessary duties under section 17 of the HFE Act 1990 (as amended). On the basis of the information provided, the Panel agreed that it was satisfied of the suitability of the Person Responsible and the premises.

15. The Panel agreed that it was satisfied that it had sufficient and satisfactory information on which to make a determination, and were in receipt of a signed application form and the relevant fee had been paid.

16. The Panel noted that the application form submitted was an old form, and that to cover the activity of 'use of embryos in training' the centre should submit an application to vary the licence to incorporate this activity.

17. The Panel referred to the guidance on periods for which renewed licences should be granted subsection 4.3, whereby the Panel considered the evidence in relation to the following areas:

    - Adherence to the regulatory principles published by the Authority
    - History of compliance with statutory requirements; Directions issued by the Authority; Licence Conditions; and the Code of Practice issued by the Authority
    - Compliance with recommendations made by Licence Committee/Executive Licensing Panel/Compliance Department

<u>The Panel's Decision</u>

18. The Panel agreed that the licence should be renewed for a period of 4 years with no additional conditions.

Signed.....Date.....4/2/10
Peter Thompson (Chair)