Renewal Inspection Report

Wessex Fertility Limited
0057

Date of Inspection: 7th April 2009
Date of Licence Committee: 22nd June 2009

Index

Centre Details

Person Responsible	Dr Susan Ingamells
Nominal Licensee	Claire Stollery
Centre name	Wessex Fertility at the Freya Centre
Centre number	0057
Centre address	The Freya Centre, 72 – 74 Angelsea Road, Southampton, SO15 5QS
Type of inspection	Renewal
Inspector(s)	Bhavna Mehta Ellie Suthers Steve Lynch
Fee paid	Yes
Licence expiry date	31st July 2009
NHS/ Private/ Both	Private

About the Inspection:

This inspection visit was carried out on 7th April 2009 and lasted for 8 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

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 approximately 300 cycles of licensed treatments a year, the majority being self funded. The centre appears to be well managed and organised.

The centre is open five days per week, Monday to Friday, from 8am to 4pm and sometimes on Saturdays, depending on the centre's workload. 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. A management buyout of the centre occurred in December 2007 and the PR together with another consultant who works at the centre are now the new owners. The Nominal Licensee, remains in post although it is expected that this will change in the near future. To date, the buyout has had no impact on staffing and the day-to-day management of the centre.

The PR reported that now the management buyout has taken place, they are looking to invest and improve several aspects of the service. These business plans also involve a review of success rates and appropriate investment to improve them and support safe business expansion.

Wessex Fertility Limited is involved in two research projects, one of 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[1] for the time period from 01/01/2007 to 31/12/2008

In vitro fertilisation (IVF)	124
Intracytoplasmic sperm injection (ICSI)	096
Frozen embryo transfer (FET)	067
Donor insemination (DI)	0
Gamete intrafallopian transfer (GIFT)	0
Research	no
Storage gametes/embryos	yes

[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.

Activities of the centre[2] for the time period from 01/01/2007 to 31/12/2008

Intra uterine insemination (IUI)	34

Summary for Licence Committee

The person responsible (PR) has been in post since 2005. The centre was first licensed in 1992 and treats NHS and privately funded patients.

Some improvements are required relating to the centre's premises and equipment practice and significant improvements are required relating to the centre's laboratory and clinical processes.

The inspection team is concerned that the effect of a number of outstanding issues may be impacting on the effective operation of the centre. The issues include:

1) Establishing a quality management system and continually improving its effectiveness as set out in the Code of Practice (CoP).
2) Provision of counselling facilities as set out in the CoP.
3) competence of staff, to perform designated activities, has not been evaluated and documented as set out in the CoP and the licence conditions.

It is recommended that the PR provides information on the measures and steps to be taken to address all breaches highlighted in this report.

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

[2] Activity relating to IUI with partner sperm is provided to the HFEA in the form of an annual return. 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.

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
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 • 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.	By the date of the next inspection.
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.	By the date of the next inspection.
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).	By the date of the next inspection.

Non-Compliance

Area for improvement	Action required	Time scale
None		

Recommendations

Area for improvement	Action required
None	

Changes/ improvements since last inspection

Recommendations	Action Taken up to the date of this inspection
Standard 9.4.2 (c) notification of the HFEA, by the Person Responsible, of Adverse Incidents and the subsequent provision of a confirmation/conclusion report. A single incident log should be maintained and all staff should be made aware of HFEA incident requirements.	The PR confirmed in Appendix C of the report that this was completed and a single log book maintained.
In the audit of one medical record, it was noted that the male partner had consented to posthumous use of embryos in a surrogacy arrangement. However he had not undergone appropriate screening as a donor, in accordance with standard licence condition A.7.1. Donors should be appropriately screened in accordance with Standard Licence Condition A.7.1	At this renewal inspection, the PR stated that all donors are screened in accordance with the licence condition. A review of donor notes reviewed at inspection verified this.
Standard 7.8.3 - procedure validation is not yet performed. Laboratory procedures should be validated.	At this renewal inspection, the inspectorate was told by that the centre has started the validation process (see body of report page 20 for further information).
Standard 9.2.6 – inter-laboratory comparisons have not yet been undertaken. The PR should implement inter-laboratory comparisons.	At this renewal inspection, the inspectorate was told by that the centre has started the process of inter-laboratory comparisons (see page 15 for further information).

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

Leadership and management

The person responsible (PR) has been in post since 1995.

On arrival at the centre, the inspectorate noted that the centre's licence was not displayed. A member of staff was advised that the centre should ensure that a copy of the Certificate of Licence (first page of the licence) describing the activities authorised by the licence is displayed at the licensed premises in a position or positions in which it can easily be read by persons who are receiving treatment services or providing gametes or embryos for use for the purpose of activities governed by the Act, or who may wish to do so. The staff explained that the licence and the complaints policy had been taken off display during the recent refurbishments. The staff responded immediately to the inspectorate's request to display the licence and complaints policy. The current licence was seen displayed in the waiting room before the inspection team left.

The PR stated that the centre is reviewing the organisational structure of the centre and staff roles. The PR is considering varying the licence to change the nominal licensee and will notify the inspectorate in due course.

Organisation of the centre

The centre has a clearly defined management structure, which regulates all activities within it. This was clearly illustrated in the centre's organisational chart supplied with the pre inspection questionnaire (PIQ).

Resource management

The number of cycles has marginally increased since the last inspection. The staffing level has also been increased to accommodate the extra work. The activities and resources

needed are continually reviewed in terms of staff, facilities, equipment, materials and information systems.

Clinical governance and Incident management
The centre has in place a protocol for assessing and reporting clinical governance issues. This protocol is compliant with the requirements of the Code of Practice (CoP) and the HFEA Direction. The PR has stated that the centre promotes a 'no blame culture' and that all staff are aware of need to report incidents.

The PIQ states that incidents are discussed during informal discussions and organised meetings. There is a process for continual improvement monitoring.

Incidents are flagged up by the individual who discovered, or is notified of the event, by completing the 'adverse event' form and passing it to their line manager who investigates it (including risk assessing the incident) and reporting it to the PR/managing director. The inspection team were shown a log of all incidents and the content concurred with information reported to the HFEA. The inspection team encouraged the ongoing reporting of incidents to the HFEA.

Risk management
Processes are in place for the recording of all non-conformities identified in processes along with corrective/preventative actions taken. All staff are encouraged to use risk assessments as a tool to monitor hazards/risks. The PIQ states that various work areas have been risk assessed this year, including transferring sperm/embryo to and from another licensed centre.

At the inspection, staff explained that risk assessments are conducted as per the centre's protocol. The risk assessment folder was reviewed by the inspectorate at inspection. All protocols are available electronically to all staff on the centre's shared drive.

Alert management
HFEA Alerts are received by the PR and disseminated to relevant departmental managers. Urgent action can be taken, if required, after discussion between them. HFEA Alerts are also discussed at the management team meetings as a standard agenda item and, if relevant, at monthly departmental meetings.

Complaints management
The centre has a complaints policy. On the day of inspection, this was displayed in the waiting room (please see comment above in the leadership and management paragraph). The centre has a written protocol for handling complaints that refers to the HFEA CoP requirements. The induction training for all new staff includes complaints handling. The centre logs, reviews and uses the data to improve the service. A patient interviewed, told the inspectorate that the centre's complaints protocol was part of the patient information pack she received before commencing treatment.

Contingency arrangements
The PIQ states that two or more managers are always available on the premises. On-call rotas ensure a doctor is on call at all times for emergencies; key-holders are on call at all times and managers have levels of authority which can be exercised in the PR's absence. This was confirmed during discussion with the PR.

A documented, formal arrangement, with Bath Assisted Conception Unit, is in place to accept delivery and responsibility for the centre's stored samples. The centre is investigating options to offer patients (in treatment) continual treatment elsewhere to cover contingencies.

The centre has a documented policy and procedure for admitting patients to hospital under emergency conditions. All patients have access to a consultant/doctor 24 hours a day by way of an emergency telephone-line.

The centre has a backup generator and can run continually for up to 26 hours on one full tank of fuel.

Establishment of third party agreements
Third party agreements (TPA) have been established with suppliers of goods or services where the goods or services may impact on quality of gametes/embryos. The TPA log and a sample of these agreements, reviewed by the inspectorate, demonstrated compliance with HFEA guidelines.

Meetings / dissemination of information
There is an effective means for communicating with and receiving information from staff. The PIQ states that staff meetings take place regularly (operational meetings, board meetings, team meetings and multidisciplinary meetings) from which notes and minutes are disseminated to personnel via word of mouth, notice boards, emails, newsletters. Minutes are also available for all staff to view on the centre's network system.

Payment of licence/treatment fees
At the date of inspection, the centre was complaint with standard licence condition A.16.3, having paid all HFEA invoices within the 28 days.

Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
No improvement required.
Areas not covered on this inspection
All areas covered.

2. Quality of service

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

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

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

Live birth rates[1]
In the time period from the 1 January 2005 to 31 December 2007 the centre's outcomes were in line with the national average.
Areas of firm compliance
Quality management system The centre has a quality manager in post who is also the centre's practice manager and Nominal Licensee (NL). The centre is working towards ISO accreditation and hopes to complete it later this year. Newly released documents are notified to staff at departmental meetings and electronically, by email. The centre reviews activity and provide the resources needed to safely achieve it, in terms of personnel (having recently recruited a number of new staff across the centre), facilities (having recently completed an upgrade of laboratory areas), equipment and materials (having purchased new equipment including incubators and blood pressure monitors). At inspection, the PR explained that the PR and the other consultant owner of the business have drawn up the centre's business plan for this financial year, reviewed activities and prepared projected plans. The business plan specifies key performance indicators (KPIs) for treatments offered (fertilisation rates / 2PN cleavage rates / biochemical and clinical PR pregnancy rates), patient satisfaction, audits and practitioner competency audits (e.g. ICSI practitioner KPIs and embryo transfer practitioner results). **Feedback** The PR explained that the staff encourage patients to express their views on their treatment. Patient satisfaction questionnaires were seen displayed in the waiting room and patients are asked to complete these. The PIQ states that feedback questionnaires are collected from visiting patients during open evenings. During the inspection, staff said that they are actively encouraged to participate in meetings and make suggestions for improvements or changes in the services provided. Evidence of this was seen recorded in the minutes of staff meetings.
Areas for improvement
The centre's quality management system (QMS) is in the very initial stages of development

and the centre should further develop an internal audit process to determine whether the QMS satisfies the requirements of the CoP (S.9.2.4.). The centre has not implemented procedures for evaluation and assessment to ensure continual improvement of the QMS (S.9.5.1), developed a system for monitoring and assessing laboratory, clinical and counselling practice (S.9.5.3.) or carried out a management review of the QMS (S.4.2.9). Feedback from patients has not been gathered or evaluated.

The PR explained at inspection the centre's process to make sure that all documents are version controlled: the footer on every document identifies the date of review, author, version number and where the document is located. However, some of the documents provided with the pre inspection questionnaire did not show evidence of document control. It is recommended that a document control procedure be established to provide for the history of document reviews and changes and to ensure that only current versions of documents are in use in line with the requirements of S.5.2.6 and A.10.27. At inspection, both the PR and the quality manager acknowledged that the QMS is a work in progress, explaining that following the inspection, the QMS is to be developed further to achieve ISO accredited later this year.

It is recommended that the PR reviews the requirements of section S.9 of the CoP and ensures that procedures for the evaluation and improvement of the quality of the service provided are developed and implemented. The PR 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.

Areas for consideration
None.
Executive recommendations for Licence Committee
The Licence Committee is asked to endorse the recommendations made in relation to: 1) Further development of the QMS 2) Document control procedures.
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
Premises Access to the centre is controlled by use of an entry phone into the centre and keypad entry locks once inside. On the day of the inspection, the premises and facilities appeared well maintained and suitably equipped. The centre appears to provide a safe working environment and at inspection, this was confirmed by staff interviewed. Arrangements are in place for cleaning, facilities maintenance and waste disposal. The centre has written protocols in place and records to demonstrate compliance were seen at inspection. **Clinical facilities** On inspection, it appeared that the centre has premises and facilities suitable for the activities for which it is licensed including facilities for reception, clinical and laboratory work and staff. Clinical facilities, including the consulting and scanning rooms ensure that patient/donor privacy and dignity are maintained. The centre has three treatment/consulting rooms and a dedicated quite room within the main clinic area. The clinical facilities appeared to provide for the privacy and comfort of those undergoing treatment. **Laboratory facilities** Laboratory facilities, including equipment, premises and materials are designed and maintained for their intended purpose, minimising risks to gametes and embryos and hazards to patients and staff. The centre has ten dewars, located in two secure areas. Health and safety measures are in place including, low nitrogen alarms fitted to all dewars, low oxygen monitors in the laboratory and cryostore areas, auto-dialler and an external indicator warning system to prevent staff entering an oxygen depleted atmosphere. The alarms connect to an auto-dialler and the centre has a documented procedure in place for responding to an alarm in case of an emergency. Laboratory facilities (ie equipment, premises and materials) are designed and maintained for their intended purpose, minimizing risks to gametes and embryos and hazards to patients and

staff.

The staff explained that current professional guidelines, legislation and regulations are followed in the laboratory and procedures comply with these. The centre's pathology laboratory is CPA accredited and participates in inter-centre/inter-laboratory comparisons (NEQAS) and external reviews: regular visits to other units and centres are made by staff from the centre. Informal networking takes place at professional meetings and training sessions. Feedback is provided to the team by staff who have visited other centres and information is exchanged continually between centres. The centre is in discussion with another local unit (HFEA licensed centre: Salisbury Fertility Centre (0197)) to arrange a more formal exchange of information, evaluation and review.

Air quality
Air quality in the laboratory is compliant with the requirements of the CoP. The centre has in place, a protocol for air quality monitoring which was seen on inspection. Test results seen at inspection for the period from January 2009 to 31st March 2009 confirmed that the processing of gametes and embryos occurs in an environment of Grade A air quality, with a background of Grade D.

Management of equipment and materials
It was observed at inspection and the staff reported that CE marked consumables only are used thereby meeting the requirements of the relevant Directives. Service records and certificates of calibration reviewed at inspection showed that critical equipment is identified and validated. The equipment was seen to be fitted with alarms to detect malfunctions and defects and the weekly monitoring log was seen at inspection.

Storage facilities for gametes and embryos
It was seen at inspection that the centre store gametes and embryos under conditions designed to ensure quality and safety. The centre has a separate quarantine tank for donor sperm and a separate tank for embryos to prevent mix up and cross contamination. All the dewars were seen to be alarmed.

It was observed that gametes and embryos are stored in a secure area and in secure dewars, with restricted access to authorised staff only. There is a documented procedure to deal with damage to dewars (N2 leak) or non-conformities in storage conditions (temperatures). The centre has a spare tank for use in case of an emergency.

Staff facilities
Staff facilities were seen at inspection and appeared to be compliant with the requirements of the CoP. Staff reported that they find the facilities suitable. The centre has provided staff with appropriate garments and equipment for personal protection and hygiene, toilet accommodation, a rest area with basic catering facilities and a supply of drinking water, a changing area and secure storage for personal effects and storage for protective clothing.

Storage of records
The PR has stated that all electronic records are protected with passwords with restricted access. All hardcopy records are stored and protected with double locking and restricted access.

The centre has in place a standard operating procedure (SOP) for disclosure of information.

The centre backs up electronic information, has secure firewalls in place to protect electronic information and all patient notes are locked in secure areas.
Areas for improvement
Counselling facilities The counselling room is situated off the main waiting area and is also used as a consulting room. It was observed at inspection that counselling facilities are not provided in quiet surroundings. There is no signage on the door to maintain privacy when the room is in use. The counsellor confirmed that this room is not ideal but considered it better than the room used previously. S.6.3.5 CoP requires centres to ensure that Counselling facilities are provided in quiet and comfortable surroundings in which sessions can be held that are private, confidential and without interruption. It is recommended that the PR reviews the Counselling facilities requirements of CoP S.6.3.5.
Areas for consideration
None.
Executive recommendations for Licence Committee
The Licence Committee is asked to endorse the recommendations made in relation to: The requirements of counselling facilities.
Evaluation
Some improvement required.
Areas not covered on this inspection
None.

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

General information regarding the centre, opening times, facilities and location are available on the centre's website and in written pre-appointment information sent to all patients. Comprehensive written patient information is readily available. Information relating to patient support groups, local meetings and the complaints procedure was displayed in the patient waiting areas.

Written information for those considering treatment, donation or egg sharing provided by the centre appears to be clear, comprehensive and easily understood. A review of patient information was compliant with the requirements of the CoP. A patient interviewed during the inspection stated that she felt the information she had received by post and at meetings with staff, was easy to read and understand. The patient explained that consent forms and welfare of the child issues were explained and that the staff at the centre gave the patient time to consider and reflect on the information. The patient confirmed that she was offered counselling sessions. A review of patient notes clearly documented the centre's system (checklist) of ensuring that patients receive the information they need before consenting to treatment.

Consents

There are documented procedures ensuring no activity involving gametes of embryos is carried out without the appropriate consents. The laboratory staff double check the consents check list and sign off before conducting treatment. A sample of patient records were reviewed at inspection and consents were found to be present and consistent with the treatments provided.

Welfare of the child

The PIQ states that if staff are suspicious of factors that may cause physical, psychological or medical harm to either an unborn child or an existing child, any staff (including the centre's counsellor) can raise such issues with their manager and if necessary, the issues may be referred to the centre's ethics committee. The centre has a standard operating procedure (SOP) in place to ensure that proper account is taken of the 'Welfare of the Child' (WOC) who may be born as a result of treatment services or of any other child who would be affected by the birth. The centre deals with potentially contentious WOC cases by referral to the ethics committee and the PR reported that she has recently refused treatment to a couple on advice from the ethics committee.

Access to health records The centre has a documented procedure in place for responding to a request by a patient for a copy of their medical notes. **Provision of information to the HFEA register** The HFEA Register department reported that the centre is compliant with the reporting of data requirements.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
None.
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	3
NMC registered nurses	4.5
Non NMC registered clinical staff	1.5
HPC registered scientists	2
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	11
Counsellors	0.25

Summary of laboratory audit
A summary of the findings of an audit of stored material was reviewed at inspection. Minor discrepancies were found in database records and these have been amended.
Summary of spot check of stored material
A spot audit was carried out on the day of inspection: eight samples were checked, as follows: • two sperm samples from dewar to file and two from file to dewar and • two embryo cryos form dewar to file and two from file to dewar. No discrepancies were found.
Areas of firm compliance
Staff training and competency The PIQ states that there are processes in place to monitor and record staff competencies and for staff annual appraisal. On inspection, discussion with staff and an audit of the staff training files demonstrated that staff are given a job description and initial basic (induction) and update training is provided, as appropriate. Comprehensive records of training and

competencies were seen for clinical staff. The nurses reported having attended courses and conferences relating to their specific responsibilities including scanning courses and skills refresher training. On the day of inspection, the staff were involved in mandatory training workshops.

The counsellor reported that she is a qualified fertility counsellor with approximately ten years experience. The counsellor is a member of BICA and regularly attends the BICA study days.

Clinical practice

Screening

The centre runs a sperm donor recruitment programme; egg sharing programme and an embryo and egg donation program. The PR has stated that all donor screening is conducted in compliance with professional body guidelines (BAS and BFS).

- ***Multiple births***

The centre has a multiple births minimisation strategy and a log for the documentation of cases in which multiple embryos have been transferred back, is kept in the laboratory, in accordance with the HFEA Direction 2008/5. This log was reviewed at inspection showing no entries.

Laboratory practice

At inspection, the donor information and screening packs were reviewed which provided evidence of compliance with the CoP requirements on recording information for all donors registered at the centre.

The documented laboratory procedures ensure that donated gametes are not used or distributed after the donor has reached the 10 family limit. The centre has processes in place, undertaken by the specialist nurses and embryology Manager, to monitor this CoP requirement-the centre's spreadsheet log was reviewed at inspection which demonstrated compliance.

Procurement, distribution and receipt of gametes and embryos

At the inspection, the inspection team were provided with the documented procedure for the receipt of sperm received from patients that produced their sample at home or at another location away from the centre which demonstrated compliance with CoP.

The centre's documented procedure for procurement, packaging, distribution, recall and receipt of gametes and embryos, reviewed at inspection, was seen to be complaint with the requirements of the CoP.

Traceability and coding

Procedures are in place to ensure all gametes and embryos and data relating to anything contacting them, are traceable from procurement to patient treatment or disposal and vice versa. The centre has a written protocol in place and the staff demonstrated that the procedure is followed.

Selection and validation of laboratory procedures

The centre participates in the inter-laboratory and internal quality assurance process provided

by the National Quality Assessment Scheme (NEQAS). This is in addition to the centre's quality process checks in collaboration with Salisbury Fertility Centre (HFEA licensed centre 0197). Further, staff reported that they are looking to participate in the ACE embryo scheme when it is finalised.

Witnessing
The inspectorate observed at inspection that each time gametes or embryos are handled, the process is witnessed and documented on the embryology work sheets. The centre has a written protocol in place for witnessing.

Counselling practice
All patients have access to a Counsellor either directly or appointments made via the centre's administration personnel. The centre has contingency access to an alternative, relevantly qualified, experienced counsellor who can be available should an alternative counsellor be required.

Counselling audit
The counselling audit for the period February 2008 to January 2009 was submitted prior to the inspection. The audit report documents that 137 counselling sessions were provided in this period.

Storage of gametes and embryos
Gametes and embryos are not stored beyond the maximum period consented for by the patient or as required by the law. The centre operates a bring-forward system in order to ensure sufficient advance notice of the end of the statutory storage period for gametes or embryos in storage, is given to patients. Discussion with staff demonstrated that audits of gametes and embryos in storage are conducted in accordance with the centre's documented procedure, which was reviewed at inspection and meets the requirements of the CoP.

Areas for improvement

Staff training and competency
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 10.11 and CoP S.6.2.9. The PR should review 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).

Areas for consideration

None.

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to:
Staff training and competency assessment requirements.

Evaluation

Some improvement required.

Areas not covered on this inspection

All areas covered.

Report compiled by:

Name: Bhavna Mehta

Designation: Inspector

Date: 8th April 2009

Appendix A: Centre staff interviewed

PR Centre staff

Appendix B: Licence history for previous 3 years

May 2008: Improvements to the premises since the last inspection in January 2007 include a more private reception area and refurbishment of the male production room. The Committee decided that the centre's licence should continue with no additional conditions. May 2007: Variation of Licence under the EUTCD legislation The Committee agreed to vary the centre's licence to incorporate the requirements of the EUTCD. 16 April 2007: Consideration of interim inspection report. An interim inspection was carried out on 9th January 2007. In response to the inspection findings, the Committee agreed that the centre should continue with no additional conditions. 21 June 2006: Consideration of renewal inspection report. 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.

Appendix C: Response of Person Responsible to the inspection report

Centre Number…0057……

Name of PR……Susan Ingamells…….

Date of Inspection…07.04.09……..

Date of Response…29.05.09……

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

Signed……

Name…Susan Ingamells…….

Date……29.05.09……

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.

Page 5 the centre is open every Saturday for urgent scans and urgent clinical work, routine embryo transfers and for a counsellors clinic from 0800-1300 In 2008 523 cycles of IVF+/- ICSi were undertaken Both NHS and Private work in undertaken at the Centre The activity figures in the table on page 5 are incorrect but correct figures have been submitted to HFEA. Is this data erroneous and do we need to supply you with new data spanning these two years for the purposes of this report.

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

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

1.The arrangements have been made for the counsellor to move from her current room to a quieter consulting room at the Freya Centre and will take place with immediate effect.

2. The Final steps of Completing the QMS process in the clinic have re-started following he inspection and completion is timetabled for dec 2009 when IS0 ())! Will also be applied for.

3. The laboratory competencies have been completed for the technical staff and trainees. These are in the process of completion for the trained embryologists.

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

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.

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Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

HFEA Licence Committee Meeting
22 June 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Wessex Fertility Centre (0057) – Licence Renewal

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Jennifer Hunt (counsellor) Hossam Abdalla (clinician)	Kristen Veblen Legal Adviser: Mary Timms, Field Fisher Waterhouse Observers: Mark Bennett, HFEA Peter Thompson, HFEA

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 (36 pages)
- no tabled papers.

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.

1. The Committee noted that the Centre was first licensed in 1992 and that the Centre's current licence would expire at the end of July.

2. The Committee considered the papers, which included the renewal inspection report, the renewal application form and previous Licence Committee minutes from 12 May 2008.

3. The Committee noted that the renewal inspection had taken place on 7 April 2009 and that improvement was required in the following areas:
   - establishment of a Quality Management System (QMS) and review of that system, in accordance with Standard 9 of the 7th Code of Practice
   - provision of counselling facilities compliant with the 7th Code of Practice, S.6.3.5
   - regular competence assessments of staff as described by 7th Code of Practice, S.6.2.9.

4. The response of the Person Responsible (PR) was noted by the Committee. It was considered to address the three breaches identified by the inspection and to outline planned action within a reasonable timeframe, in line with that recommended by the Executive.

5. In particular, the Committee was pleased that prompt action had been taken in relation to provision of more suitable counselling facilities and that the completion of the QMS process had been restarted following the inspection.

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

6. The Committee noted that there were no issues regarding the character, qualifications or experience of the Person Responsible or her ability to perform her duties under section 17 of the HFE Act 1990 (as amended). The Committee agreed that the PR had throughout her tenure discharged her responsibilities as PR satisfactorily and the Committee was satisfied she continued to be a suitable PR.

7. On the basis of the information provided by the report, which demonstrated that the Centre's premises met the statutory requirements and had been shown to be fit for purpose (apart from the counselling facilities, which had now been addressed by the Centre), the Committee was satisfied of the suitability of these premises.

8. The Committee agreed that it was satisfied that the breaches in relation to the Centre's practices had been, or were in the process of being corrected

and on this basis agreed that it was satisfied as to the suitability of the practices used by the Centre.

9. The Committee noted that it was in receipt of a signed application form and that the relevant fee had been paid.

10. Although satisfied with the response of the PR detailing progress in relation to the breaches, the Committee remained particularly concerned that a QMS was not yet in place and fully implemented at the Centre, and had not been checked by the inspectorate to ensure that it was in place and fully implemented. For this reason the Committee decided to grant a licence for a period of three years, rather than five, without any additional conditions.

11. For the same reasons, the Committee recommended that the Executive inspect the Centre within a period of 12 months from the grant of the renewal to ensure that suitable action had been completed in relation to counselling facilities, staff competency assessments and in particular the Centre's new QMS.

Signed..... Date..7/July/09
David Archard (Chair)