Renewal Inspection Report

Date of Inspection: 6/7 July 2010
Length of inspection: 11 hours
Inspectors Parvez Qureshi
Jenny McLaughlin
Kathryn Mangold (External Advisor)
Roup Kaur (HFEA observer)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between 11 November 2008 and 20 October 2010

Date of Licence Committee: 20 October 2010

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence 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 which make the decision about the centre's licence renewal application.

Centre details

Centre Name	Herts and Essex Fertility Centre
Centre Number	0030
Licence Number	L0030-15-B
Centre Address	Herts and Essex Fertility Centre, Bishop's College, Churchgate, Cheshunt, EN8 9XP
Telephone Number	01992 785 060
Person Responsible	Mr Michael Ah-Moye
Licence Holder	Mr Andrew Glew
Date Licence Issued	1 February 2008
Licence expiry date	25 November 2010

Additional conditions applied to this licence	N/A

Contents

Page

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:
The Herts and Essex Fertility Centre has been licensed since January 2008. Prior to this, the centre was based at Holly House Hospital,was known as the Essex Fertility Centre and had been licensed since 1992.

The centre is open seven days a week. Opening hours are Monday-Friday 8:30-17:30 and on Saturdays and Sundays as required.

Since the last inspection in November 2008 no major changes have been made to the premises.

The Person Responsible (PR) is a consultant gynaecologist and obstetrician and is registered with the General Medical Council (GMC). He is also a member of the Royal College of Obstetricians and Gynaecologists (RCOG) and has extensive experience of working within the reproductive medicine field.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 April 2009 to 31.March.2010*
In vitro fertilisation (IVF)	271
Intracytoplasmic sperm injection (ICSI)	294
Frozen embryo transfer FET)	125
Donor insemination (DI)	17
Intra uterine insemination (IUI)	82 (Note: cycles provided in the period 1 January to 31 December 2009.

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

*These data were extracted from the HFEA register for the period 1 April 2009 to 31.March.2010. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

Summary for licensing decision:

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

- the PR is suitable and has discharged his duty under section 17 of the HF&E Act 1990 (as amended). The PR has successfully completed the HFEA's PR Entry Program
- the premises are considered largely suitable
- the practices are considered largely suitable
- the centre has submitted appropriately completed documentation in accordance with General Directions 0008 in application for renewal of its licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

Recommendation to the Executive Licensing Panel:

The centre has addressed the recommendations made in the previous inspection report but further development in a number of areas was required at the time of the inspection.

Post inspection the inspectorate made the following recommendations:

- The PR should ensure that if a woman withdraws her consent to her nominated second parent being treated as the legal parent, or consents to a different person being the legal parent of any child resulting from treatment, the PR notifies the original nominated second parent in writing of this.
- The PR should put measures in place to ensure that all reportable incidents are reported to the HFEA within the prescribed timeframe.

Following review of the draft report, the PR has provided assurance and evidence that all of these recommendations have been implemented.

In relation to the following recommendations, the PR has provided assurances that the recommendations will be implemented and where requested has submitted timelines for completion of the actions:

- The PR should ensure if the centre has laboratories or contracts with third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, these laboratories must obtain accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard.

- The PR should develop a standard operating procedure (SOP) to be followed when submitting data to the HFEA.
- The PR should implement a programme to validate all critical equipment at the centre.
- The PR should establish required standards of quality and safety, in the form of quality indicators for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence.

- The PR should ensure trained and competent persons must audit the activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence against compliance with the approved protocols, the regulatory requirements and quality indicators. These audits must be performed in an independent way, at least every two years. Findings and corrective actions must be documented.
- The PR should ensure competency assessments for all staff are conducted and documented.

The centre has been proactive in responding to the findings of this and the previous report and the inspection team consider 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.

Details of Inspection findings

1. Risk to patients and children born as a result of treatment services

Focus

- **The risks of fertility treatment to the health of patients and children born as a result of treatment**
- **Welfare of the Child** – all assisted conception processes should only be conducted in a manner that takes into account the welfare of any child that may be born as a result of treatment services
- **Ensuring patients receive treatment using the correct gametes or embryos** – patients should have confidence that the gametes or embryos used in their treatment are either their genetic gametes or embryos created with their gametes (or in the case of donor gametes that the gametes used are from the correct donor)
- **Ensuring donor gametes are only used where appropriate screening has taken place** – the health of patients and children, born as a result of treatment services, could be at risk if gametes from unscreened donors are used in the provision of treatment services

▶ Take account of 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 (Principle 4).

Evidence of how the centre demonstrates compliance with this principle.

Welfare of the Child (WoC) – Guidance Note 8
The centre has a policy in place for the process to be followed when carrying out a WoC assessment (T33(b). Staff reported that prior to any patient being provided with treatment services an account is taken of the welfare of any child who may be born as a result of the treatment. Evidence of this was seen from an audit of five patients' notes which contained WoC forms completed and signed by both partners (T56).

The centre has established quality indicators relevant to the assessment of WoC. Regular audits of patient records are conducted by centre staff to ensure completed WoC forms are in place (T35).

Staff reported that in cases where further information has been sought or discussion has taken place regarding WoC, the views of those consulted and the views of the patients are documented in the patient records (Cop 8.18).

What the centre does well.

What they could do better.

Welfare of the Child (WoC) – Guidance Note 8
Not all staff were able to provide documented evidence of the assessment of their competency to carry out WoC assessments (T15(a)).

▶ Conduct 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 (Principle 7).

Evidence of how the centre demonstrates compliance with this principle.

Surrogacy: Guidance Note 14
The centre provides treatment involving surrogacy. Review of patient notes and discussion held with the centre's Nurse Coordinator confirmed that the centre screens and registers gametes providers in surrogacy arrangement as donors (T52 and Directions 0003). In addition the centre staff reported that donor sperm is quarantined for 180 days (T53(c)).

Donor assisted conception: Guidance Note 20
The centre's donor coordinator reported it is mandatory for patients having treatment with donor gametes to undergo counselling prior to the treatment. Both patient information and discussions held with staff highlighted the importance of informing children of their donor origins (CoP guidance 20.7 – 20.8). The centre's laboratory director confirmed that treatment with gametes provided by a donor who has not consented to their identity being known is limited for sibling use (T54).

The quality management system – Guidance Note 23
Since the last inspection in November 2008, the centre has further developed and has implemented a quality management system (QMS). The QMS consists of a quality manual, SOPs for all activities, guidelines, training and reference manuals and reporting forms (T33). In addition the centre has established quality indicators for licensed activities and has conducted audits including provision of information, consent, WoC and witnessing (T35 and T36). The centre has a process in place for an annual review of the performance of the QMS to ensure continuous and systematic improvement. Evidence of this was submitted as part of the inspection documents and also an audit plan for 2010 was seen during the course of the inspection.

Currently the quality manager role is shared between the laboratory director and the clinical services manager. They reported that a document control procedure has been established that records the history of document reviews and ensures that only current versions of documents are in use (T34). Evidence of this was noted in the documents submitted prior to the inspection and those reviewed at the time of the inspection.

Donor recruitment, assessment and screening (guidance note 11):
The centre recruits egg sharers and has a SOP in place for the process to be followed when selecting and recruiting donors (T33b).

A review of five sets of patient records confirmed that all donors had been selected on the basis of their age and each file included a documented health and medical history in compliance with T52(a). All of the patient records reviewed contained completed screening results for HIV, Hepatitis B, Hepatitis C, Syphilis, Chlamydia and CMV in compliance with T52(b) and other tests in accordance with current professional guidance produced by the relevant professional bodies.

Sperm to be used for donation is quarantined for a minimum of 180 days, prior to repeat screening of the donor (T53(c)). A procedure is in place to identify when additional screening may be required (T52(g)). The centre's egg share coordinator reported that the centre can provide donors with the following information if requested: the number of persons born as a result of the donation, the sex of each of those persons and the year of birth of each of those persons (Act 31ZD(3).

Egg sharing arrangements (guidance note 12):
The centre has an egg sharing programme in place and according to information submitted to the HFEA they provided 17 treatment cycles between April 2009 and March 2010.

Payment for donors (guidance note 13):
Staff reported that this year only one altruistic egg donor has been recruited and the compensation paid for loss of earning was compliant with the requirements of HFEA Directions 0001 version 1. When sperm is imported the centre ensures that the donor has not received compensation for loss of earnings that exceeds the prescribed amount in Directions 0001 version 1.

What the centre does well.

What they could do better.

Donor recruitment, assessment and screening (guidance note 11)

The laboratory in which the donor screening tests are carried out is only ISO and not CPA accredited.

▶ Ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose (Principle 8).

Evidence of how the centre demonstrates compliance with this principle.

Witnessing – Guidance Note 18
The identification of samples and patients is witnessed by two members of staff at all critical points. Witnessing was observed during an egg collection procedure and was found to be compliant with the centre's witnessing SOP and the Code of Practice (T33b). Additional evidence was seen in the form of a checklist for embryo discard and expiry date review for stored embryos. It was observed that only one sample is processed under the laminar flow hood at a time. An electronic witnessing programme is used in the laboratory

and was observed to be effective. Manual witnessing is carried out at sperm collection (labelling of pots), embryo freezing and insemination. Manual witnessing is carried out by two members of staff at critical processing points and takes place at the time of the procedure.

A master list of name, status and signature of all staff trained in witnessing is maintained by the centre, evidence of this was seen in the patient notes (T71). The centre has a witnessing SOP in place.

The centre has established quality indicators relevant to witnessing (T35). The findings of a witnessing audit conducted in May 2010 were seen during the inspection. The findings of the audit and corrective actions were documented and signed off when completed. The centre's embryologists provided documented evidence of the assessment of their competence in carrying out witnessing (T15(a)).

Third party agreements – Guidance Note 24

Third party agreements established with those third parties who provide goods and services that influence the quality and safety of gametes and embryos were seen by the inspectorate. (T111, T115). The laboratory director reported that to date no issues have arisen with third parties regarding the ability to meet the required standards (T112).

What the centre does well.

What they could do better.

Nothing noted at the time of inspection.

▶ Ensure that all staff engaged in licensed activity are competent and recruited in sufficient numbers to guarantee safe clinical and laboratory practice (Principle 9).

Evidence of how the centre demonstrates compliance with this principle.

Staff – Guidance Note 2

An organisation chart is in place which defines accountability and reporting relationships (T11). The centre has assessed the workforce requirements within the last year (CoP 25.10). The PR reported that currently they are operating with a full staff complement and he considered that the number of staff is adequate for the current volume of work being undertaken by the centre (T12). Documented evidence was seen of staff having adequate opportunity for relevant professional development (T15).

The PR is the centre's nominated registered medical practitioner and therefore is able to advise on and oversee the medical activities (T16).

What the centre does well.

What they could do better.

Staff in the centre are qualified and competent for the tasks they perform. However, not all staff were able to provide documented evidence of the assessment of their competency to

carry out designated task (T15(a)).

▶ Report all adverse incidents (including serious adverse events and reactions) to the HFEA, investigate all complaints properly, and share lessons learned appropriately (Principle 11).

Evidence of how the centre demonstrates compliance with this principle.

Adverse incidents – Guidance Note 27
There is a procedure in place for reporting adverse incidents to the HFEA (T118). Members of staff were able to demonstrate this during their discussion with the inspection team. A review of the centre's incident log showed that since the last inspection in November 2008, the PR has reported five adverse incidents to the HFEA including two diagnoses of Ovarian Hyper-Stimulation Syndrome (OHSS).

Complaints - Guidance Note 28
Since the last inspection of the centre in November 2008, the HFEA has not received any complaints regarding this centre. The centre's complaints procedure was seen during the inspection and evidence was provided that complaints reported to the centre were being investigated and managed in line with the centre's policy. The complaints log seen for 2009 and 2010 indicated that all complaints had been resolved. Staff reported that complaints are discussed at quality management meetings, and evidence of this was made available for inspection team.

What the centre does well.

What they could do better.

Adverse incidents – Guidance Note 27
The laboratory director reported that a recent audit of practice identified that three OHSS incidents had not been reported to the HFEA. However, he stated that the outstanding incidents will be reported to the HFEA as a matter of urgency. Subsequent to the inspection the outstanding OHSS incidents have been reported by the PR.

2. Patient Experience

Focus

- **Ensuring patients and donors are treated fairly and that any treatment is conducted in suitable premises by trained competent staff** – treatment should only be carried out in licensed premises and staff must been trained and competent to perform their jobs. All patients and donors should be treated fairly and without discrimination

- **Guaranteeing patients, donors and partners' independent decision making** – this should be done through the careful giving of appropriate and accurate information and the offering of counselling, and the subsequent taking and recording of effective consents

- **Outcome data** – variation in quality of practice and subsequent treatment results

▶ Treat prospective and current patients and donors fairly, and ensure that all licensed activities are conducted in a non-discriminatory way (Principle 1).
Evidence of how the centre demonstrates compliance with this principle **Treating people fairly – Guidance Note 29** Members of staff reported that the centre has a policy on treating patients fairly and ensures all licensed activities are conducted in a non-discriminatory manner. Patients are provided with treatment carried out in licensed premises by staff trained and competent to perform their jobs. In addition, all patients are provided with treatment using the same SOPs and they follow the same patient pathway.
What the centre does well.
What they could do better. Nothing noted at the time of inspection.

▶ Have respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors (Principle 2).
Evidence of how the centre demonstrates compliance with this principle **Counselling: Guidance Note 3** An SOP for the process to be followed when providing counselling was seen by the inspectorate (T33 (b)). The centre's counsellor holds a recognised counselling qualification; is accredited by the British Association for Counselling and Psychotherapy (BACP) and the British Infertility Counselling Association (T14). The centre's counselling service is well promoted by the centre and patients are encouraged to make an appointment with a counsellor (T58). It is the centre's policy that before consent is taken from all gamete donors and recipients that they are offered counselling on the implication of their decision (T60). The counsellor was able to provide documented evidence of the

assessment of her competence to provide counselling (T15(a)).

Confidentiality and privacy – Guidance Note 30
Discussions held with staff, a review of information submitted prior to the inspection and the tour of the premises indicated that overall respect for privacy, confidentiality, dignity, comfort and well being of patients is maintained.

All information at the centre is kept confidential and the centre's management reported that there is a SOP in place to ensure that information is only disclosed in circumstances permitted by law (T43 and (T33(b)). A SOP for the control of access to heath data and records is in place. The centre's management also reported that all staff have been trained in maintenance of confidentiality [T15(a)].

What the centre does well.

What they could do better.
Nothing noted at the time of inspection.

▶ Give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions (Principle 5).

Evidence of how the centre demonstrates compliance with this principle

Information to be provided prior to consent – Guidance Note 4
Prior to the inspection the centre conducted an audit of their patient information against the HFEA Guidance. A sample of the information was also checked by the inspectorate and was found to be compliant. The centre's patient information submitted pre-inspection and that seen during the course of the inspection was found to provide information about the nature of the treatment, consequences and risks, analytical tests, confidentiality and consent (T58). The centre holds regular information evening for prospective patients.

There is a SOP in place for the process to be followed when providing information to patients prior to consenting to treatment (T33(b)).

Patient questionnaires are used to assess the feedback on the quality of information given to them. Regular audits are carried out, against quality indicators, of patient records to check that there is a record of the information provided and that the record is consistent with the consent forms signed. A review of patients' notes showed that a checklist for providing information is in place and being used (T35 & T36).

Costed treatment plans
Patients are provided with information regarding the cost of their treatment before it commences. The costed treatment plan provides details of the main elements of treatment proposed. However, patients are also informed of other additional costs, such as those for drugs and storage of embryos, which they may incur depending on the course of their treatment (Cop 4.3).

What the centre does well.

What they could do better.
Nothing noted at the time of inspection.

▶ Ensure that patients and donors have provided all relevant consents before carrying out any licensed activity (Principle 6).

Evidence of how the centre demonstrates compliance with this principle

Consent to treatment, storage, donation and disclosure of information: Guidance Note 5
Six sets of patient notes examined during the inspection were found to contain effective consent, including consent for the disclosure of information to researchers and consent for the use of gametes and embryos in the provision of treatment (T57). The centre has a SOP in place for the process to be followed when obtaining consent (T33(b)). Copies of patient photo identification were observed in the patient notes and staff confirmed that the identity of the person providing consent is verified when consent is provided (CoP 5.10).

Evidence was provided by the PR showing that the centre has established quality indicators relevant to obtaining consent (T35) and these have been audited and where required corrective actions have been documented and implemented.

Legal parenthood: Guidance Note 6
Patients and their partners having treatment with donor gametes or embryos are informed about parenthood laws (T60)). The centre has established procedures to ensure that treatment is not provided where a person who has consented to be the second parent of a child born has withdrawn their consent to parenthood before the woman being treated has been advised of the withdrawal of consent (T64(b)).

What the centre does well.

What they could do better.

Legal parenthood: Guidance Note 6
The centre has not established procedures to ensure that if a woman withdraws her consent to her nominated second parent being treated as the legal parent, or consents to a different person being the legal parent of any child resulting from treatment, the original nominated second parent is notified in writing of this ([T65).

Live Birth Rates

Relative success rates from the HFEA held register data 1 January 2007 to 31 December 2009 show the centre's success rates are in line with national averages with the following exceptions:

The IVF/CSI for the age group below 35 years being significantly above the national averages.

Multiple Births

Evidence of how the centre improves its live birth rates and reduces the number of multiple births.

Multiple births (Guidance note 7)
The PR reported an overall multiple pregnancy rate at the time of inspection of 18.0%.

In compliance with Directions 0003, the centre/PR has provided evidence that the centre maintains a documentary record of their Multiple Births Minimisation Strategy (3(a)) including:

- how the centre identifies suitable cases for single embryo transfer (SET), including criteria in relation to embryo assessment and patient selection criteria (5(a)).
- how the centre aims to reduce the multiple birth rate and how to ensure that the rate does not exceed the maximum specified rate of 20% (5 (b)).

The centre maintains a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer as set out in the strategy. (3(c)) From February 2010 to June 2010 the centre has carried out 29 double embryo transfers in patients who met the criteria for single embryo transfer all of which are recorded in the log.

Where more than one embryo has been transferred the centre has recorded in patients records an explanation of the reasons for transferring more than one embryo in that particular case and a note confirming that the risks associated with multiple pregnancy have been fully discussed with the patient (7(a) (b)).

Where three embryos or four eggs are transferred the centre has provided detailed record in each patients records explaining the reason for transfer and provided a summary log in the format laid out in directions (1(a) and (b).

The centre has carried out regular audits and evaluations of the progress and effectiveness of the strategy. Evidence of this was seen in the centres audit programme and discussions at clinical meetings (3(b)).

What the centre does well.
The centre has successfully reduced their multiple pregnancy rate to well below the HFEA's target.

What the centre could do better.
Nothing noted at the time of inspection.

3. Protection of embryos

Focus

- **Safe procurement, processing, storage, application and disposal of gametes and embryos** – gametes and embryos must only be procured, processed, used, stored and disposed off in accordance with the law

▶ Have respect for the special status of the embryo when conducting licensed activities (Principle 3).

Evidence of how the centre demonstrates compliance with this principle

Procuring, processing and transporting gametes and embryos: Guidance Note 15
The centre has procurement and processing SOPs in place for all laboratory procedures including newly developed ones for vitrification and laser assisted hatching (T33(b)). Evidence of laboratory validation for all process, based on historical data and national success rates was made available at inspection (72).

The centre has established quality indicators relevant to procurement and processing procedures including fertilisation rate, pregnancy rate and witnessing and traceability (T35). All procedures are audited on a regular basis and where required corrective action is taken and documented (T36).

Five sets of patient records were audited during the inspection which confirmed that the justification for the use of their gametes or embryos was documented in each case (T49). There are two sperm production rooms on site. However, the laboratory director reported that where sperm is procured at home, this is documented the gamete provider's records (T68).

The centre's transport and distribution of gametes and embryos procedures were observed to be compliant (T95) and (T108).

Storage of gametes and embryos: Guidance Note 17
There is an SOP for the process to be followed when storing gametes and/or embryos (T33(b)) Evidence of this was seen during the inspection.

The storage procedures have been validated based on centre results (T72). The centre has established quality indicators relevant to storage. All samples are being stored with consent in place and samples are not stored beyond consent (T35). A storage tank audit was conducted by the centre in January 2010 against quality indicators. Where required, nonconformities had been documented and corrective action had been implemented (T36).

Prior to storage the providers of gametes and embryos are screened for HIV, Hepatitis B and Hepatitis C (T50).

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 (CoP 17.7).

There is a monthly review procedure in place. A letter is sent to patients whose storage period ends within the year. A second letter is sent at six months. The centre has a procedure in place in the event the second letter is not responded to.

Training: Guidance Note 22
With patient consent, the centre uses embryos for training purposes. The laboratory director confirmed that no embryos used for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, are kept or used for the provision of treatment services.

What the centre does well.

What they could do better.

Procuring, processing and transporting gametes and embryos: Guidance Note 15
Not all embryologists were able to provide documented evidence of the assessment of their competence in and processing procedures (T15(a)).

Storage of gametes and embryos: Guidance Note 17
Not all relevant staff were able to provide documented evidence of the assessment of their competence in storing cryopreserved material (T15(a)).

Screening tests are carried out by a pathology laboratory which is not accredited by Clinical Pathology Accreditation (CPA) but is International Organisation for Standardisation (ISO) 9001:2000 certified.

▶ Ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose (Principle 8).

Evidence of how the centre demonstrates compliance with this principle

Imports and exports (guidance note 16):
Since the last inspection in November 2008, the centre has imported 17 samples. There have been no exports during this period. The laboratory staff confirmed that each sample is received with the appropriate documentation to satisfy the PR that the requirements of HFEA direction 0006 have been met.

Traceability - Guidance Note 19
All gametes and embryos are traceable from procurement of gametes to patient treatment or disposal and vice versa (T99). All relevant data relating to anything coming into contact with those gametes or embryos is traceable. There is a documented SOP to ensure traceability (T87). An electronic system in place which tracks patient gametes embryos and all material coming into contact with them, including batch number and expiry dates.

The centre has established quality indicators for traceability, these were audited in June 2010 with findings and corrective actions documented and signed off (T36). Laboratory staff were able to provide documented evidence of the receipt of training in traceability procedures (T75). Dishes and tubes at all stages of procurement, processing, use and storage of gametes and embryos are labelled with the patient's name, date of birth and

hospital number (T89). Traceability data is stored in patient notes which in turn are stored for 30 years (T103).

ICSI: Guidance Note 21
There is a SOP in place for the process to be followed when performing ICSI (T33(b)]). The procedures for ICSI have been validated and evidence of this was seen in the main laboratory validation document (T72). Quality indicators for ICSI are monitored on a monthly basis (T35). An audit of ICSI is included in the laboratory procedure audit plan (T36).

Premises and facilities: Guidance Note 25
The activities authorised by the licence are carried out in the premises specified in the licence (T1). A copy of the Certificate of Licence was displayed in the patient waiting area (T5). Evidence of regular cleaning and disinfection of the premises was made available for the Inspectorate (T26). Air quality test reports and discussions held with the laboratory staff showed that the environment where gametes and embryos are processed achieves Grade C air quality, with a background of Grade D air quality (T20).

Equipments and materials: Guidance Note 26
Staff at the centre provided documented evidence of regular cleaning and disinfection of equipment, the maintenance and regular inspection of equipment in accordance with manufacturer's instructions and that all equipment that effects critical processing or storage parameters are subject to monitoring, alerts and alarms (T23, T24 and T26). The centre has an on call rota for response to alerts or alarms including, dewars and incubator alarms, out of opening hours. All medical devices used are CE marked, where possible.

What the centre does well.

What they could do better.

Premises and facilities: Guidance Note 25
Blood sample pregnancy tests for egg share recipients are carried out in the centre's laboratory. The centre also uses an external pathology laboratory for blood testing. Both laboratories are ISO certified but not accredited by CPA.

Equipments and materials: Guidance Note 26
Some of the laboratory equipment has not been validated, although a schedule for completion of all equipment validation was seen to be in place.

4. Good governance and record keeping

Focus

- **Where gametes or embryos are used complete and accurate information should be recorded and reported to the HFEA in a timely manner** – incomplete and / or inaccurate information may lead to the wrong information being provided to offspring and / or researchers
- **Ensuring gametes and embryos are only stored in accordance with effective consent and within the statutory timeframe**
- **Ensuring identifying information is only disclosed in accordance with consent**
- **Inspection theme 2010 - 2012** – for this period, this should include the following:
  - Patient consent to the disclosure of information, held on the HFEA register, for use in research
  - Consent issues in relation to the storage of embryos (including cooling off period)

▶ Maintain accurate records and information about all licensed activities (Principle 10).
Evidence of how the centre demonstrates compliance with this principle All patient/partner records reviewed at the time of inspection were seen to be clear, legible, well organised and complete. Each record reviewed was seen to include: patient's first name, surname, date of birth, age and sex. Details were seen of how the patient has been identified (passport/driving licence): the treatment provided; a medical history; welfare of the child assessment; relevant documented consents and clinical and laboratory data and the results of tests carried out (T46). The centre has procedures in place to ensure that records are protected from unauthorised amendment and retained and readily retrieved in this condition throughout their specified retention period ([T47). The centre's traceability SOP details that records are maintained for 30 years after clinical use (T48).
What the centre does well.
What they could do better. **Record keeping and document control: Guidance Note 31** The PR has not developed a SOP to be followed when submitting data to the HFEA in compliance with the requirements of Directions 0005 (T33(b)). Quality indicators relevant to submission of data to the HFEA have not been established (T35). The procedures for submission of data to the HFEA have not been audited (T36).

▶ Conduct all licensed activities with regard for the regulatory framework governing treatment and research involving gametes or 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-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare (Principle 13).
Evidence of how the centre demonstrates compliance with this principle The PR provided all information as required by the application process prior to inspection. Members of staff cooperated fully with the inspection team and all further information requested at the time of and post inspection was provided in a timely manner. The PR has responded to the recommendations from the previous inspection.
What the centre does well.
What they could do better. Nothing noted at the time of inspection.

5. Changes / improvements since the last inspection on 11 November 2008

Area for improvement	Action required	Action taken as evidenced during this inspection
The centre takes an average of 50 days to pay treatment fees. The HFEA payment terms are 28 days. Payment outside these terms is a breach of Code of Practice Standard (CoP) 7th standard licence condition A13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this licence as PR), the PR agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.	The PR should review the arrangement for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.	Invoices are now paid on time. No further action required.
The inspectorate were informed that 24 third party agreements have been confirmed with signed contracts but that they are awaiting response from another five third party suppliers. CoP 7th A.5.1 and S.4.2.10	The Centre should continue efforts to establish written agreements with all third parties for external activities which influence the quality and safety of gametes and embryos procured or processed.	All in place and in date. No further action required.
A review of the quality management system has not yet been conducted. The quality manager reported that they have been in the current premises since January and that a review is planned for the beginning of next year.	The quality management system should be reviewed.	Annual Reviews have taken place and the inspectorate was provided with a copy of the last meeting. No further action required.

Area for improvement	Action required	Action taken as evidenced during this inspection
CoP 7th S.4.2.8 and S.4.2.9 require that the centre management conduct a regular, at least annual, review of the quality management system and all its services.		
A document control system is n place and documents provided prior to the inspection included evidence that they had been subjected to document review. However some of the documents contained references to outdated editions of the HFEA. CoP 7th S.5.2.5	The PR must ensure that the system of document review is effective and ensures that documents remain 'fit for purpose'	All documents have been reviewed on an annual basis and any references to the old Code of Practice have been removed. No further action required.
Although it was reported that a patient questionnaire is under development, user feedback on the service provided at the centre has not yet been gathered in a systematic manner. CoP 7th S.9.2.1	The PR is encouraged to begin the process of collating user feedback on the general service to ensure compliance with Code of Practice Standard 9.2.1. This Standard requires that as a measure of the performance of the quality management system, the centre shall monitor information relating to user perception as to whether the service has met their needs and requirements. The Standard also specifies that the methods used to obtain feedback should include user surveys regarding all aspects of the service.	Patient questionnaires are issued and quarterly reports generated. No further action required.
Formal audits on the quality management system have not yet been conducted CoP 7th S.9.2.4	It is recommended that the programme of audits is effectively implemented and maintained, as required by	Audits of the QMS have been conducted. The centre currently has six internal auditors for

Area for improvement	Action required	Action taken as evidenced during this inspection
	CoP 7th S.9.2.4 so that the PR can determine whether the quality management system: (a) conforms to the planned arrangements for assisted conception processes, to the requirements and expectations of the Cop 7th standards and to the quality management system requirements (including quality indicators) established by the centre.	conducting audits of the QMS. No further action required.
Critical laboratory processes have not yet been validated. CoP 7th S.7.8.3 and Licence Conditions 1.11	It is recommended that the PR identifies the key processes which will need to be validated to ensure compliance with Licence Conditions 11.11 and Code of CoP 7th S.7.8.3. A programme of validation should be developed: the programme should take into account the particular needs of the unit and prioritise the validation of those processes considered to be most likely to impact on the quality of the service	Critical laboratory processes have been validated. No further action required.
Traceability records for key equipment used during the processing of gametes/embryos are not retained. The Centre must ensure that logs of equipment, environmental monitoring and of products coming into contact with embryos or gametes are maintained and stored for the relevant time periods, as outlined in standard licence conditions A.3.2, A.10.30 and CoP 7th S.7.3.1.	Appropriate records must be maintained.	The incubators have been added to the laboratory records. No further action required.

Area for improvement	Action required	Action taken as evidenced during this inspection
Not all members of staff have had their competency to perform designated tasks assessed. CoP 7th Licence Condition 10.9, S.6.2.9.and Guidance 1.3.	The PR should ensure that the competence of each person to perform designated activities is evaluated at intervals specified in the quality management system and re-training undertaken when required as per Licence Condition 10.9 and CoP 7th S.6.2.9. The PR should also ensure compliance with CoP 7th Guidance 1.3.1 which requires all nurses to be able to provide evidence of competency in the duties performed either by certification of a recognized qualification or by written testimonial by another suitable qualified and competent person in that discipline/function (e.g. ultrasound, embryo transfer, IUI, egg collection etc.)	Competencies have been developed for all relevant staff and this is work in progress, the majority of staff have completed competencies for critical procedures.
Compliance with British Infertility Counselling Association (BICA) good practice guidelines were noted during the inspection Feedback from patients attending counselling sessions has not been gathered to date. The counsellor reported that she has not attended any multidisciplinary meetings at the centre. CoP 7th G.7.3 requires that counsellors should follow current professional guidance on good practice in infertility counselling.	That the current professional guidance on good practice in infertility counselling is followed. In particular: It is recommended that feedback from patients attending counselling sessions is gathered so that the counsellor is able to review periodically the effectiveness, quality and accessibility of the counselling service, in accordance with the British Infertility Counselling Association (BICA) good practice guidelines. It is recommended that the PR	Questionnaires are given to all patients by the counsellor and a quarterly feedback report is generated. The counsellor now attends the head of departments meetings. No further action required.

Area for improvement	Action required	Action taken as evidenced during this inspection
	ensures the counsellor has appropriate access to meetings in accordance with Code of Practice Guidance 6.2.2.g and the BICA Guidelines for Good Practice.	
Donors are not routinely screened for *Neisseria gonorrhoea*. The patient records for two egg sharers were reviewed and both did not include evidence of screening for the test CoP 7th Guidance 4.9.1	It is recommended that the PR reviews the professional guidelines on screening for donors and ensures that donors of gametes and embryos are screened in accordance with the current professional guidance produced by the relevant professional bodies.	Neisseria gonorrhoea is screened for as part of the centre's donation screening. No further action required.
In one set of patient records, the welfare of the child assessment had not been repeated despite a child being born to the patients since the previous assessment.	It is recommended that the PR reviews the process for assessing welfare of the child to ensure compliance with CoP 7th G.3.2.4.	Staff have been made aware of this requirement. No further action required.
The centre staff could not provide the inspectorate with evidence that the emergency resuscitation trolley had been subject to daily checks in compliance with UK Resuscitation Council Guidelines.	Records to be maintained of the checks on resuscitation equipment. This would enable the PR to audit the checking system as per UK Resuscitation Council Guidelines	The resuscitation trolley is checked on a daily basis and a log of this is maintained. No further action required.
Counselling sessions are provided solely at the counsellor's home. The PR reported that he has not seen where patients are counselled and was unable to tell the inspectorate about whether or not the premises are suitable. CoP 7th S.6.3.5 and G.7.4.2	It is recommended that the PR takes action to assure himself of the suitability of the premises for counselling sessions and to satisfy himself that the counselling records are securely stored.	The counselling premises have been inspected by a senior member of staff and considered fit for purpose. The premises are independent and are part of a suite of commercial offices. A leaflet with a map has been developed as some patients found it hard to find the premises. Patient

Area for improvement	Action required	Action taken as evidenced during this inspection
		records are kept in a secure place by the counsellor. No further action required.
The centre's protocol for the transport of gametes is not fully compliant with the recommendations of Alert 21: Transport Hazards.	The PR should review the procedures for transport of gametes in consideration of the recommendations of Alert 21.	Relevant protocols have been adapted. No further action required.
In line with the centre's policy for Welfare of the Child (WOC) assessment, questionnaires completed by each partner were seen in each set of records inspected. However, there was no documentation within the patient records which indicated that the content of the questionnaire had been reviewed by clinical staff and whether this influenced the decision to offer treatment to the patients. CoP 7th G.3.5.1	It is recommended that the PR reviews the procedures for considering Welfare of the Child and ensures that decisions about provision of treatment are fully documented.	Clinicians now sign the relevant forms; this was noted in the patient records. No further action required.
There are a large number of outstanding errors in the data submitted to the HFEA through the electronic data interchange (EDI) system for the period January-November 2008.	It is recommended that the PR refers to the HFEA policy Collection, Confirmation and Publication of Register Data and ensures compliance with paragraph 4.6.7 which requires that error reports made available by the authority are reviewed by their licensed centres on a weekly basis. This is in order to prevent a build up of unresolved data issues, which may affect the quality of the data held by the Authority in its statutory register.	This was confirmed by HFEA registry team. No further action required.

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

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
None identified at the time of this inspection.					

Major area of non compliance

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

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

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Donor recruitment, assessment and screening The centre uses an external pathology laboratory for blood testing which they could not demonstrate was an accredited laboratory.	Standard licence condition T21 Cop Guidance note 11 Guidance Note 25	The PR should ensure if the centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, these laboratories must obtain accreditation by CPA(UK) Ltd or another body accrediting to an equivalent standard. .	Written evidence to demonstrate that the laboratory is accredited to be submitted by the time PR responds to this report.	The pathology laboratory that we use is accredited with ISO9001:2000. A certificate is attached and we feel that this is an acceptable alternative to CPA accreditation. This pathology laboratory serves a number of other Fertility Centres.	The HFEA has no evidence to support the assertion that ISO accreditation is equivalent to CPA accreditation. The centre have been informed of this and have been provided with an opportunity to provide additional information to support the claim.
Legal parenthood: The centre does not have a documented procedure to ensure if a woman withdraws her consent to her nominated second parent being treated as the legal parent, or consents to a different person being the legal	Standard licence condition T65 Guidance Note 6	The PR should develop an SOP to ensure that if a woman withdraws her consent to her nominated second parent being treated as the legal parent, or consents to a different person being the legal parent of any child resulting from treatment, the PR must notify the	To be submitted by the time PR responds to this report.	Please see attached SOP which has been reviewed – (Consent SOP).	The submitted consent SOP has been reviewed and appears to be compliant with requirements. The inspectorate considers this to be an acceptable response.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
parent of any child resulting from treatment, the PR must notify the original nominated second parent in writing of this.		original nominated second parent in writing of this.			
Equipments and materials: Guidance Note 26 The centre has not validated all critical equipment.	Standard licence condition T24 CoP Guidance Note 26	The PR should ensure that all critical equipment and technical devices are identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions. Where equipment or materials affect critical processing or storage parameters (eg, temperature, pressure, particle counts, microbial contamination levels) they must be identified and be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect	The PR should submit a detailed plan listing all critical equipment to be validated and provide timeframes for completion of validation before the report is to be considered by Executive Licence Panel on the 23 September 2010. The PR should submit quarterly reports to the centre's inspector regarding the progress of implementation of this plan until it is completed.	A complete list of validation is attached. Many of the critical pieces are already validated and time frames have been added to those that require validation.	The inspectorate considers this to be an acceptable response. Progress to be reviewed at the time of next inspection.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
		malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with a critical measuring function must be calibrated against a traceable standard if available.			
Record keeping and document control: Guidance Note 31 Quality indicators relevant to submission of data to the HFEA have not been established (T35). The procedures for submission of data to the HFEA have not been audited (T36).	Standard licence condition T35 and T36 CoP Guidance Note 31	Required standards of quality and safety, in the form of quality indicators for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, must be established. Trained and competent persons must audit the activities authorised by this licence and other activities carried out in the course of providing	An action plan to be submitted by the time PR responds to this report.	We will develop an SOP and relevant quality indicators for the submission of HFEA data. We expect this to be completed by 31.12.2010.	The inspectorate considers this to be an acceptable response. Progress to be reviewed by 31.12.2010

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
		treatment services that do not require a licence against compliance with the approved protocols, the regulatory requirements and quality indicators. These audits must be performed in an independent way, at least every two years. Findings and corrective actions must be documented.			
Adverse incidents Guidance Note 27 Three OHSS incidents had not been reported to the HFEA within the required time frame	Standard licence condition T118 Directions 11	The PR should put measures in place to ensure that all reportable incidents are reported to the HFEA within the prescribed timeframe.	By the time PR responds to this report.	All HFEA reportable events will be reported in the time frame required. The last incidents (OHSS) were not reported due to a breakdown in communication. All staff have been made aware of the process of reporting severe OHSS cases to the authority.	The inspectorate considers this to be an acceptable response.

Other areas of practice that requires improvement

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

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Staff Guidance Note 2 Not all staff were able to provide documented evidence of the assessment of their competence to perform their designated tasks	Standard licence condition T15a Guidance Note 2.1b Guidance Notes 15 and 17	Competency assessments should be undertaken and documented for all staff.	An action plan for the completion of competence assessment listing all staff members and the competence assessments to be performed to be submitted to the HFEA by the time the PR responds to this report.	See attached competency register.	The inspectorate considers this to be an acceptable response. To be reviewed at the time of next inspection.
Record keeping and document control: Guidance Note 31 There is no SOP in place for submitting data to the HFEA in compliance with the requirements of Directions 0005 and (T33(b)).	Standard licence condition T33b Guidance Note 31 Directions 0005	The PR has not developed a SOP to be followed when submitting data to the HFEA in compliance with the requirements of Directions 0005 and (T33(b)).	By the time PR responds to this report.	We will develop an SOP and relevant quality indicators for the submission of HFEA data. We expect this to be completed by 31.12.2010.	The inspectorate considers this to be an acceptable response. Progress to be reviewed by 31.12.2010.

Additional information from the Person Responsible
We are pleased with the report and the issues highlighted will be addressed to ensure that we fulfil the regulatory requirements within the time frames given.

HFEA Executive Licence Panel Meeting

20 October 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 4

Centre 0030 (Herts and Essex Fertility Centre) - Renewal Inspection Report (Treatment and Storage)

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

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

The Panel also had before it:

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

Consideration of Application

1. The forerunner of this centre was first licensed in 1992 as a storage only centre. The centre then varied its licence in January 2008 to became a treatment and storage centre and changing its name to the Herts and Essex Fertility Centre.

2. The Panel noted that since the last inspection in November 2008, no major changes have been made to the premises.

3. The Panel noted that the Executive considers that the Person Responsible (PR) is suitable and has discharged his duty under section 17 of the HF&E Act 1990 (as amended). The PR is registered with the General Medical Council (GMC), is a member of the Royal Obstetricians and Gynaecologists (RCOG) and has extensive experience working within the reproductive medicine field. The PR has also successfully completed the Person Responsible Entry Programme (PREP) for treatment and storage.

4. The Panel considered the Renewal Inspection Report and noted that since the previous inspection the PR had acted on some of the recommendations made, but had not implemented all of these areas at the time the current inspection took place. However, following the inspection, the PR has provided assurances to the Executive that all outstanding recommendations from the previous inspection have now been implemented.

5. The Panel noted that the Executive is now satisfied that all current recommendations have been addressed or are in the process of being addressed.

6. The Panel noted from the report that there is a difference of opinion between the Executive and the PR regarding the accreditation of the pathology laboratory. Whilst the Panel can appreciate the PR's point of view, the Panel agreed that it is a condition of all licences that all laboratories are CPA accredited and would endorse the Executive's recommendation.

7. The Panel was particularly concerned with the failure to report some cases of OHSS, given the risks to the women involved and would urge the PR to ensure that all staff are made aware of the importance of reporting OHSS to the HFEA.

8. The Panel noted that the PR has also submitted a variation of licence application, to allow the centre to conduct Laser Assisted Hatching as a licensable activity.

9. The Panel noted that the Executive has reviewed the completed application form, protocol for laser assisted hatching, patient

information, consent for laser assisted hatching and found this information to be satisfactory.

10. The Panel noted the Executive's recommendation for the renewal of the centre's treatment and storage licence for a period of four years without any additional conditions, and for the licence to be varied to add Laser Assisted Hatching as a licensable treatment.

11. The Panel had regard to its Decision Tree. It was satisfied that the application was submitted in the form required, and contained the supporting information required by General Direction 0008. It was also satisfied that the appropriate fee had been paid.

12. The Panel was satisfied that the application designated an individual to act as the Person Responsible (PR) and that the PR had consented to act as such.

13. The Panel was satisfied that the character of the PR is such as is required for supervision of the licensed activities and that the PR will discharge the duties under section 17 of the Act.

14. The Panel was satisfied that the licence renewal application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

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

16. The Panel was satisfied that the application does not involve the use of embryos for training purposes, nor does it involve the testing of embryos.

Decision

17. The Panel had regard to 'Guidance on periods for which new or renewed licences should be granted.' The Panel took into account evidence of the 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 treatment/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.

18. As it was satisfied that the evidence before it revealed no concerns regarding the requirements set out in paragraph 4.3, the Panel agreed to renew the centre's treatment and storage licence for a period of four years with no additional conditions. The Panel also agreed that Laser Assisted Hatching should be added to the licence as a licensable activity.

19. The Panel endorsed all of the Executive's recommendations made within the report, noting the PR response and progress already made.

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

Peter Thompson (Chair)