Interim Inspection Report

Date of Inspection: 29 July 2010
Length of inspection: 7 hours
Inspectors: Bhavna Mehta
Paul Knaggs

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between April 2009 and 20 October 2010

Date of Licence Committee: 20 October 2010

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Executive Licensing Panel which make the decision about the continuation of the centre's licence.

Centre details

Centre Name	Wessex Fertility Limited
Centre Number	0057
Licence Number	L0057-16-C
Centre Address	Anglesea House 72 - 74 Anglesea Road. Southampton SO15 5QS
Telephone Number	02380 706000
Person Responsible	Dr Sue Ingamells
Licence Holder	Dr Chantal Dominique Simonis
Date Licence issued	01 August 2009
Licence expiry date	31 July 2012

Additional conditions applied to this licence	None.

Contents

Report to Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

The inspector considers that, overall there is sufficient information available to recommend the continuation of the centre's licence years without additional conditions.
The inspector also recommends that the Executive Licensing Panel requires that the Person Responsible complies with following recommendation within the prescribed timeframes set out in the inspection report:

- Validation of critical equipment and processes:
  Two laboratory processes were seen to have validated.
  The centre is encouraged to continue with the planned validation of processes, including the clinical processes and to complete the validation of all critical processing procedures.

Details of Inspection findings

Brief description of the centre and its licensing history:

Wessex Fertility Limited is located on the outskirts of Southampton in a purpose built two-storey building. The laboratory, theatre and recovery area are all located on the ground floor with secure access. The waiting area, consultation/treatment rooms, counselling facilities, administration and staff facilities are all located on the second level.

The centre was first licensed in 1992 and treats private and NHS patients. The centre has a satellite IVF arrangement with the Royal Bournemouth NHS Foundation Trust (HFEA licensed centre 0288) and the BMI The Hampshire Clinic (HFEA licensed centre 0285). The centre provides treatment, mainly to self funded patients. The centre appears to be well organised and managed.

The centre is open five days per week, Monday to Saturday, from 8am to 4pm. A range of treatment is provided every day.

The Person Responsible (PR) has been in post since February 2005. She is a consultant gynaecologist and obstetrician and has extensive experience within the reproductive medicine field. The PR is registered with the General medical Council and is on the specialist register.

Wessex Fertility Limited is involved in a research project, which uses human embryos donated for research. The research takes place at the University of Southampton, also licensed by the HFEA (R0142).

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1/04/2009 to 31/03/2010*
IVF	249
ICSI	461
DI	31
IUI	50

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

*These data were extracted from the HFEA register for the period 1/04/2009 to 31/03/2010. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. The live birth rates resulting from IVF /ICSI cycles in all age groups were in line with national averages.

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. The centre provides written general information on the cost of treatments to patients following initial consultation. The senior nurses follow this up with the patients, discussing and answering any queries. A personalised, written and costed treatment plan is provided to patients, once a course of treatment has been agreed. The plan details the main elements of the treatment proposed and the cost of that treatment.
What they could do better. None identified at this inspection.

Consent - particularly consent to disclosure to researchers and consent to storage
What the centre does well. The lead nurse demonstrated a good understanding of the requirements of consent taking, including consent to disclosure to medical or other researchers (so the researchers can contact the patient about specific research projects or carry out non-contact research), consent to storage (including the the12 month 'cooling off' period) and the parenthood provisions. Patient records include a signed consent to the disclosure of identifying information for use in research. HFEA consent forms and patient information sheets are provided to patients at initial consultation. Audits of patient records are conducted by two members of the nursing and a member of the embryology staff to verify that patient consent, including consent to disclose identifying information, is accurately documented. Any errors or omissions are documented and corrective actions taken.
What they could do better. None identified at this inspection.

Multiple births

What the centre does well.

The PR reported an overall multiple pregnancy rate at the time of inspection (2009 audit) of 17%.

In compliance with Directions 0003, the centre has provided evidence that the centre maintains a documentary record of their Multiple Births Minimisation Strategy (MBMS), including:

- how the centre identifies suitable cases for single embryo transfer (SET), including criteria in relation to embryo assessment and patient selection criteria
- how the centre aims to reduce the multiple birth rate and how to ensure that the rate does not exceed the maximum specified rate of 20% (target for 2010/11)

The centre maintains a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer as set out in the strategy.

Where more than one embryo has been transferred the centre has recorded in the patient's records an explanation of the reasons for transferring more than one embryo in that particular case and a note confirming that the risks associated with multiple pregnancy have been fully discussed with the patient.

Where three embryos or four eggs are transferred the centre has provided detailed record in each patients records explaining the reason for transfer and provided a summary log in the format laid out in directions.

The centre has carried out regular audits and evaluations of the progress and effectiveness of the strategy.

The PR explained at inspection that the MBMS strategy has been revised.

What they could do better.

None identified at this inspection.

Validation of critical equipment and processes

What the centre does well.

All critical equipment and technical devices are identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions. Where equipment or materials affect critical processing or storage parameters, these are also identified and appropriately monitored, and the necessary corrective action is taken.

At inspection, two laboratory processes were seen to have validated. This validation was based on studies performed by the establishment itself and on data from published studies.

What they could do better.

The centre is encouraged to continue with the planned validation of processes, including the clinical processes and to complete the validation of all critical processing procedures. The centre staff may wish to use the Association of Clinical Embryologists validation templates.

Witnessing

What the centre does well.

The centre's witnessing practise is to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory processes. Witnessing checks are recorded in patient/donor medical records. These records include the signature of both the person performing the activity and the person who witnesses the procedure. The date and time of the witnessing check is recorded. Standard Licence condition T71 requires the name and status to be recorded and the centre maintains this on the signature log of staff that carry out the witnessing activity and checks.

The centre carries out regular audits of patient records are conducted by two members of staff to verify that witnessing checks are recorded. Any errors or omissions are documented and corrective actions taken.

What they could do better.

None identified at this inspection.

Gamete and embryo donation – reimbursement, information provision and screening
What the centre does well. The reimbursements made to donors are restricted to expenses incurred in the UK. The centre offers weekend appointments so as to avoid compensation for loss of earnings. The centre reimburses the actual expenses incurred where the donor provides receipts. The centre verifies car mileage claims by checking the distance to the centre using a motoring organisation's website. All other claims are verified in accordance with the centre's protocol. This protocol was reviewed at inspection and is compliant with the requirements of Direction 0001.
What they could do better. None identified at this inspection.

Welfare of the Child (in relation to basic partner treatment services only)
What the centre does well. The PR and staff provided verbal and written evidence that before any woman is provided with any treatment services account is taken of any child born as a result of treatment by the staff at the centre. The counsellor is available for both staff and patients/partners to discuss or further explore any issues that may be raised when considering the welfare of any child born as a result of treatment.
What they could do better. None identified at this inspection.

Embryo testing (if applicable)
What the centre does well. This theme does not apply to this centre.
What they could do better. N/A

2. Changes / improvements since the last inspection on 7 April 2009

Area for improvement	Action required	Action taken as evidence during this inspection
The centre has not established processes: • to determine the effectiveness of the Quality Management System (QMS) (CoP S.9.2.4), • for evaluation and assessment to ensure continual improvement of the QMS (S.9.5.1), • for quality indicators (S.9.5.2), • for developing a system for monitoring and assessing laboratory and clinical practice (S.9.5.3.) or 1. to carry out a management review of the QMS (S.4.2.4).	It is recommended that the person responsible reviews the requirements of Code of Practice (CoP) S.9 to ensure that procedures for the evaluation and improvement of the quality of the service provided are developed and implemented. The person responsible should also ensure that a management review of the quality of the service is carried out in line with the requirements of S.4.2.9.	Action taken. The centre has put in place a quality management system and implement this system to continually improve the quality and effectiveness of the service provided in accordance with the conditions of their licence and the guidance on good practice as set out in the HFEA's Code of Practice. No further action required.
The counselling room is not provided in quiet surroundings.	It is recommended that the PR reviews the counselling facilities requirements of CoP S.6.3.5.	Action taken. The room has been sound proofed and signage is in place to indicate when room is in use. No further action required.
Training files for the laboratory staff, reviewed at inspection, did not show how the individual had demonstrated confidence in the performance of their designated tasks. This is a breach of licence condition A 10.11and CoP S.6.2.9.	It is recommended that the PR reviews the licence condition and the CoP requirements to ensure that the competence of each person to perform designated activities been evaluated at intervals as specified in the QMS and re-training undertaken when required (S.6.2.9) and document this assessment (A.10.11).	Action taken. Training files show that staff training has have been updated as required and adequate opportunity for relevant professional development is provided. They document that each individual has demonstrated competence in the performance of their designated tasks. No further action required.

3. Areas of concern

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

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
None		

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non compliance requires immediate action to be taken by the Person Responsible

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
None					

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Validation of critical processes: Two laboratory processes were seen to have been validated. The centre is encouraged to continue with the planned validation of processes, including the clinical processes and to complete the validation of all critical processing procedures.	T72	Complete the validation of all critical equipment and processes (laboratory and clinical). The PR should submit a detailed plan, including a list of all critical processes to be validated and quarterly reports to the centre's inspector regarding the progress of implementation of this plan until it is completed.	31 October 2010	Validation of the laboratory and clinical porcesses is an ogoing priority in the clinic. Further validations have been completed since the inspection and all will be completed within 6 months. A full programme with a detailed plan will be submitted as requested by 31.10.10.	The PR's comments are noted. The detailed plan, including a list of all critical processes to be validated and quarterly reports to the centre's inspector regarding the progress of implementation of this plan should be submitted by 31 October 2010.

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from good practice.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
None.					

Additional Information from the Person Responsible

HFEA Executive Licence Panel Meeting

20 October 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 6

Centre 0057 (Wessex Fertility Limited) - Interim Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Nick Jones, Director of Compliance Juliet Tizzard, Head of Policy	Joanne McAlpine Observing: Claudia Lally, Compliance Business Support

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The centre, which provides treatment to both NHS and private patients, obtained its first licence in 1992. The centre has a satellite IVF arrangement with the Royal Bournemouth NHS Foundation Trust (centre 0288) and BMI The Hampshire Clinic (centre 0285). It has a good history of regulatory compliance and the current licence, active until 31 July 2012, has no additional conditions placed upon it.

2. The Panel noted that the Person Responsible (PR) has been in post since February 2005, is a consultant gynaecologist and obstetrician and has extensive experience within the reproductive medicine field. The PR is registered with the General Medical Council and is on the specialist register.

3. The Panel noted that the centre is a large centre and has carried out 209 treatments during 2009/10.

4. The Panel considered the Interim Inspection Report and was satisfied that the centre was broadly compliant. The Panel noted that there were some areas of non-compliance highlighted within the report. However, it was satisfied that the PR has committed to implement all remaining recommendations within the required deadlines.

5. The Panel agreed that since the previous inspection in 2008, there is good evidence of compliance.

Decision

6. The Panel agreed to the continuation of the centre's licence without any conditions placed upon it. The Panel endorsed the Inspectorate's recommendations and associated timeframes for the PR to meet these recommendations.

Signed: Peter Thompson Date: 2/11/2010.

Peter Thompson (Chair)