Interim Inspection Report

Wessex Fertility Centre
0057

Date of Inspection: 9th January 2007
Date of Licence Committee: 16th April 2007

CENTRE DETAILS

Centre Address	Anglesea House, 72 - 74 Anglesea Road, Southampton, SO15 5QS
Telephone Number	02380 706 000
Type of Inspection	Interim Inspection
Person Responsible	Susan Ingamells
Nominal Licensee	Claire Stollery
Licence Number	L0057/14/b
Inspector(s)	Parvez Qureshi
	Sarah Hopper
	Marion Witton
	Tahir Hussain
Fee Paid - date	07/02/2007
Licence expiry date	31/07/2009

Index

About the Inspection:
This inspection visit was carried out on the 9th January 2007 and lasted for 6 hours. The report covers the pre-inspection analysis, the visit and information received between February 2006 and December 2006.

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 interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the 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, recommendations 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.

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 Wessex Fertility Clinic has its own purpose built premises at Anglesea House and has a good history of regulatory compliance. A range of assisted conception treatments are offered to self funded patients. The Person Responsible is appropriately qualified and found to be familiar with administrative and managerial aspects of the service. Sufficient numbers of appropriated qualified and competent staff are employed at the centre.

The centre carried out 606 treatment cycles in the last year. The opening hours are from 8am to 4pm Monday to Friday and 8am to 12 pm on Saturdays. The doctors and embryologists are available 24 hours a day on a rota system.

There is an organisational structure in place which defines role of each member of staff. Since the last inspection there have been no changes in the premises.

Activities of the Centre

Licensed treatment cycles	606
Donor Insemination	12
Unlicensed treatments	Gift / IUI / Ovulation Induction
Research	None
Storage	Yes

Summary for Licence Committee

The inspection team recommends the continuation of the centre's license.

Risk Assessment

11%

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	X	

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 or Code of Practice

Breach	Action required	Time scale
None	None	N/A

Recommendations	Time scale
Communication – Review and improve the effectiveness of meetings and the dissemination of any outcomes.	As soon as possible
Male Production Room and the disabled toilet facilities - dual purpose of the room require consideration	Six months
The entrance to the centre needs to be signposted.	As soon as possible
Some files need to be better organised	As soon as possible

Proposed licence variations

None proposed

Changes/ improvements since last inspection

Recommendation	Action taken
The centre's protocol for assessing the welfare of Children born as a result of treatment did not reflect the current practice.	The immediate action was taken by PR and the new form with required changes was submitted to HFEA.

The patient information leaflet showed the results of live birth per embryo transfer.	The Person Responsible agreed to change it to Live birth per cycle.
The inspection team found errors in the consent forms	The HFEA team noticed that improvements have been taken in filling up the forms.

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 findings from inspection
Evidence is drawn from:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
A Quality Manual System (QMS) has been setup for the EU Tissues & Cells Directive EUTD application which has enabled the team to identify where improvements were needed and to put them into place. An organisational chart showing main functions and lines of accountability within the unit was submitted before the inspection. A new consultant and an embryologist have joined the unit recently. All new staff undergoes a comprehensive induction programme and evidence was provided to the inspection team. Health and safety issues have been put into place with advice from the Health Care Commission. The inspection team was informed by the PR that there are contingency arrangements in place in the event of an emergency with Bath Conception unit and agreements are in place between the two centres. Weekly management team meetings are held from which information is shared with other staff members. The counsellor is invited to staff meetings which are held to coincide with her contracted hours. It was pointed out by the inspectorate that the primary purpose of minutes is as a formal record of meetings and not as a substitute for communication. Few people read minutes. The PR stated that newsletters are provided every two weeks but more often if necessary for staff with key messages which are more likely to be read. The PR reported that teaching sessions are held for staff and HFEA alerts are raised at these sessions. The Senior embryologist had a copy of the most recent incident alert and had a specific file containing all previous alerts. Information from the HFEA finance department showed that there were no issues with the centre over the payment of treatment fees.

Areas for improvement
On many occasions staff are unable to attend meetings due to workload. The internal communication process requires review and updating.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All Areas covered

Evaluation
Some improvements required

2. Quality of service

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

Summary of findings from inspection:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates
The IVF/ICSI and FET success rates for all age groups are higher than the national average. The PR acknowledged that the DI success rates are below the national average. The Senior Embryologist stated that this was probably a result of the poor quality of donor sperm that they receive from donor banks. The PR is undertaking an investigation to try and identify how the DI rates could be improved. The Senior Embryologist stated that sperm donor recruitment has begun at the centre. The selection of the donors will be based on the sperm counts and they plan to be selective about who they take on. They are not advertising for sperm donors yet but plan to in the future.
Areas of firm compliance
The ethos of the centre, according to the PR, is to provide personalised attention and stress the individual package of care to patients. The centre is small enough for staff to get to know patients and they are encouraged to telephone with any concerns. Patient questionnaires issued by the centre acknowledge the personal care and attention provided by staff. The patient information provided to the inspection team included information on success rates. The PR explained that there is a suitable procedure for verifying patient's identity through their GP. The patients' records were seen to be stored in suitably secured cabinets with restricted access. All staff interviewed was aware of the confidentiality, privacy and dignity of the patients. A patient was interviewed and was found to be happy with the information she had received regarding her proposed treatment plan. She felt that an adequate time was given to read and understand the literature and ask questions to staff prior signing consent forms. All the consent forms are worked through in the presence of a member of centre staff. Arrangements for confidentiality are good. Not all staff have access to all areas and visitors to the centre (e.g. medical students) sign confidentiality agreements according to the PR.

The Child Protection policy was viewed as one female under 18 is being treated for hormonal problems.

Complaints are dealt with and improvements made accordingly. There is a complaint procedure which is clearly visible in the patient waiting area. The complaints are logged and all correspondence and resulting actions recorded. The complaints file was reviewed during the inspection visit.

There is a good uptake for counselling and patient feedback is positive. Patients are made aware of the counselling service via patient information and by staff. As part of the treatment cycle every patient has one meeting with the counsellor with any additional sessions being booked as required. Currently there is no waiting list. The counselling audit supplied for the inspection confirmed that there were a total of 209 referrals from January 2006 to December 2006, with implications followed by therapeutic counselling being the most frequent sessions.

Areas for improvement
Low DI live birth rates need to be investigated by the PR
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered.

Evaluation
Some improvements are required.

3. Premises and Equipment

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

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
Since the last inspection no major changes have been made to the premises. Access to the unit is restricted to staff only. The premises were found to be clean, private and suitable for the licensed activities on the day of inspection. The laboratory facilities have swipe card access and are fitted with locks. All the storage dewars were seen to be locked and alarmed, and the dewar top up record was seen. The inspection team considered the current cryostore facilities at the unit to be adequate for the volume of work being carried out. There is controlled access to the cryostore area which is fitted with a low oxygen monitoring system. All the dewars are alarmed. The inspection team considered that the protocols for responding to alarms were satisfactory. All key pieces of equipment were seen to have been serviced recently and a record has been kept of the service dates. A system of monitoring equipment is in place. No new equipment has been installed since the last inspection but new flow hoods are about to be ordered in line with the requirements of the EUTD. Due regard is given to preventing accidents, incidents and in the last year an exercise was undertaken where by staff were asked to identify potential hazards. The male production room is sited opposite the andrology laboratory and this room is also used as a disabled toilet. It was noted by the inspectors that there is no access for disabled people upstairs and they have to be seen downstairs.
Areas for improvement
The inspection team raised the suitability of the men's production room and were informed that due to limitations with space this is the only place that male partners could produce. The entrance to the centre needs to be signposted. The following suggestions were made to the centre:- Considering access for disabled people in the general clinic if the clinic expands Consider rearranging the waiting room to provide more privacy Providing better facilities for men's production room

Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered

Evaluation
Some improvements required

4. Information

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

Summary of findings from inspection:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
A sample of patients' records was reviewed during the inspection. These were found to be well organised. In cases where patients had had more than one treatment, the associated paperwork was not sufficiently well separated. Four records belonging to patients who had donated embryos for research were checked as a follow on from an inspection to the receiving centre (0121) last year. From these, an error was seen in one set of notes. According to the Senior Embryologist this had occurred on a weekend – although the consent forms were checked the discrepancy on the HFEA 007 form was not noted until the following Monday. At this point it was remedied with the patient re-doing the consent form. Movement of embryos to research on a weekend does take place. A new step has been put in place in these cases and all paperwork is checked by two embryologist on the Friday before hand. The Senior Embryologist explained that there are measures in place now ensure that all consent forms are correct. The Senior Embryologist stated that these witnessing steps had occurred but had not been documented. She has recently reviewed this and amended the witnessing checklist to include all parts of the procedure. Amended checklists were provided to the inspectorate.
Areas of firm compliance
The PR stated that the EDI responsibility is shared amongst the team members. The PR reported that all the paperwork has been updated as part of the QMS exercise and evidence was seen of a well organised document control from this exercise. The patient information was very comprehensive and this was evidenced by the inspection team and the view was shared by the patients interviewed. The files identified from the list of patients were found easily and within a quick timeframe. The centre has an arrangement with a Spanish Clinic in Marbella for a donor egg scheme. The work up for patient's treatment takes place at centre 0057 but actual treatment takes place in Spain. The success rates from the Spanish centre are said to be much higher than in England possibly due to the younger egg donors.

Areas for improvement
Patient reported that changes to information during treatment (i.e. charges for storage was not well communicated) Some files need to be better organised
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered

Evaluation
Some improvements required

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff (to be filled up by centre staff)

GMC registered doctors	
NMC registered nurses	
HPC registered scientists	
Scientists working towards registration	
Support staff (receptionists, record managers, quality and risk managers etc)	

Summary of laboratory audit
A rolling audit of stored samples is performed during the course of each year. A summary of the previous year audit was provided prior to the inspection. No discrepancies were reported. Regular internal audits of laboratory results are conducted. Statistics on fertilisation rate, cleavage rate and pregnancy rates are kept and are monitored by one embryologist. A folder containing this information was seen. Samples have been imported from the USA once but they do not plan to repeat this as it was a lengthy process. Batch numbers for disposables are kept and a note of culture media batch number is added to the laboratory sheets.

Summary of spot check of stored material
A spot check of gametes and embryos was performed during the inspection which included 2 sets of embryos from record to tank and 2 others from tank to records. No problems were noted during this. The same numbers of sperm samples were checked and again no problems were noted.

Areas of firm compliance
It was noted from the scientific inspector that all requested paperwork was produced quickly on request and was of a good standard. The PR stated that the clinic manager is responsible for organising recruitment of the new staff and the system is working well. Examples of staff files confirmed that references and professional registration were checked as is ID through checking passports. Verification forms have to be completed by male patients to confirm that they have produced the sample. Two versions of this form exist, one for patients who have produced at home and one for patients who produced at the centre. All sperm samples, not just oncology samples are split into two vessels. Embryos for oncology patients are split between dewars. Evidence of this was seen during the spot check. The CPD was assessed and a trainee embryologist stated that she is satisfied with the support she has received and began working at the centre in October 2006 following a training plan. Training logs include a list of competencies that are signed off and this includes a section on new equipment. Two trainees are currently employed in the laboratory, both are registered with ACE and one has begun the Certificate. The CPD for staff is paid by the centre's training budget. Recent in-house courses included life support. One nurse stated that she attended inter-European fertility meetings.
Areas for improvement
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered

Evaluation
No improvements required.

Report compiled by:

Name……Dr. Neelam Sood

Designation……HFEA Executive

Date……09/01/2007

Appendix A: Centre Staff interviewed

Seven members at the centre including two patients were interviewed.

Appendix B: Licence history for previous 3 years

21st June 2006

The Committee noted that the centre had previously been granted a one year licence. They decided to renew the centre's licence for a period of three years with no additional conditions.

Change of PR and Nominal licensee 2005

Licence committee on 09 February agreed to recognise Ms S Ingamells as a new PR and Ms L Wingham as a new NL.

Licence Renewal Inspection 10/03/2004

It was also noted that Mr G Masson continues as Person Responsible.

Notes
Mr Masson on 'gardening leave' from the 24th February – 24th March 2004, at the Princess Anne Hospital 0121, due to fraud allegations.

Centre 0057 & 0121 were historically inspected together. 0057 was set up as an independent centre in December 2003

2003

Licence Committee 18th December 2003
The Licence Committee agreed to vary the licence to recognise the change of premises of centre 0057 from 18th January 2004 from:

Wessex Fertility Unit
BUPA Hospital Southampton
Chalybeate Close
Tremona Road
Southampton
SO16 6UY

to:

Wessex Fertility Limited
Anglesea House
72-74 Anglesea Road
Southampton
SO15 5QS.

02380 706000 = New Phone number

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……

Name of PR……..

Date of Inspection……..

Date of Response……

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

On the 20th of March we received confirmation from the Person Responsible that the following actions have been taken in response to the recommendations made in the inspection report:-

- Effective communication by email is discussed with the staff explaining the need for it and all minutes of meetings and internal news-letters are now published on a central electronic location to which all staff has easy and continual access.
- The meeting time will also continue to be used as a seminar / training opportunity.
- Consideration has been given to improve the men's production room but no fundamental change is possible for this facility on the premises until more space is available. Samples may be produced in the home environment by arrangement.
- Wording agreed for new entrance sign to building. Awaiting for new sign board.
- Standard of Procedures now written for the improved organisation of filing in patients notes.

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

Signed……

Name……..

Date……

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

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

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

16 April 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 3

Wessex Fertility Centre (0057)
Interim inspection

Members:
Walter Merricks, Lay Member – Chair
Ruth Fasht, Lay Member
Jennifer Hunt, Senior Infertility Counsellor, Hammersmith Hospital
Hossam Abdalla, Director of Lister Fertility Centre

In Attendance:
Trish Davies, Director of Regulation
Frances Clift, Legal Adviser
Claudia Lally, Committee Secretary

Observing:
Roger Neuberg, Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary

Conflicts 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 (26 pages)
- no papers were tabled.

1. The papers for this item were presented by Neelam Sood, HFEA Inspector. Dr Sood informed the Committee that this centre is a stand-alone centre in purpose built premises. The centre has a good history of regulatory compliance and carries out around 600 treatment cycles per year. Of the four recommendations made by the inspection team (listed at page 7 of the inspection report) all but one of these have now been implemented by the centre. The remaining issue concerns the possibility of changing the male production room. The centre has agreed to take this into account at the forthcoming re-organisation of its premises to take place within the next six months.

2. The Committee noted the response of the Person Responsible appended to the report at annex C. In particular, the Committee noted the prompt response of the centre to the recommendations made by the inspection team.

3. The Committee agreed that the centre's licence should continue with no additional conditions.

Signed…… … Date……..
Walter Merricks (Chair)