Inspection Report

Date of Inspection: 7 & 8 February 2012
Purpose of inspection: Renewal of Treatment and Storage Licence
Length of inspection: 12 hours
Inspectors & Auditors: Bhavna Mehta; Ellie Suthers; Lynne Nice; Siobhain Kelly & Rick Gourd

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 29 July 2010 and 10 April 2012.

Date of Executive Licensing Panel: 20 April 2012

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the Code of Practice (CoP), to ensure that centres are providing a quality service for patients. 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 Authority's Executive Licensing Panel (ELP) which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Wessex Fertility Limited
Centre number	0057
Licence number	L0057-16-d
Centre address	The Freya Centre 72 - 74 , Anglesea Road, Southampton, Hampshire, SO15 5QS, UK
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

Page

Report to Executive Licensing Panel

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 centre is open six days per week, Monday to Saturday, from 8am to 4pm.

The centre holds a Treatment and Storage licence and was first licensed in 1992, providing treatments to self funding and NHS patients. The centre's licence was last renewed on 1 August 2009 for three years only, since the licence committee which considered the application had concerns regarding the absence of a quality management system at the centre. The centre addressed this problem soon thereafter. The ELP on 20 October 2010 which considered the report of the last interim inspection at the centre had no significant concerns. The centre is the primary centre in a satellite IVF arrangement with BMI The Hampshire Clinic (HFEA licensed centre 0285).

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).

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

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 01 Jan 2011 – 31 Dec 2011*
In vitro fertilisation (IVF)	464
Intracytoplasmic sperm injection (ICSI)	336
Gamete intrafallopian transfer (GIFT)	0
Frozen embryo transfer (FET)	208
Donor insemination (DI)	89
Partner insemination	In 2010, 38 cycles were performed
Egg share provider (sharer)	9
Egg share recipient	8
Egg donation (non-egg share)	9

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

Outcomes*
For IVF/ICSI, HFEA held register data for the period 01 Jan 2011 – 31 Dec 2011 show the Centre's success rates are in line with national averages. For the year 2010 the centre reported 38 cycles of partner insemination with 3 pregnancies.

*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.

Summary for licensing decision

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

- the PR is suitable and has discharged her duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008 in application for the renewal of their licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including two major areas of non-compliance which led to the following recommendations:

- The centre's transportation SOP and labelling documentation should be reviewed and updated to include the requirements of SLC T107
- The PR should ensure the accuracy of data provided via the EDI system regarding the registration of treatment forms for the forms, including those identified by the register audit team.

Since the inspection visit the PR has confirmed and provided evidence that both recommendations have been fully implemented.

Recommendation to the Executive Licensing Panel

The inspection team considers that overall there is sufficient information available to recommend the renewal of this centre's licence for a period of four years without additional conditions. In making this recommendation it is noted that the PR has responded to all recommendations made in this inspection report.

Details of inspection findings

1. Protection of patients and children born following treatment

Focus

The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned.

▶ **Witnessing and assuring patient and donor identification** (Guidance Note 18)
What the centre does well. The centre double checks the identification of gametes and embryos and the patient or donor to whom they relate at all critical points of the clinical and laboratory process (SLC T71). The centre has documented SOPs describing the witnessing procedure for all critical points specified in CoP Guidance 18.4. Witnessing steps observed during the inspection were performed in accordance with CoP Guidance. Observations of witnessing steps for three patients undergoing treatment during the course of this inspection and an audit of five sets of patient notes were found to include records of all required witnessing steps. Evidence of comprehensive training and competence assessment for staff performing witnessing was seen on inspection (SLC T15 (a)). The centre has established quality indicators (QI) for witnessing and audits of compliance with witnessing requirements are performed annually. The report of the last audit, performed in September 2011, was reviewed on inspection and documented a minor issue. The laboratory manager explained the corrective action that had been implemented as a result of this finding (SLC T35 and T36).
What the centre could do better. Nothing identified at this inspection.

Patient selection criteria and laboratory tests
- Procuring, processing and transporting gametes and embryos (Guidance Note 15)
- Counselling (Guidance Note 3)

What the centre does well.

Procuring, processing and transporting gametes and embryos
Justification for the use of gametes in treatment, based on the patient's medical history and therapeutic indications was seen to be documented in patient notes reviewed on inspection (SLC T49).

Centre staff confirmed that laboratories undertaking diagnosis and investigation of patients are accredited by Clinical Pathology Accreditation (UK) Limited (CPA). Reports of test results observed in patient notes reviewed at inspection were all from CPA accredited laboratories (SLC T21).

Counselling
From the evidence provided on inspection the centre strongly advocates and offers counselling to all patients and partners prior to treatment (SLC T58). Counselling is provided in a comfortable and confidential environment by a fully qualified, accredited and experienced counsellor. Staff at the centre provided evidence to show that the counselling practice is audited annually as part of the quality management system and an assessment of patient satisfaction through a patient questionnaire/survey. The audit report of December 2011 identified that no corrective actions were required.

What the centre could do better.
Nothing identified at this inspection.

Donor recruitment, assessment and screening (Guidance Note 11)
Payments for Donors (Guidance Note 13)
Donor assisted conception (Guidance Note 20)

What the centre does well.
In interviews, staff stated that the centre only uses donated gametes from identifiable donors in treatment in the UK. The centre provides treatment with and recruits egg donors, egg sharers and sperm donors.

The centre works with a clinic in Spain where patients seeking egg donation are referred to for treatment. The PR provided evidence to demonstrate that the centres work closely together to give patients a choice for the treatment, including providing information about treatment and offers of counselling to patients using this referral system. The agreement between the patient and the Spanish clinic is made independently of centre 0057.

Donor recruitment, assessment and screening
Verbal and documentary evidence was provided that donors are selected on the basis of their age, health and medical history (SLC T52a) and are screened for all conditions required by SLC T52. The screening tests are carried out in a CPA accredited laboratory (SLC T53a). Procedures are in place to identify when a donor may need additional screening and were described at inspection (SLC T52 (g)). Donor sperm is quarantined for a minimum of 180 days and then the donor is re-screened (SLC T53c).

The centre records all treatments and outcomes and therefore can provide donors with information on the number of children born, their year of birth and their sex (HF&E Act 1990 (as amended) section 31ZD (3)).

There is a SOP for the process to be followed when selecting and recruiting sperm donors

(SLC T33b). When selecting and recruiting sperm and egg donors there is a checklist to ensure all screening and consent forms are completed.

The centre has established QIs for selecting and recruiting sperm donors (SLC T36) and audits of compliance with requirements are performed annually. The report of the last audit, performed in September 2011, was reviewed on inspection and identified that no corrective actions were required.

Payments for Donors
The reimbursements made to donors are restricted to expenses incurred in the UK. The centre offers weekend appointments 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 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 the centre could do better.
Nothing identified at this inspection.

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)
- Intracytoplasmic sperm injection (ICSI) (Guidance Note 21)

What the centre does well.

Quality Management System
Evidence presented indicated that the centre has a well-developed QMS (SLC T32) consisting of a quality manual (SLC T33a), quality policy, regularly reviewed and document controlled SOPs for all key activities (SLCs T33b; T34) and training and reference manuals (SLC T33d). Quality indicator (QI) monitoring of key practices is performed (SLC T35) based on retrospective audit of patient medical records and analysis of laboratory data. The centre has performed practice audits of practice against SOPs, taking corrective actions if QIs breach control limits. The compliance of SOPs with CoP requirements is reviewed annually (SLC T36). The performance of the QMS is reviewed annually by the management team (CoP Guidance 23.13).

Traceability
The centre records information about all the media, consumables and equipment that comes into contact with gametes, from the time they were obtained until the time the gametes were used in treatment or were allowed to perish. The centre has a procedure to ensure this information will be kept for 30 years.

The centre's traceability SOP was reviewed and describes the process by which traceability of consumables and reagents which come into contact with gametes is ensured (SLC T33b).

Observations of practice in the laboratory and a review of the centre's logs of all reagents and materials used on inspection demonstrated that all relevant traceability data is recorded. A spot check of consumables in use in the laboratory against those recorded in the logs as being in use, demonstrated that data is recorded accurately (SLC T102).

The centre has established QIs for traceability (SLC T36) and audits of compliance with requirements are performed annually. The report of the last audit, performed in November 2011, was reviewed on inspection and it identified that the one corrective action required had been implemented.

Validation

Evidence was provided on inspection to show that all critical processing procedures and equipment used in these processes, have been validated on the basis of published studies. The validation documentation was reviewed at inspection and was considered by the inspection team to demonstrate compliance with SLC T24 and T72.

Equipment and materials

The laboratory staff have documented procedures for the operation of all critical equipment, including information to direct actions in the event of failure or malfunction of specified equipment (SLC T27). Instruction manuals for key equipment were also noted to be readily available to staff in the work area.

The scientific inspector observed that equipment critical to processing or storage parameters which influence gamete and embryo quality and safety are subject to appropriate monitoring (scheduled preventative maintenance, regular calibration and parameter monitoring) and alarms, which are maintained and tested regularly (SLC T24). Staff also provided a monthly log recording the regular cleaning and decontamination of equipment in the laboratory and clinical areas (SLC T26).

Staff were able to confirm that all disposable sterile equipment is CE marked where possible (SLC T30).

Premises

A tour of the centre confirmed that all licensable activities are carried out on the licensed premises which are within the same building (SLC T1). A copy of the centre's current licence was seen to be displayed in the main patient waiting area (SLC T5). Documented evidence of cleaning logs were available to review on inspection (SLC T26).

The centre monitors the air quality daily and the monitoring log was reviewed at inspection. Documented evidence was provide on the day of inspection to demonstrate that the processing of gametes and embryos takes place in an environment of at least grade C air quality in the critical work area with a background air quality of grade D (SLC T20).

Adverse incidents

The centre is compliant with the HFEA requirements for incident reporting. A review of the centre's incident log confirmed that incidents reportable to the HFEA recorded at the centre correlate with those reported to the HFEA (SLC T118).

Third party agreements

The centre staff were able to demonstrate that there are third party agreements in place for all goods and services that influence the quality and safety of gametes and embryos. These agreements were available for review on the day of inspection (SLC T111). The centre has a compliant third party agreement with its satellite clinic - BMI The Hampshire Clinic (HFEA licensed centre 0285) (General Direction 0010 (2)). A complete list of all third parties is maintained and was seen to have been recently reviewed (SLC T115).

What the centre could do better.

Nothing identified at this inspection.

Multiple Births (Guidance Note 7)

In April 2010 – March 2011, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20%[1]. This multiple clinical pregnancy rate represents performance likely to meet or to not exceed at a statistically significant level, the target multiple birth rate for this period of 20% (General Direction 0003).

What the centre does well

On-going monitoring of the centre's multiple clinical pregnancy rate suggests that the centre is not likely to exceed the April 2011 – March 2012 multiple birth rate target of 15% (Standard Licence Condition T123)

The PR has also provided sufficient evidence to demonstrate compliance with HFEA General Direction 0003 in that:

- staff were able to describe their progress towards reducing their multiple pregnancy rates and subsequent multiple birth rates;
- staff at the centre have audited their strategy and protocols as part of the quality management audit programme;
- staff have maintained a log of women receiving double and triple embryo transfers who meet the criteria for single embryo transfer;
- staff have maintained a log which indicates the reasons for variation from the single embryo transfer policy and outcomes which are also recorded in the patients records.

What the centre could better

Nothing identified at this inspection.

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the centre does well.

Person Responsible

The PR has academic qualifications in the field of medicine as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii) and has more than two years of practical experience which is directly relevant to the activities authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1033/7). The PR is the nominated medical practitioner who oversees medical activities at the centre (SLC T16). She is registered with the General Medical Council (GMC) and is on the specialist register.

Staff

The other consultants at the centre are also registered with the GMC.

The PR was able to confirm that staff working under the auspices of the licence are qualified and suitable persons to participate in the activities authorised by the licence (HF&E Act 1990 (as amended) Section 17 (1) (a)). The centre's Business Manager explained that all staff have professional body registration and that all staff members

[1] A multiple clinical pregnancy rate of 25% is calculated as likely to result in a multiple live birth rate of 20%.

participate in induction and on-going mandatory training. The centre has policies to support staff professional development and performance appraisals (SLCs T12 and T14).

The PR stated that workforce requirements had been assessed within the last year and will continue to be monitored. At the time of inspection, it was reported that in this financial year, one member of staff in the administration team had left due to retirement and that the staff complement is sufficient in all disciplines for the current workload (SLC T12).

The Laboratory Manager is registered with the Health Professions Council (HPC) as a clinical scientist (SLC T14).

From the documents reviewed at inspection, the staff were able to demonstrate evidence of the assessment of their competence to perform their designated tasks (SLC T15 (a)).

What the centre could do better.
Nothing identified at this inspection.

Welfare of the Child (Guidance Note 8)

What the centre does well.
From discussions with staff and review of information provided by centre staff, the inspectors conclude that before any woman is provided with treatment services, proper account is taken of the welfare of any child who may be born as a result of treatment and of any other child who may be affected by the birth (SLC T56). The clinical staff were able to describe an appropriate process for conducting a welfare of the child (WoC) assessment and their actions in the event that matters of concern arise, giving examples of how this has been managed with specific case instances.

Five sets of patient records were audited on inspection. In each instance the file contained WoC questionnaires completed by the patient and partner which had been reviewed by a member of staff prior to the commencement of treatment. None of the completed questionnaires recorded that further information was sought however none of the questionnaire responses gave rise to concern.

The centre has a documented SOP to guide the WoC assessment (SLC T33(b)) and staff were able to provided good descriptive evidence of their training and competence to conduct WoC assessments.

The centre has established QIs for WoC assessments (SLC T35) and a quality objective that all patient records should contain a completed copy of the WoC assessment before treatment is commenced. Audits of compliance with requirements are performed annually (SLC T36). The report of the last audit, performed in November 2011, was reviewed on inspection and it identified that no corrective actions were required.

What the centre could do better.
Nothing identified at this inspection.

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)
- Provision of costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12) – *if applicable*
- Surrogacy (Guidance Note 14) – *if applicable*

What the centre does well.

Treating patients fairly

Members of staff reported that there are policies in place on treating patients fairly, which ensure all licensed activities are conducted in a non-discriminatory manner (SLC T49) and that careful consideration is given as to how the centre may meet the needs of individual patients and their circumstances.

Confidentiality and privacy

A tour of the centre demonstrated that all patient confidential information is stored securely with access restricted to authorised personnel only. Areas where conversations personal to individual patients and partners may occur were seen to be private and opportunities to be overheard reduced to a minimum.

All staff are asked to read and sign a confidentiality agreement on the maintenance of confidentiality (SLC T43). Maintaining confidentiality also forms part of the corporate mandatory induction and training (SLC T15 (a)). Documented procedures are in place to maintain data security safeguard against unauthorised data modifications, resolve data discrepancies and to respond to applications to access confidential records and correctly identify the applicants (SLC T44).

Complaints

The centre's has a complaints policy. Information on how service users may make a complaint is displayed in patient areas. Since the last inspection, the centre has received one complaint and correspondence reviewed demonstrated that this has been resolved.

Provision of a costed treatment plan

Self funding patients and their partners are provided with clear written information regarding the anticipated costs of their treatment once the treatment pathway has been decided and a copy is filed in the patient's records. This written information is discussed during consultation, at which time costs and other implications of treatment or queries may be clarified. Detailed information regarding the cost of treatment is also available from the centre's website. A review of five sets of patient records demonstrated evidence for compliance with CoP Guidance 4.3.

Egg sharing arrangements
The centre has an egg sharing scheme. All egg sharers are screened in accordance with legal requirements and are registered with the HFEA as donors (SLC T52). All egg sharers have provided the appropriate consents (SLC T57). The centre has appropriate agreements with both the egg shares and the patients receiving treatment with the donated eggs.

What the centre could do better.
Nothing identified at this inspection.

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (including cooling off periods)
- Information about Intracytoplasmic sperm injection (Guidance Note 21)
- Information about legal parenthood (Guidance Note 6)

What the centre does well.
The PR explained that patients, including those initiating treatment at the satellite unit at centre 0285, are provided with information about the centre, success rates and current prices. Information is also available on the corporate and satellite centre's websites.

All prospective patients are invited to an information evening to discuss any aspect of treatment and enable them to visit the centre. This allows them to make an informed choice before committing to a consultation and the corresponding charges.

The centre's website and written information were reviewed and were found to be compliant with Chair's Letter CH(11)02 and the relevant CoP requirements.

Information provided prior to consent
From information provided and discussions with staff on the day of inspection, the inspectors conclude that proper information is provided to patients and their partners prior to giving consent to treatment as required by Schedule 3 (1) (b) of the HF& E Act 1990 (as amended). Staff who are involved in the information giving process confirmed that prospective patients are sent all relevant consents and related written information regarding their proposed treatment. The proposed treatment and its implications are then discussed.

Information about storage of embryos (cooling off period)
From discussions with staff and from written information seen on inspection, the centre was able to demonstrate that patients and their partners are provided with information regarding an individual gamete provider's right to vary or withdraw their consent to continued storage of the embryos created with their gametes. Staff described that, in the event of a dispute between gamete providers regarding the continued storage of their embryos, a 12 month 'cooling off' period will be instigated. In the event that a mutual decision cannot be reached, the embryo(s) will be allowed to perish one year from the date on which the centre was notified in writing that consent had been withdrawn by one of the gamete providers unless the end of the statutory storage period is reached before this date (HF&E Act 1990 (as amended), Schedule 3, 4A and CoP Guidance (interpretation of mandatory requirements) 5H).

Information about ICSI
As part of the treatment information provided in writing and verbally during consultation, patients and their partners identified as likely to benefit from having ICSI, are given specific information regarding this procedure and any associated risks. This was confirmed by discussion with staff, a review of written patient information and from information check lists seen in patient notes on inspection (HF&E Act 1990 (as amended), Schedule 3, 3(1) (b)).

Information about legal parenthood
Staff interviewed during the inspection demonstrated a good understanding of the requirements of legal parenthood legislation and stated that when required patients are provided with the relevant information. Staff were also able to appropriately describe the process to be followed in the event that one or other partner withdrew or varied their consent to legal parenthood. Written information for patients and their partners is available.

The centre has established QIs to the effect that the patient satisfaction survey responses are monitored for satisfaction with the amount and clarity of information provided prior to and throughout the treatment process (SLC T35). The provision of information has been audited as part of the corporate patient satisfaction survey and the patient information audit most recently conducted (in November 2011) was seen on inspection (SLC T36). The audit identified the need for a documented procedure to follow when giving patient information and a draft of this was discussed at inspection.

A checklist for providing information was seen in a sample of five patient files reviewed at inspection which provided evidence that patients are given information relating to the parenthood provisions before consent.

What the centre could do better.
Nothing identified at this inspection

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)
- Consent to legal parenthood (Guidance Note 6)

What the centre does well.
Staff at the centre provided evidence to demonstrate that appropriate written consent is obtained by suitable qualified and competent staff before gametes or embryos are used in treatment (SLC57).

Consent to treatment, storage, donation, training and disclosure of information
At inspection an audit of ten sets of patient records undergoing various treatments such as IVF/ICSI; egg donation; egg sharing and donor insemination demonstrated that all had correctly completed consent forms; all had completed and documented identity checks and all, apart from one signature missing on one consent form, had accurately completed the consent to disclosure of information. The record with one missing signature was provided to the PR for correction and she gave her assurance that it will be corrected before this inspection report goes to the ELP.

The centre has established a QI requiring 100% of all patients to have appropriately signed consents in place before commencing treatment (SLC T35). An audit of consenting practice was conducted in November 2011 (SLC T36) and the audit report recorded that corrective action was required to update the consenting SOP. A review of the consent SOP demonstrated that this corrective action has been implemented.

Consent to legal parenthood
The centre has a SOP in place to obtain the relevant written records of consent to parenthood before treating a woman with donor sperm or embryos. Also, checklists in the patient records were seen to be completed which indicated that the relevant parenthood laws had been discussed with the patients (SLC T60).

The centre has a procedure in place to ensure that no treatment is provided where a person who has previously consented to be the second parent of a child has withdrawn

their consent to parenthood before informing the woman being treated that they have withdrawn it. Also, in the event of a nominated second parent withdrawing their consent to parenthood, a procedure is in place to ensure that the named woman is not treated until she is informed of this (SLC T64b).
What the centre could do better. Nothing identified at this inspection.

3. Protection of gametes and embryos

Focus
The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)]

- Licensed activities only take place on licensed premises
- Only permitted embryos are used in the provision of treatment services
- Embryos are not selected for use in treatment for social reasons
- Embryos are not created by embryo splitting
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman
- Embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies
- Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
- No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority

What the centre does well.
Following a tour of the licensed centre premises, review of documentation provided by the centre and discussions with staff, the inspection team consider that they have sufficient information to determine that all activities for which the centre is licensed are conducted within the precincts to which that licence applies. Embryos are only created, stored and used in treatment where permitted by law (SLC T1).

The inspection team consider that following discussion with centre staff and a review of documentation and records relating to imported gametes, it can be concluded that no money or benefit is given or received for the supply of gametes or embryos except where authorised by the Authority. Donor compensation records indicated that compensation paid to donors is within the prescribed limits of General Direction 0001.

What the centre could do better.
Nothing identified at this inspection.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17) – *only applicable for centres licensed to store gametes and / or embryos*

What the centre does well.
A review of the centre's storage records and discussions with staff confirmed that all material currently in store at the centre has been appropriately screened (HFE Act Schedule 3A, SLC T50 (b)). Staff were aware of the changes to the statutory storage periods for gametes and embryos and understood the provision for a 12 month 'cooling off' period if gamete providers are in dispute about what to do with stored embryos.

Evidence was provided by laboratory staff that the centre has established QIs relevant to storage. Dewar audits are performed annually and the last audit, conducted in November 2011, documented the required corrective actions and their implementation (SLCs T35 and T36). All samples, are stored with proper consent to storage.

Documented evidence was seen for one laboratory staff member of the assessment of competence in storing cryopreserved material (SLC T15a).

What the centre could do better.
Nothing identified at this inspection.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15) – *only applicable for centres that has distributed or exported gametes and / or embryos*
- Export of gametes and embryos (Guidance Note 16) – *only applicable for centres that has exported gametes and / or embryos*
- Receipt of gametes and embryos (Guidance Note 15) – *only applicable for centres that has received gametes and / or embryos*
- Import of gametes and embryos (Guidance Note 16) – *only applicable for centres that has imported gametes and / or embryos*

What the centre does well.

Distribution of gametes and embryo
The centre has a SOP describing the procedure for the distribution of gametes and embryos, including the required labelling of the shipping container (SLCs T33 (b) and T107). The centre uses receipt and dispatch checklists to ensure the procedure is followed accurately and that all required information is provided, as evidenced during the review of a completed checklist for the receipt of imported sperm (SLC T110). The dispatch checklist includes the requirement to:

1. Record the date and start time of transport (SLC T107);
2. Seal the container with a security tag prior to transport (SLC T108);
3. Submit gamete/embryo movement forms to the HFEA (General Direction 0005).

Evidence of validation of the temperature of the dry shipper was seen (SLC T108).

The SOP also defines the responsibilities and actions that are required if a distribution is recalled, including the investigation of the recall as an adverse incident (CoP interpretation of mandatory guidance 15C).

The centre has a third party agreement in place with a courier that ensures the required conditions are maintained during the distribution of samples (SLC T111).

Import/export of gametes and embryos
Between October and December 2011 the centre has exported three sperm samples. Staff confirmed that the samples were sent with the appropriate documentation to satisfy the PR that the requirements of General Direction 0006 had been met. A review of the supporting documentation confirmed compliance with General Direction 0006.

What the centre could do better.
The centre's distribution/transportation SOP does not describe the procedure for logging the temperature of the shipper at the start of transport (SLC T107).

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
  - maintaining up-to-date awareness and understanding of legal obligations
  - responding promptly to requests for information and documents from the HFEA
  - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

Record keeping

- Record keeping and document control (Guidance Note 31)

What the centre does well.

All patient records reviewed at the time of inspection were seen to be clear, legible, well organised and complete. Each record reviewed was seen to include the patient's first name, surname, date of birth, age and sex. Details of how the patient had been identified by staff were also evidenced. Patient's notes also included details of the services provided to them, a medical history, relevant documented consents, laboratory data and the results of tests carried out (SLC T46). The centre has procedures in place to ensure that records are protected from unauthorised amendment and are retained and readily retrieved in this condition throughout their specified retention period (SLC T47).

What the centre could do better.

Nothing identified at this inspection.

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)]

- Obligations and reporting requirements of centres (Guidance Note 32)

What the centre does well.

Obligations and reporting requirements of centres

The PR provided all information required by the application process prior to inspection. Centre staff cooperated fully with the inspection team and all further information requested for the inspection was provided in a timely manner.

Licensed Treatment Reporting

From the 119 IVF treatments and 67 DI treatments that were checked, 91% of treatments were reported within five working days (General Direction 0005).

What the centre could do better.

The register audit found that from the sample of 119 IVF treatments and 67 DI treatments, one IVF treatment and two DI treatments had not been reported to the HFEA register (General Direction 0005).

Whist the accuracy of information entered onto forms was good, errors were identified. The accuracy of information is particularly important on donor information forms, and it is on these forms were a few errors were found. Failure to record this information accurately could result in the HFEA passing on incorrect information to the future offspring of that donor (General Direction 0005).

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)
- Disclosure of information, held on the HFEA Register, for use in research

What the centre does well.

Confidentiality and privacy
Discussions held with staff, a review of information submitted for the inspection and a tour of the premises, indicated that information about patients is not disclosed unless under circumstances permitted by law (SLC T43)

Disclosure of information, held on the HFEA Register, for use in research
The register audit found that the primary details of whether the patient had consented for use of their information on the register in research had been all completed correctly. No other issues were identified.

What the centre could do better.
Nothing identified at this inspection.

5. Changes/improvements since the last inspection on 29 July 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
Validation of critical processes: Two laboratory processes were seen to have been validated. The centre is encouraged to continue with the planned validation of all processes, including the clinical processes and to complete the validation of all critical processing procedures. (SLC T72) By 31 October 2010	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.	The validation and the quarterly updates were submitted as requested until the plan was completed on 30 June 2011. The delay to the timeline given was due to staff changes at the centre. The new quality manager took over responsibility for this work and has used the ACE templates to ensure effective completion of this recommendation. Evidence of validation was reviewed during this inspection – please refer to the body of this report (Section 1 – Good clinical practice).

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 required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and 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, embryo or to a child who may be born as a result of treatment services
- 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 and reference	Action required and timescale for action	PR Response	Executive Review
The transport conditions, including temperature and time limit, must be specified SLC T107	The centre's SOP should be reviewed and updated to include the procedure for: 1. Logging the temperature and other conditions of the shipper at the start of transport, including a – c referred to in the area of practice column (SLC T107) By the time the PR responds to this report.	The SOP refers to a form that always accompanies the dry shipper and this has now been amended to clearly state the requirements of T107 including the need to transport the shipper in normal atmospheric condtions and the time limit for transport. All gametes and embryos are transported to/from Wessex Fertilitly by a dry shipper. The shipper has no means of logging internal temperatures during transport.	The amended form that accompanies the dry shipper has been submitted with the PR's response and this is compliant with the requirements of SLC T107. No further action required.
The register audit found that one IVF treatment and two DI treatments were not on the HFEA register. Whilst the accuracy of information entered onto forms was good, errors were	The PR should ensure the accuracy of data provided via the EDI system regarding the registration of treatment forms for the forms, including those identified by the register audit team.	The IVF cycle was duly reported as required by the HFEA on the 7th December 2011. The two missed IUI cycles that had been collected and validated in the clinic in December 2011have now	The HFEA Register team have confirmed that the centre has taken action to correct the errors identified at this inspection. It is acknowledged that the PR

identified. The accuracy of information is particularly important on donor information forms, and it is on these forms were a few errors were found. Failure to record this information accurately could result in the HFEA passing on incorrect information to the future offspring of that donor. (General Direction 0005).	Action to correct the errors identified at this inspection and to prevent re-occurance should be completed by the time the PR responds to this report.	been transmitted by the EDI report. The clinic has put in place a second audit step to ensure all cycles are reported within the given timelines.	has taken action to strengthen this process to ensure submission of data is timely and accurate. No further action required.

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 statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

20 April 2012

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 2

Centre 0057 – West Fertility Limited – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Hannah Darby, Senior Policy Manager David Moysen, Head of IT	Lauren Crawford Observing: Paula Robinson, Head of Business Planning Rachel Fowler, Policy & Information Manager

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 Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that the centre had applied for the renewal of its treatment and storage licence and that an inspection of the centre had taken place on 7 and 8 February 2012.

2. The Panel noted that the centre is located on the outskirts of Southampton and provides a wide range of treatments to self-funding and NHS patients.

3. The Panel also noted that the centre is the primary satellite centre in a satellite IVF arrangement with BMI The Hampshire clinic.

4. The Panel noted that the centre was first licensed in 1992 and ELP considered the most recent interim inspection of the centre in October 2010.

5. The panel noted that, at the time of the inspection, the centre's success rates for IVF/ICSI were in line with the national average, and that the treatment cycle figures for partner IUI in 2010 was 38 with 3 pregnancies.

6. The Panel also noted the centre's multiple clinical pregnancy rate suggests that the centre is not likely to exceed the Year 3 multiple birth rate target of 15%.

7. The Panel noted that, at the time of the inspection, there were two major areas of non-compliance which led to the following recommendations:

    - The centre's transportation SOP and labelling documentation should be reviewed and updated to include the requirements of SLC T107

    - The PR should ensure the accuracy of the data provided via the EDI system regarding the registration of treatment forms, including those identified by the register audit team.

8. The Panel noted that, since the inspection, the Person Responsible (PR) has provided satisfactory evidence that both recommendations have been fully implemented.

9. The Panel noted that accurate and timely transmission of information to the HFEA is important and needs to be maintained.

10. The Panel noted the Inspectorate's recommendation to renew the centre's licence for a four year period with no additional conditions.

11. The Panel confined its consideration to the evidence before it.

The Panel's Decision

12. The Panel referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and contained the supporting information required by General Direction 0008.

13. The Panel was satisfied that the qualifications and character of the PR is such as is required for the supervision of the licensed activities and that the PR will discharge the duties under section 17 of the HF&E Act 1990 (as amended).

14. The Panel noted that the PR has been in post since 2005 and is a consultant gynaecologist and obstetrician and has extensive experience within the field of reproductive medicine. She is also registered with the General Medical Council and is on the specialist register.

15. The Panel was satisfied that the licence renewal concerns treatment services which relate to gametes or embryos intended for human application.

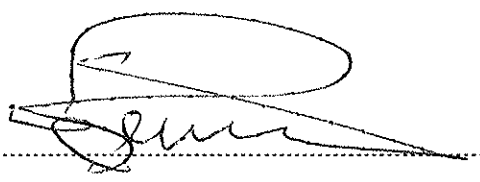
16. The Panel was satisfied that the premises to be licensed are suitable for the conduct of licensed activities based on evidence provided within the report.

17. The Panel noted that although the application indicates the use of embryos for training is applied for, there is no mention of this activity being performed in the report.

18. The Panel referred to 'Guidance on periods for which new or renewed licences can be granted'. The Panel took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states [The Executive Licensing Panel] will normally only grant a renewal licence for treatments/ storage non-medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.

19. In considering the length of the licence, the Panel noted that the PR has responded to all recommendations made in this inspection report and also recognised the effective response to developing a QMS system since the licence was last renewed, for 3 years, in 2009. On the basis of the PR's responses to the inspection report and the recommendations identified, the Panel agreed that it had no concerns.

20. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions.

Signed  Date 3 May 2012

Mark Bennett (Chair)