Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 29 and 30 May 2013

Purpose of the inspection: Renewal of licence for treatment (including embryo testing) with storage.

Inspection details:
The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Date of Executive Licensing Panel: 16 August 2013

Centre name	Hewitt Fertility Centre
Centre number	0007
Licence number	L/0007/15/e
Centre address	Hewitt Centre for Reproductive Medicine Liverpool Women's Hospital Crown Street Liverpool L8 7SS
Person Responsible	Professor Charles Kingsland
Licence Holder	Mrs Kathryn Thompson
Date licence issued	01 November 2008
Licence expiry date	31 October 2013
Additional conditions applied to this licence	None

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- The experience of patients and donors
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This section provides information on the performance of the centre since the last inspection

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This section sets out the areas of practice that require the attention of the Person Responsible (PR) and the PR's response. Some of the requirements will have been met from the time of inspection to the publication of this report as shown in the summary, Section 1.

Section 1: Summary report

Brief description of the centre and its licensing history:
Hewitt Fertility Centre has held a licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 2,264 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2013. In relation to activity levels this is a large centre.

The centre has satellite agreements with five clinics and a transport in vitro fertilisation (IVF) agreement with the Countess of Chester Hospital (HFEA licensed centre 0280).

An application to vary the centre's licence to reflect a change of centre name to Hewitt Fertility Centre was approved by an ELP on 25 January 2013. In addition, an application to vary the centre's licence to add embryo testing to their licence was approved on 8 February 2013.

Activities of the centre:

Type of treatment	Number of treatment cycles for the period 01 April 2012 - 31 March 2013
In vitro fertilisation (IVF)	882
Intracytoplasmic sperm injection (ICSI)	770
Frozen embryo transfer (FET)	465
Donor insemination (DI)	147
Partner insemination (1 January 2012 – 31 December 2012)	62

Other licensable activities	✓
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓

Outcomes*

For IVF and ICSI, HFEA held register data for the period January 2012 - December 2012 show the centre's success rates are in line with national averages with the following exceptions:

- the clinical pregnancy rates for ICSI for patients aged 37 and under are below the national average at a statistically significant level;
- the clinical pregnancy rates for FET for patients aged 40 and under are below the national average at a statistically significant level.

In 2012, the centre reported 62 cycles of partner insemination with 12 pregnancies. This equates to a 19% clinical pregnancy rate which is consistent with the national average.

Between 1 April 2010 and 31 March 2011, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 21%; this represented performance that was not statistically likely to lead to a multiple live birth rate greater than the 20% target for this period[2].

Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 13%; this represented performance that was not statistically likely to lead to a multiple live birth rate greater than the 15% target for this period[2].

*The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. The HFEA considers differences in a centre's success rates and multiple pregnancy rates from the national averages are only statistically significant if they occur at a significance level of $P \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

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

The ELP is asked to note the areas of practice that require improvement including two critical, five major and seven 'other' areas of non-compliance or poor practice which have resulted in the following recommendations.

Since the inspection and prior to this report being presented to the ELP the PR has provided evidence that the following recommendations have been implemented:

Major areas of non compliance:

- the PR should ensure that the dry shipper used to transport gametes and embryos is validated.

'Other' areas of non-compliance or poor practice that require improvement:

- the PR should consider the risks of not labelling tubes/dishes used during egg collection;
- the PR should ensure that the centre's standard operating procedure (SOP) for traceability includes the requirement for equipment to be traceable.

The PR has given a commitment to fully implement the following recommendations:

Critical areas of concern:

- **the PR should ensure that no gametes or embryos are kept in storage for longer than the consented period;**
- **the PR should ensure the centre complies with the data submission requirements set out in Direction 0005.**

Major areas of non compliance:

- the PR should ensure that all witness signatures are recorded;
- the PR should ensure that quality indicators (QIs) are established for submission of data to the HFEA;
- the PR should ensure that all licensed activities are audited including the submission of data to the HFEA within a two year cycle;
- the PR should ensure that written agreements established with third parties who provide goods or services that influence the quality and safety of gametes and embryos in addition to the written agreement with the transport centre are compliant with the relevant standard licence conditions.

Other' areas of non-compliance or poor practice that require improvement:

- the PR should ensure that information provided to patients who have consented to the use of their embryos in training includes whether any information will be fed back to them;
- the PR should ensure that SOPs are in place to ensure that patient/donor records are retained for at least 30 years (or for such longer period as may be specified in Directions);
- the PR should ensure that the centre's website is compliant with Chair's letter CH(11)02;
- the PR should ensure that donor information forms supplied to the HFEA in accordance with donor registration form guidance include pen portrait and goodwill message sections;
- the PR should ensure that procedures are in place whereby if one gamete provider withdraws consent to the storage of embryos the centre provides information about counselling or mediation services as appropriate.

Recommendation to the Executive Licensing Panel

The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

Significant improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides.

As outlined in the body of the report, the inspection team has significant concerns about the reliability of data submissions and data submission systems. These issues are considered likely to be impacting on the centre's ability to accurately report licensed treatments to the HFEA. It is also noted that an issue relating to data submission was documented in the centre's previous inspection report.

Information submitted by clinics to the HFEA is used to provide donor conceived people, their parents and donors with access to information about the donor and about any donor-conceived genetic siblings/children. The information is also used to monitor centres' performance.

Failure to submit accurate information impacts on the HFEA's ability to provide individuals with this information. In consideration of this, and in recognition that the centre has not been able to address these issues previously, the inspection team can only recommend the renewal of this centre's licence for a period of three years. In making this recommendation it is anticipated that a focused interim inspection will be undertaken within one year to ensure that the centre has an opportunity to demonstrate progress in addressing the concerns outlined in this report: if the centre is not able to demonstrate this progress then the Authority will have an opportunity to consider whether regulatory sanctions are warranted.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient, and children born following treatment

Witnessing and assuring patient and donor identification (Guidance note 18)

What the centre does well.

The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are broadly compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better.

On inspection, 10 sets of witnessing records were reviewed. The centre uses an electronic witness system, but for two manual steps, the signature of one of the witnesses was not recorded (Standard Licence Condition (SLC) T71).

In addition, in one set of notes, a record of the witness step at embryo transfer, confirming the embryos are the correct ones to transfer was omitted. This step would usually be an electronic witness step, but the processes used in this case required manual witnessing to be performed. The scientific inspector is satisfied that witnessing did occur, it was just not recorded (SLC T71 and CoP Guidance 18.4(f)).

See recommendation 3.

Patient and Donor selection criteria and laboratory tests

- Screening of patient and / or donors prior to procuring, processing and / or transporting gametes and embryos (Guidance notes 11 and 15)
- Payments for Donors (Guidance note 13)
- Donor assisted conception (Guidance note 20)

What the centre does well.

Screening of patients and donors

The centre's procedures for screening patients and donors are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes

and/or embryos.

Payments for donors
Payments to donors are fully in line with the requirements of the HFEA. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception
People born as a result of donation are entitled to request and receive their donor's name and last known address, once they reach the age of 18. Therefore it is important that centres use donated gametes or embryos from identifiable donors.

What the centre could do better.

A sample review of historic licensed treatment reporting identified four treatments in which donor gametes have been used, but where the reporting was outstanding at the time of inspection. It is highly likely that other treatments undertaken prior to the sample period reviewed have also yet to be reported. This potentially impacts upon the ability of the HFEA to fulfil statutory obligations to provide information to the donor conceived and donors. See section 4. Information Management for further details.

Good clinical practice

What the centre does well.

Multiple births (Guidance note 7)
The single biggest risk of fertility treatment is a multiple pregnancy.

The progress in reducing the clinical multiple pregnancy rates suggests that the centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target. The inspection team congratulates the centre on this achievement.

Process Validation (Guidance note 15)
The centre has fully validated all critical processing procedures to ensure that these procedures are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Traceability (Guidance note 19)
The centre's procedures are broadly compliant with HFEA requirements to ensure it has the ability -
(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
(b) identify the donor and recipient of particular gametes or embryos,
(c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and
(d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (Guidance note 23)
The centre has a quality management system in place that is partially compliant with HFEA requirements. The centre demonstrated that the quality management system is used to monitor and analyse their outcomes and is working to optimise their success rates and improve the quality and safety of the treatment and services it provides to patients.

Third party agreements (Guidance note 24)
The centre has agreements in place which cover the:
(a) procurement, testing or processing of gametes or embryos on behalf of the licensed centre, or
(b) supply of any goods or services (including distribution services) to the licensed centre which may affect the quality or safety of gametes or embryos.

Transport and satellite agreements (Guidance note 24)
The centre has five satellite agreements and one transport IVF agreement. The transport centre at the Countess of Chester Hospital is staffed by the Hewitt centre embryology team and follows the Hewitt centre's processes and procedures. The Countess of Chester is also licenced by the HFEA for treatment (insemination using partner sperm). An interim inspection was conducted there on 24 January 2013. This inspection resulted in three recommendations (one major and two 'other') relating to transport IVF / ICSI procedures, all of which have been implemented within the timescales specified. A senior member of the Hewitt centre responsible for laboratory processes during transport IVF / ICSI was present at the inspection.

Treatment outcomes are assessed and audited within the Hewitt centre's quality management system and consumables used at the transport centre are supplied and monitored by the Hewitt centre. Equipment used in the transport IVF process has been validated by and is maintained by Hewitt centre staff.

The Scientific Director stated that the monitoring of procedures at the transport and satellite centres are included in the audit schedule. Evidence was provided that the transport and satellite centres have been visited by senior Hewitt centre staff within the last six months and formal meetings are held biannually.

Equipment and materials (Guidance note 26)
All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff, with one exception noted in section "distribution and / or receipt of gametes and embryos" (see recommendation 7).

Premises (Guidance note 25)
The centre conducts all of the licensed activities in an appropriate environment, in line with good clinical practice. All diagnostic testing is carried out in a suitable, accredited laboratory.

Adverse incidents (Guidance note 27)
The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all of the adverse incidents that have occurred and shares the lessons learned in order to continuously improve the services it offers.

What the centre could do better.

Traceability (Guidance note 19)
At egg collection, not all containers used during the procurement of eggs are labelled with the patient/ donor's full name and a further identifier or a uniquely identifying donor code (SLC T101). See recommendation 8.

The centre ensures that records are maintained of the critical equipment that comes into contact with gametes or embryos and which can affect their quality or safety. However, the centre's SOP for traceability does not include this requirement (SLC T99). See recommendation 9.

Quality management system (Guidance note 23)
Quality Indicators:
QIs or objectives relating to data submission processes have not been established (SLC T35). See recommendation 4.

Audit:
The centre has not audited their processes and procedures for the submission of data to the HFEA for compliance with approved protocols, QIs and regulatory requirements in the previous two years nor have they audited the procedures for consent, provision of information and welfare of the child assessment provided at their transport and satellite centres (SLC T36). See recommendation 5.

The centre has recently performed an extensive review and update of their quality management system. At the time of the inspection a new database for the management of the quality management system (Q pulse) had only been in operation for four months and was being used in parallel with the previously established systems. Whilst the inspection team was satisfied that the quality management system was an improvement to the previous system and fit for purpose it was acknowledged that there was a significant amount of work to be done to align the existing stand alone systems in operation in each discipline to ensure a cohesive, fully functional and integrated quality management system.

Third party agreements (Guidance note 24)
The quality manager stated that all third party agreements (TPA) had recently been reviewed and formulated as required by the Trust in accordance with their protocols.

From a review of the TPAs in place, the inspection team concluded that the agreements were generic and did not contain sufficient detail to reflect the centre's requirements of individual suppliers providing goods or services which may influence the quality and safety of gametes and embryos.

The following specific issues were noted:

- four of the TPAs reviewed did not include the identification of person(s) responsible for managing the relationship between the centre and the third party (T114(b))
- the TPA with the established transport centre was incomplete and still under review.

See recommendation 6.

Staff engaged in licensed activity

What the centre does well.

Person Responsible (Guidance note 1)
The PR has a key role to play in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision the licensed activities are authorised. The PR has the primary (legal) responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:

- that suitable practices are used in undertaking the licensed activities;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with.

The PR has academic qualifications in the field of medicine and has more than two years practical experience which is directly relevant to the activity to be authorised by the licence.

The PR has successfully completed the HFEA PR Entry Programme (T/1005/7).

Staff (Guidance Note 2)
The centre has suitably qualified and competent staff to carry out all of the licensed activities and associated services.

What the centre could do better.
Nothing noted on inspection.

Welfare of the Child (Guidance note 8)

What the centre does well.

The centre's procedures for taking into account the welfare of the child are compliant with HFEA requirements. The centre 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.

What the centre could do better.
Nothing noted on inspection.

Embryo Testing

- Preimplantation genetic screening (Guidance note 9)
- Embryo testing and sex selection (Guidance note 10)

What the centre does well.

The variation of the centre's licence to include embryo testing was approved by an ELP on 8 February 2013 and at the time of the inspection the centre had not commenced its

embryo testing programme.

The centre's SOPs, process validation and staff competence were assessed by the Executive as part of the variation application and centre staff confirmed that no changes have been made since the application was made. Therefore the following details were confirmed.

The centre's procedures for performing embryo testing are compliant with HFEA requirements ensuring that:

- no embryo will be transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA;
- no information derived from tests conducted will be used to select embryos of a particular sex for social reasons;
- no embryo will be tested unless it meets the statutory tests i.e. that the embryo is at a significant risk of having a serious genetic condition.

The centre ensures that people seeking embryo testing will be given: written information, every opportunity to discuss the implications of their treatment, and access to clinical geneticists, genetic counsellors and infertility counsellors where required.

What the centre could do better.

Nothing noted on inspection.

2. The experience of patients

Patient feedback

What the centre does well.

During the inspection visit the inspector spoke to one patient who provided feedback on her experiences. A further 20 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive, with fifteen of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better.

Nothing noted on inspection.

Treating patients fairly

What the centre does well.

Egg sharing arrangements (Guidance note 12)

The centre's procedures for egg sharing arrangements are compliant with HFEA requirements to ensure that:
(a) care is taken when selecting egg and sperm providers donating for benefits in kind
(b) egg and sperm providers are fully assessed and medically suitable, and
(c) the benefit offered is the most suitable for the egg or sperm provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)

The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements to ensure that the arrangement is legal and protects the rights of the surrogate and the commissioning couple. Patients providing gametes in surrogacy arrangements are screened as donors in order to safeguard the health of the surrogate.

Complaints (Guidance note 28)

The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. The centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Treating patients fairly (Guidance note 29)

The centre treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors.

Counselling (Guidance note 3)
Counselling is offered by appropriately experienced counsellors to all patients and donors providing consent to treatment and / or donation and legal parenthood. The provision of counselling is compliant with HFEA requirements.

What the centre could do better.

Nothing noted on inspection

Information

What the centre does well.

The centre's procedures for providing information to patients and / or donors are broadly compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

Provision of costed treatment plans (Guidance note 4)
The centre provides an individual costed treatment plan to all of its self funding patients. This ensures that patients know the full cost of their proposed treatment before deciding on whether to proceed or not.

What the centre could do better.

The patient information regarding the use of embryos for the purpose of training staff does not include details of whether any information will be fed back to the patients (SLC T97(d)). See recommendation 10.

A review of the centre's website noted the following non-compliance with Chair's letter CH(11) 02:

- live birth rates are not recorded;
- national rate and like for like comparison are not provided;
- reference to the HFEA as the source of national information is not made.

See recommendation 12.

Consent

What the centre does well.

The centre's procedures for obtaining consent are broadly compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research
The HFEA Register started operating in August 1991 and is a rich source of information about assisted reproductive technologies (ART), its outcomes and the factors that contribute to the birth of a baby following treatment. This information can be used by researchers and, in certain circumstances, linked to other health registers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment. Whereas the HFEA is permitted to disclose non-identifying information to researchers it can only provide identifying information with the consent of patients or donors. Therefore, it is important that patients and donors are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA. The centre's procedures for doing this ensure that the HFEA holds an accurate record of the patient or donor's consent, so that it only releases identifying information, to researchers, with their consent.

What the centre could do better.

On the day of the inspection the centre had six samples of cryopreserved sperm and 34 sets of cryopreserved embryos in storage for which the consent had expired. (Schedule 3, 8(1) and 8(2), HF&E Act 1990 (as amended)).

The centre's bring forward system was considered in principle to be effective and well managed. However, if contact is made with the patient(s) and they provide written confirmation, on a local centre form, that they would like to extend the storage period, the centre consider this to be a form of 'implied' consent and are reluctant to allow material to perish if appropriate consent is not then obtained, despite many attempts to contact them.

See recommendation 1.

The centre has procedures in place for dealing with disputes that may arise when one gamete provider withdraws consent to the storage of embryos. However, the centre does not provide information about counselling or mediation services as appropriate (CoP Guidance 5.35).

See recommendation 14.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well.

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities and that:

- 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.

What the centre could do better.

Nothing noted on inspection.

Storage of gametes and embryos

What the centre does well.

The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

The centre's procedures for storing gametes and embryos are broadly compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety.

What the centre could do better

Please refer to the section 'Consent' and recommendation 1.

Distribution and / or receipt of gametes and embryos

What the centre does well.

The centre's procedures for distributing and / or receiving gametes and embryos are broadly compliant with HFEA requirements. This ensures that all gametes / embryos sent to other licensed centres within or outside the UK are appropriately labelled and relevant information is sent to the other centre to ensure the continued quality and safety of the gametes and embryos. The centre only accepts gametes and embryos from other centres

if the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in a way that does not comprise their quality and safety.

What the centre could do better.

Whilst the procedures for distributing and / or receiving gametes and embryos are considered to be compliant, it was noted that one piece of equipment used in this process (dry shipper) has not been validated (SLC T24). See recommendation 7.

Use of embryos for training staff (Guidance note 22)

What the centre does well.

The centre's procedures for using embryos for training staff are compliant with HFEA requirements. This ensures that embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

The centre uses embryos to train staff in the following activities:

- Embryo biopsy
- Blastocyst biopsy
- Cryopreservation and thawing techniques
- Vitrification
- Assisted hatching
    - Mechanical
    - Chemical
    - Laser
- Embryo handling and manipulation
- Assessment of embryos

All of these activities have been authorised by the Authority.

What the centre could do better.

See previous section "information". Patient information pertaining to the use of embryos in training does not include whether any information will be fed back to them or not (SLC T97(d)). See recommendation 10.

4. Information management

Record keeping and submitting information to the HFEA

What the centre does well.

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are broadly compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities including information on donors and on any children conceived as a result of their donation. In order to maintain this register, clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information, about licensed activities, to the Authority are partially compliant with HFEA requirements. It is important that the centre ensures the HFEA can supply accurate information to a donor-conceived person and their parents.

What the centre could do better.

Not all licensed treatment activity has been reported to the HFEA in accordance with Direction 0005.

Compliance with data submission requirements has not been audited by the centre in the last two years (SLC T36).

The improving trend in the quality of data provided by the centre pre-inspection has not been sustained: the form submission error rate has deteriorated from 4% pre-inspection to 12% at the time of writing.

As part of the licence renewal process an audit of information submitted to the HFEA is conducted at inspection. Historically there have been significant non-compliance issues regarding the submission and validation of data provided to the HFEA. In order to confirm whether these historic issues had been resolved, the centre provided the inspection team with a report of data submitted for the most seriously affected period (1 April 2006 to 31 March 2012) from the centre's own data management system.

The information in this report was compared to an extract from the HFEA register for the same period. The comparison showed that:

- the computer generated record provided by the centre was incomplete (did not include all the treatments for which data has previously been submitted to the HFEA);
- four IVF and four DI treatments appeared not to have been reported to the HFEA (treatments recorded on the centre's computer generated report were not found on the HFEA register); and
- some IVF treatments have been reported more than once.

A number of related issues were also noted as follows:

- the insemination dates recorded on the report provided by the centre did not reflect the insemination dates already reported to HFEA;
- some IVF treatment dates were missing from the centre's extract making it difficult to reconcile the treatments with those previously reported to HFEA;
- treatments that appeared on the centre's own report could not subsequently be found on the centre's own IT system;
- centre staff are not always able to view all the treatment records of an individual patient on the centre's computer system (on the day of inspection it was only possible to see the most recent records of a selected patient's treatment). This may contribute to staff submitting duplicate reports to the HFEA.

See recommendation 2.

A review of donor files identified two instances where donor goodwill messages and pen portraits had not been submitted to the HFEA in accordance with form guidance (SLC T9(e). See recommendation 13.

Retention of records:
The centre follows the Trust policy for retention of records. The policy does not include the requirement that records should be kept for at least 30 years (or for such longer period as may be specified in Directions) after clinical use, or the expiry date (SLC T48). See recommendation 11.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2011 recommendations for improvement were made in relation to seven areas of major non-compliance and eleven 'other' areas of non-compliance.

The PR provided information and evidence that most of the recommendations were fully implemented. On the day of inspection however, it was noted that the following "major" recommendations have not been fully implemented:

- to ensure the backlog of unreported treatment forms is cleared;
- to develop agreements with all third party suppliers of goods and services and evaluate their ability to comply with the required standards;
- to develop QI monitoring of all critical processes and activities;
- to ensure that data submission to the HFEA is accurate and within the timeframes specified (General direction 0005) specific to a large number of outcome forms which have not yet been submitted.

Risk Based assessment Tool (RBAT) alerts:

During the time period January 2012 to February 2013 the PR received 14 RBAT alerts raising concern regarding the following:

- reporting of treatments to the HFEA where donor gametes had been used;
- pregnancy rates following ICSI for patients under 38 years;
- pregnancy rates following FET for patients under 40 years.

Whilst the PR responded to the issues raised by the alerts he did not do so in the required time frame.

The centre has taken the following action to address the reduced pregnancy rates for ICSI in the affected age group, these include:

- revising the ovarian stimulation protocol;
- modifying ICSI equipment to reduce temperature fluctuations;
- engaging an external consultant to review ICSI practices in the laboratory that led to several minor recommendations which have been implemented.

The centre's own monitoring of ICSI success rates over the last three months was reviewed on inspection and demonstrated a significant upward trend in success rates. The scientific director was confident that this demonstrated the impact of the improvement strategy implemented by the centre and documented above. The HFEA's monitoring of success rates has a three month time lag (centres are given up to eight weeks after the treatment cycle completion date to report early pregnancy outcomes) and so monitoring at the time of the inspection did not extend beyond December 2012.

In response to the alerts concerning FET the centre has:

- consulted with peers nationally to benchmark their practice;
- conducted a review of practice, equipment and consumables used;
- reviewed and amended their SOPs for FET;
- conducted a comparative audit pre and post practice revision.

The HFEA's monitoring of the centre's FET success rates indicates that this is a historic issue that has now been resolved.

In consideration of the information provided by the centre, it is concluded that the PR has taken steps to ensure the use of suitable practices in compliance with HF&E Act 1990 (as amended), Section 17 (1d) and that no further regulatory action in relation to success rates would be proportionate at this time. The centre's success rates will continue to be the subject of on-going monitoring.

Areas of practice requiring action

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, or a significant shortcoming from the statutory requirements. 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
1. On the day of the inspection the consent for the storage of cryopreserved gametes and embryos for 40 patients had expired. Schedule 3, 8(1) and 8(2) HF&E Act 1990 (as amended).	The PR should provide the HFEA with an update on the number of patients for whom gametes and embryos remain in store without effective consent by the time this report is considered by ELP. Also by the time this report is considered by ELP, where gametes and embryos remain in store without effective consent, a plan should be submitted to the HFEA documenting the centre's intended actions and the anticipated timescale for their implementation. The PR should provide monthly updates to the HFEA on progress in implementing the proposed	The PR acknowledges that the system to enusre effective consent to storage remains in place has lead to this deficiency. The PR has instructed that the process be altered to categorically state to patients that unless effective consent is in place (in a timely manner) then stored material WILL be removed from storage as	The inspector has received the report and notes that the number of cryopreserved gametes/embryos in storage where the consent has expired has reduced to 13. The inspector also notes the reasons for the remaining gametes/embryos being continued in storage and requests that the PR inform the inspector when this situation has been resolved.

	actions. The PR is reminded of guidance issued by the HFEA in CH(03)02 (http://www.hfea.gov.uk/2721.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material. Report to be received by 30 August 2013.	this is a legal requirement. SOPs to be reviewed and revised. A report detailing current status is provided.	**Further action required** It is noted that critical non-compliances are normally required to be resolved prior to consideration by committee. The inspector notes that in this case it would not be expected that this could be resolved in a short time frame. The Executive does not consider that this outstanding area of non-compliance is any impediment to the delivery of a safe service.
2. There are on-going and significant concerns about the reliability of data submissions and the centre's systems for submitting information to the HFEA. General Direction 0005. This issue has been escalated to a critical level of non-compliance as this was of concern at the last inspection. It is	The PR must ensure compliance with the data submission requirements detailed in Direction 0005. The PR should develop a plan of action to investigate and resolve both the historic reporting omissions and the IT system issues that may be impacting on the accuracy of treatment reporting. A copy of this action plan, including the timescale for the implementation should be submitted to the centre's inspector by the time this report is considered by ELP.	The PR acknowledges that whilst significant progress has been made in complying with data submission requirements further action is required. An action plan has been devised (provided) to investigate and resolve both the historic reporting omissions and the IT system issues impacting on the accuracy of treatment reporting.	The inspector has received the action plan and looks forward to receiving monthly progress updates. Compliance will continue to be monitored closely by the inspector and the HFEA audit team. If significant progress is not made and maintained in the timescales required a management review will be held and consideration will be made as to whether to refer the issues back to the licensing

acknowledged that the centre has worked hard to correct issues identified previously however, the discovery of further historic failures at this inspection is of continued concern.	Monthly updates on progress in implementing the action plan should be provided to the centre's Inspector. The outstanding licensed treatment reporting identified at the time of inspection must be addressed immediately. Action plan to be received by 30 August 2013.	Additional quality indicators (monthly) have been devised to monitor our continual performance within this area and these will be provided to the Centres Inspector by the Centres Quality Manager. The outstanding licensed treatment reporting identified at the time of inspection have been addressed immediatley and are being resolved as matter of priority. A report of progress will be provided by 30th August 2013.	panel. **Further action required** It is noted that critical non-compliances are normally required to be resolved prior to consideration by committee. The inspector notes that in this case it would not be expected that this could be resolved in a short time frame. The Executive does not consider that this outstanding area of non-compliance is any impediment to the delivery of a safe service.

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
3. On inspection, 10 sets of witnessing records from within patients' notes were reviewed. The centre uses an electronic witness system, but for two manual steps, the witness signatures were not recorded. In one set of notes, a record of the witness step at embryo transfer, confirming the embryos are the correct ones to transfer was omitted. (SLC T71 and CoP Guidance 18.4(f)).	The PR should ensure that witness signatures are recorded at the time that witnessing is carried out. The centre had scheduled a witnessing audit to be performed in June 2013. The results of this audit and any corrective actions required should be provided to the centre's inspector. By 30 August 2013.	The PR acknowledges that witnessing signatures were not recorded for two manual witnessing steps identified at the inspection. However, as described below the PR is confident that in these cases the appropriate witnessing took place. The missing signatures were from the embryologist performing the procedure and not the 2nd person witnessing. The embryologist performing the procedure is responsible for ensuring that the witnessing process is performed as quickly as possible without compromising the safety of the gametes/embryos. Furthermore, at the HFC all witnessing processes are electronically witnessed so there is always record of who	The inspector has received the amended witnessing SOP and looks forward to receiving the results of the audit by 30 August 2013. The inspector is satisfied with the response. **Further action required.**

		performed the witnessing steps. The manual double witnessing processes already require the gametes/embryos to be out of the incubator longer than normal, therefore the 2nd witness always immediately signs and adds the time to the witnessing paperwork while the gametes/embryos are dealt with safely. Changes have been made to the SOP for the 2nd witness to ensure that the member of staff performing the signs the paperwork and ensure that the signing is not missed in future. In the case of the absence of a witnessing record at ET identified by the Inspector, an additional manual witnessing step has been added for ET when required. The Witnessing Audit is in progress (the SOP specifies that this be performed over a ten week period) and a report will be provided by end August 2013.	
4. QIs have not been established for data submission (SLC T35).	The PR should ensure that QIs are established for all licensed activities. The PR should provide the inspector with documented evidence of the establishment	See 2, above	The inspector looks forward to receiving the documented QIs for data submission by 30 August. **Further action required.**

	of QIs for data submission. By 30 August 2013.		
5. The centre has not audited their processes and procedures for the submission of data to the HFEA for compliance with approved protocols, QIs and regulatory requirements in the previous two years nor have they audited the procedures and process for consent, provision of information and welfare of the child assessment provided at their transport and satellite centres (SLC T36).	The PR should ensure that all licensed activities are audited within a two year cycle. The PR should provide details of when these activities will be audited by 30 August 2013. As they are completed, a copy of each audit and any actions required should be provided to the centre's inspector. All required audits should be completed by 30 November 2013.	The PR acknowledges these deficiencies within the audit schedule. The QM has been instructed to revise the audit schedule to include the deficient areas which will be provided to the Authority by end August 2013. In addition all required audits will be completed by end November 2013.	The inspector is satisfied with the response and looks forward to receiving a copy of the audit schedule by 30 August 2013. The inspector also looks forward to receiving confirmation that all required audits have been completed by 30 November 2013. **Further action required**
6. TPAs were considered generic and did not contain sufficient detail to reflect the centre's requirements of suppliers providing goods or services which may influence the quality and safety of gametes and embryos.	The PR should ensure that all TPAs are reviewed to ensure compliance with SLC T111, T114 and Directions 0010 where applicable. A summary report of the findings of the review including a list of all TPAs included in the review should	The HFC TPAs were recently revised in accordance with the NHS Standard Contract, however, the PR acknowledges this approach did not fully meet the requirements of the HFEA. As such, the QM has been instructed to revise the Centre's TPA such that it meets the requierments of i. the HFEA,	The inspector is satisfied with the response and looks forward to receiving the summary report by 30 August 2013. **Further action required**

The following specific issues were noted: • four of the TPAs did not include the identification of person(s) responsible for managing the relationship between the centre and the third party (T114(b)) • the written agreement with the established transport centre was incomplete and still under review. General Direction 0010 and SLC T111.	be provided to the centre's inspector by 30 August 2013. In addition, the report should also document any corrective actions required to ensure compliance and the anticipated timescales for the implementation of the corrective actions. By 30 August 2013.	ii. the NHS and iii. UKAS (formerly CPA). This will then be issued to all 'third parties' and a report on progress submitted by end Aug 2013.	
7. The dry shipper used to transport gametes and embryos has not been formally validated. (SLC T24).	The PR should ensure that all critical equipment is validated. Evidence of validation should be provided to the centre's inspector. By 30 August 2013.	The PR acknowledges the requirement and importance of critical equipment validation. Specifically, the dry-shipper has been decommissioned July 2013 - a specialised courier only to be used for any future transport of gametes/embryos. SOP update to reflect this.	The inspector is satisfied with the response. **No further action.**

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
8. At egg collection, not all containers used during the procurement of eggs are labelled with the patient's/donor's full name and a further identifier or a uniquely identifying donor code (SLC T101).	The PR should consider the risks of not labelling the tubes used during egg collection. The centre's inspector should be informed of any actions taken to mitigate the risks of misidentification. By 30 August 2013.	Risk assessment performed (provided) in support of not labelling all the egg collection tubes and witness step now in place to ensure that the workstation is clear at the start/end of the procedure	The inspector has received the risk assessment and is satisfied with the response. **No further action.**
9. The centre's SOP for traceability did not include the requirement for equipment to be traceable (SLC T99).	The PR should ensure that the centre's traceability SOP includes the requirement for equipment traceability. The centre's inspector to be provided with a copy of the amended SOP. By 30 August 2013.	Traceability of equipment added to SOP (provided).	The inspector has received the amended SOP and is satisfied with the response. **No further action.**
10. The patient information regarding the use of embryos in staff training does not include details of	The PR should ensure that patient information regarding the use of embryos in staff training includes details of whether any	Addition of patient information stating what staff training may be performed and that the patients will not be informed regarding use for	'The PR's response is noted and it is recommended that he reviews the requirements of SLC T97. The inspector

whether any information will be fed back to the patient (SLC T97(d).	information will be fed back to the patient. The centre's inspector to be provided with a copy of the information. By 30 August 2013	training unless specifically requested.	considers that SLC T97 requires that the patients are told of the nature of the training for which embryos will be used. Patients should also be informed if additional information about the embryos, gained as a result of their use in training, will be available and if this will be fed back to them. The inspector looks forward to receiving a copy of the amended patient information by 30 August 2013. **Further action required**
11. Where the centre has adopted the Trust policy for the retention of records, this policy does not reflect the requirement that records are to be kept for at least 30 years (or for such longer period as may be specified in Directions) after clinical use, or the expiry date (SLC T48).	The PR must ensure that the SOP in use at the centre directs that records are kept for at least 30 years (or for such longer period as may be specified in Directions) after clinical use, or the expiry date. The centre's inspector to be provided with a copy of the amended SOP. By 30 August 2013.	The PR has instructed the QM to liaise with the Trust Head of Integrated Governance to ensure that the Trust policy reflects the requirement that HFC records are kept for at least 30 years (or for such period as specified in Directions). A copy of the amended SOP will be supplied by end Aug 2013.	The inspector is satisfied with the response and looks forward to receiving a copy of the amended SOP by 30 August 2013. **Further action required**

12. A review of the centre's website noted that it was not fully compliant with Chair's Letter (CH(11)02).	The PR should ensure that the centre' website is compliant with Chairs Letter CH(11)02. By 30 August 2013.	The PR acknowledges the content of Chair's letter CH(11)02 and has given instruction to ensure that the content of CH(11)02 is suitably reflected on the Centre's website. These amendments will be in place by end Aug 2013. In addition a yearly audit of website content will be encorporated into the Centre's audit schedule.	The inspector is satisfied with the response and will review the centre's website for compliance with Chairs letter CH(11)02 at the beginning of September 2013. **Further action required**
13. A review of donor files identified two instances where goodwill messages and pen portraits had not been submitted to the HFEA in accordance with form guidance (SLC T9e).	The PR should ensure that donor goodwill messages and pen portraits are submitted to the HFEA in accordance with form guidance. By 30 August 2013. Three months after the implementation of corrective actions the centre should audit a random sample of ten sets of donor records (i.e. relating to donor registrations within the 3 months following the implementation of corrective actions) to ensure that this issue has been effectively addressed.	The PR acknowledges this deficiency and has given instruction in accordance with the HFEAs recommendation. The required audit will be included in the Centre's audit schedule.	The inspector is satisfied with the response and looks forward to receiving the results of the audit by 30November 2013. **Further action required**

	By 30 November 2013.		
14. The centre has procedures in place for dealing with disputes that may arise when one gamete provider withdraws consent to the storage of embryos. However, the centre does not provide information about counselling or mediation services as appropriate (CoP Guidance 5.35).	The PR should ensure that procedures are in place whereby if one gamete provider withdraws consent to the storage of embryos the centre provide information about counselling or mediation services as appropriate. The PR should provide the inspector with an amended SOP. By 30 August 2013	The PR acknowledges this deficiency and has instrcuted that the SOP be amended to include reference to counselling and mediation services.	The inspector is satisfied with the response and looks forward to receiving a copy of the amended SOP by 30 August 2013. **Further action required**

Reponse from the Person Responsible to this inspection report

HFEA Executive Licensing Panel Meeting

16 August 2013

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

Minutes – Item 1

Centre 0007 – (Hewitt Fertility Centre) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard – Head of Policy and Communications (Chair)	Rebecca Loveys
Jasper Squire – Computer Programmer	Observing:
Matthew Watts – Regulatory Policy Manager	Sam Hartley – Head of Governance and Licensing

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 this is a large centre which provides a full range of fertility services and has been licensed since 1992.

2. The Panel noted that the centre is on a five year licence due to expire in October 2013 and that the renewal inspection took place on 29 and 30 May 2013.

3. The Panel noted that the centre provided 2,264 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2013.

4. The Panel noted that for 2012 the centre's success rates are in line with national averages with the following exceptions:

    i. The clinical pregnancy rates for ICSI for patients aged 37 and under are below the national average at a statistically significant level;

    ii. The clinical pregnancy rates for FET patients aged 40 and under are below the national average at a statistically significant level.

5. The Panel noted that between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 13%, and that this represented performance that was not statistically likely to be different from the 15% multiple live birth rate target for this period.

6. The Panel noted that, at the time of inspection, two critical, five major and seven other areas of non-compliance were identified.

7. The Panel noted that non-compliances first identified during the centre's 2011 interim inspection remain unresolved, notably the critical area of non-compliance relating to concerns about the reliability of data submissions and the centre's systems for submitting information to the HFEA.

8. The Panel noted in particular this outstanding issue, which has been escalated to a critical area of non-compliance because it remains unresolved since the centre's last inspection. Failure to submit accurate information impacts on the HFEA's ability to provide reliable information to donor conceived people.

9. The Panel noted that the Inspectorate recommends this centre's licence is renewed for a period of three years, rather than the normal four years, due to this unresolved non-compliance. It also noted the Inspectorate's intention to carry out a focussed inspection at the centre next year.

10. The Panel urged the centre to take swift action to address the outstanding non-compliances and expects the Inspectorate to see a notable improvement at the centre at its next inspection.

Decision

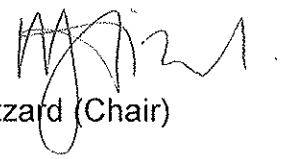
11. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

12. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of the licensed activities.

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

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

15. The Panel endorsed the Inspectorate's recommendations and timescales made in the report. The Panel agreed to renew the centre's licence for a period of three years with no additional conditions.

Signed: 
Juliet Tizzard (Chair)

Date: 21 August 2013