Executive Licensing Panel - minutes

Centre 0007 (Hewitt Fertility Centre) Renewal Inspection Report

Friday, 9 September 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) David Moysen Jessica Watkin	Head of Business Planning Head of IT Policy Manager
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
External adviser		
Observers		

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel considered the papers, which included a completed application form, inspection report and licensing minutes for the last three years.

1.2. The panel noted that the Hewitt Fertility Centre, centre 0007 is located at Liverpool Women's Hospital in Liverpool. The centre provides a full range of fertility services including embryo testing. The centre has satellite agreements in place with five clinics and also has a transport IVF agreement with the Countess of Chester Hospital, centre 0280. In relation to activity levels this is a large centre.

1.3. The panel noted that the centre has been licensed by the HFEA since 1992.

1.4. The panel noted that in the 12 months to 31 March 2016, the centre provided 3708 cycles of treatment (excluding partner intrauterine insemination).

1.5. The panel noted that for IVF and ICSI, HFEA-held register data for the period 1 January 2015 to 31 December 2015 showed the centre's success rates were in line with national averages.

1.6. The panel noted that in 2015, the centre reported 64 cycles of partner insemination with four pregnancies which equates to a 6% clinical pregnancy rate. This is likely to be consistent with the national average.

1.7. Between 1 January 2015 and 31 December 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 5%. This represents performance that is likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

1.8. The panel noted that at the time of the renewal inspection on 14 and 15 June 2016, one critical, six major and two other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has committed to fully implementing all of the recommendations within the prescribed timescales.

1.9. The panel noted that significant improvement is required in order for the centre to demonstrate the suitability of their practices.

1.10. The panel noted that the PR is encouraged to continue to use the Quality Management System to best effect to monitor and improve their success rates so as to improve the quality of the service offered to patients.

1.11. The panel noted that the inspectorate recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

2. Decision

2.1. The panel had regard to its decision tree.

2.2. The panel noted that an application form and fee had been submitted and that the application contained the supporting information required by General Directions 0008. The PR mistakenly submitted an application for renewal of a treatment and storage (without embryo testing) licence, however the PR has confirmed in writing that she wishes to apply for renewal of a licence for treatment (including embryo testing) and storage. This area of practice was reviewed at this inspection and the Executive supports this application.

2.3. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.4. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.5. The panel were pleased to see that the centre has a low multiple pregnancy rate.

2.6. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

2.7. The panel noted that there are recommendations with timescales for implementation set shortly after this Executive Licensing Panel meeting and agreed that the inspectorate should provide the panel with an update, at the next available meeting, confirming whether the outstanding recommendations were implemented within the prescribed timescales.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Paula Robinson

Date

16 September 2016

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: 14 and 15 June 2016

Purpose of inspection: Renewal of a licence to carry out treatment (including embryo testing) and 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.

Inspectors: Janet Kirkland, Susan Jolliffe, Karen Conyers, Neil McComb, Joel McChesney.

Date of Executive Licensing Panel: 9 September 2016

Centre name	Hewitt Fertility Centre
Centre number	0007
Licence number	L/0007/16/b
Centre address	Liverpool Women's Hospital, Crown Street, Liverpool, L8 7SS, United Kingdom
Person Responsible	Ms Karen Schnauffer
Licence Holder	Liverpool Women's NHS Foundation Trust.
Date licence issued	01 November 2013
Licence expiry date	31 October 2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Hewitt Fertility Centre has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services including embryo testing.

The centre provided 3708 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2016. In relation to activity levels this is a large centre.

The centre's current licence was granted for a period of three years, rather than the usual four and was varied in August 2014 to reflect a change of Person Responsible (PR).

The Hewitt Fertility Centre has satellite agreements in place with five clinics and a transport IVF agreement with centre 0280, Countess of Chester Hospital.

The PR mistakenly submitted an application for renewal of a treatment and storage licence when she intended to apply using the form for renewal of a treatment (including embryo testing) and storage licence; i.e. for the activities for which the centre is currently licensed. The PR has confirmed in writing that she wishes to apply for renewal of a licence for treatment (including embryo testing) and storage. This area of practice was reviewed at this inspection and the Executive supports this application.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 January 2015 to 31 December 2015 show the centre's success rates are in line with national averages.

In 2015, the centre reported 64 cycles of partner insemination with four pregnancies This equates to a 6% clinical pregnancy rate which is likely to be consistent with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between 1 January 2015 and 31 December 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 5%: this represents performance that is likely to be statistically different from the 10% multiple live birth rate target.

[1]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. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

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 has submitted an application for treatment and storage. The centre is currently licensed for treatment (including embryo testing) and storage and the PR has confirmed that she wishes the application to be considered as one for a treatment (including embryo testing) and storage licence;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by 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 that at the time of the inspection there were a number of areas of practice that required improvement including one critical, six major, and two 'other' areas of non-compliance.

Since the inspection visit the PR has given a commitment to fully implement all actions relating to the following recommendations in the prescribed timescales:

Critical area of non compliance:

- **the PR should ensure that gamete donors are screened in accordance with standard licence conditions and professional body guidelines.**

Major areas of non compliance:

- the PR should ensure that all required audits are carried out and include an audit against regulatory compliance, and that they are documented in a consistent manner to include a summary of findings and corrective actions where applicable;
- the PR should ensure that third party agreements are in place with third party premises where surgical sperm retrievals are performed;
- the PR should ensure that CE marked medical devices are used wherever possible;
- the PR should ensure that all relevant incidents and adverse events are reported to the HFEA;
- the PR should ensure that patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms;
- the PR should ensure the accuracy and timeliness of the centre's submission of data to the HFEA.

'Other' areas that require improvement:

- the PR should ensure that documentation regarding the timing of the administration of controlled drugs is recorded in patients' files;

- the PR should ensure that the validation of the suction pump used for egg collections is documented.

Recommendation to the Executive Licensing Panel

The inspection team notes and commends the centre on achieving a low multiple pregnancy rate and, in so doing, reduce the single biggest risk of infertility treatment. The inspection team also notes that the centre's success rates are consistent with the national average. However, recommendations are made in response to one critical and six major areas of concern.

Significant improvement is required in order for the centre to reflect suitable practices. The centre has a QMS in place and the PR is encouraged to continue to use it to monitor and improve the service provided. The centre's inspector will continue to monitor the centre's performance.

The inspection team recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

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

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

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

Donor selection criteria and laboratory tests
Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are partially compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. 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 (Guidance note 20)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic

siblings) from the HFEA or the clinic where they received treatment. Therefore, it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements in this regard and ensure the donor conceived will be able to receive the required information.

What the centre could do better.

Screening of donors (Guidance note 11)
The centre's egg donation standard operating procedure (SOP) describes a process whereby screening in accordance with standard licence conditions is performed prior to acceptance on the donor programme. The SOP also directs that screening is repeated close to the time of donation (approximately day seven of ovarian stimulation prior to donation). However, this second screen does not include all required tests. The records of two egg donors were reviewed on inspection. In both cases the donor's blood samples for screening were obtained at the time of donation, but the samples had not been screened for Hepatitis B surface antigen, Hepatitis B core antibody, Hepatitis C, or syphilis at this time (SLC T52(b), SLC T53(b); see recommendation 1).

The inspection team acknowledges that these screening tests had been performed prior to the donors being accepted and were negative. However, this cannot be considered to provide assurance that the donors were negative for all required tests at the time of donation as in one instance initial screening had been conducted six months prior to the donation and in the other case three months prior to the donation.

Immediately following the inspection, the PR assured the centre's inspector that the centre's screening practices for egg donors and the related SOP had been updated to include all screening tests required at the time of donation. The PR also confirmed that where patients are currently attending the centre for treatment involving donor eggs or embryos created with donor eggs, she would ensure that the donors have been screened in accordance with regulatory requirements.

Suitable premises and suitable practices
Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The premises of the centre's satellite and transport facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to processes gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements for accreditation by Clinical Pathology Accreditation (CPA) (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are broadly compliant with guidance.

Prescription of intralipid 'off label'
Intralipid therapy is not provided at this centre.

Pre-operative assessment and the surgical pathway
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is a multiple pregnancy. The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created

with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- if sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes / embryos sent to other licensed centres within or outside the UK are:
- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability to:
- identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- identify the donor and recipient of particular gametes or embryos;
- identify any person who has carried out any activity in relation to particular gametes or embryos; and
- 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 (QMS) (Guidance note 23)
The centre has a QMS in place that is partially compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are partially compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage transport and satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by transport and satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements.

The centre is broadly compliant with HFEA requirements to validate critical equipment.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are partially compliant with HFEA requirements. The centre reports some adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Medicines management
An audit of patients records performed on inspection identified an instance where the time of administration of a controlled drug was not recorded in the patient record. Section 6.8.1 V (1) of the centre's own Management of Controlled drugs policy states that; 'for CDs administered the following details should be recorded: date and time when dose administered' (SLC T2; see recommendation 8).

QMS (Guidance note 23)
Several non-compliances were noted with the quality management system:

- an audit of counselling did not include a summary of findings or documentation of corrective actions;
- an audit of donor recruitment, selection and screening has not been performed within the last two years;
- the SOP to direct the process for egg and embryo donation, and egg donor recruitment has not been audited against compliance with regulatory requirements as it does not include the requirement to screen for Hepatitis B surface antigen, Hepatitis B core antibody, Hepatitis C virus or syphilis at the time of donation (SLC T36; see recommendation 2).

Third party agreements (Guidance note 24)
The centre undertakes procurement by way of surgical sperm retrievals at unlicensed premises and has not established written agreements to cover these activities (SLC

T111; see recommendation 3).

Equipment and materials (Guidance note 26)
The following medical devices used by the centre are not CE marked: containers used for semen sample collection and serological pipettes (SLC T30; see recommendation 4).

The centre has not documented the validation of the suction pumps used for egg collection (SLC T24; see recommendation 9).

Adverse incidents (Guidance note 27)
A review of the centre's incident log on inspection identified two adverse incidents which had not been reported to the HFEA (SLC T120; see recommendation 5). The inspection team noted that these incidents were not related to breaches of confidentiality but to other areas of practice.

Staff engaged in licensed activity

Person Responsible (PR)

Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activities to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (number T/1271/82).

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

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

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided are compliant with HFEA requirements.

Safeguarding
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre does not undertake pre-implantation genetic diagnosis only pre-implantation genetic screening. The centre's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is 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 and
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons.

The centre ensures that people seeking embryo testing are given written information and are given every opportunity to discuss the implications of their treatment.

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

2. The experience of patients

Patient feedback

What the centre does well

During the inspection no patients came forward to provide feedback on their experiences to members of the inspection team. Nine patients have provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive, with eight of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received and three that they also had complaints.

From discussions with staff and a review of the responses to the centre's patient questionnaire, the inspection team considers that the centre actively seeks patient feedback and acts appropriately on it.

On the basis of patient 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 identified at this inspection.

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF& E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg sharing arrangements are partially compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind
- egg providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

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 wellbeing of prospective and current patients and donors.

The centre has reported several incidents involving breaches of confidentiality. In February 2016 the centre was visited by the HFEA Clinical Governance lead to provide support to the centre team in their actions towards addressing this area of concern.

The actions that the PR has taken to address the incidents were discussed in detail on the inspection visit and the inspection team were satisfied that the centre could demonstrate learning from the incidents and had taken corrective action, therefore no recommendation will be made at this time. Progress in this area will continue to be monitored through the incident reporting system and dialogue with the PR.

What the centre could do better

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The centre's SOP for the screening of egg donors, which also applies to egg sharers, does not reflect the requirements for screening as per standard licence conditions and professional body guidance. This non compliance is described in the 'Screening of Donors' and 'Quality Management System' sections above.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and / or donors are 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.

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

Consent and Legal parenthood Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos are not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about its effectiveness and, in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre did not send a report of the audit to the HFEA within the required timeframe however it was received in August 2014. The audit showed that three couples were potentially affected by legal parenthood consent anomalies. Following contact with these patients and receipt of further information, two of the cases did not require further action and one proceeded to a court hearing.

On this inspection, we reviewed the centre's legal parenthood audit methodology and found that it had been performed according to the method specified by the HFEA. The PR has informed the couples who have been affected by legal parenthood consent anomalies and the centre is continuing to offer support.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

The inspection team discussed in detail the centre's procedures for ensuring that consent to legal parenthood is in place with members of the centre's team. The donor coordinator described a process where counselling is mandatory for all patients prior to treatment with donor gametes and that donor sperm is not allocated to a patient until documented evidence of consent to legal parenthood is in place.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed a patient record where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood was seen to be in place prior to consent and treatment. In summary, the inspection team considers that the centre's processes for obtaining effective legal parenthood consent are compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are partially compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing fertility treatment and those born following such treatment.

What the centre could do better:

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
At the time of the inspection, discrepancies were found between four completed patient/partner disclosure consents in patient files (15 checked in total) and the related consent data submitted for inclusion on the register (see recommendation 6). It should be noted that in the cases identified, the records indicated that the patients had consented to disclosure however the data submitted to the HFEA recorded that they had not consented to disclosure. Whilst this clearly does not indicate that the consent provider's decision was accurately submitted to the HFEA register it does not infer that there is a risk of inadvertent disclosure of information by the HFEA.

The centre's designated HFEA Form Returnee has been provided with the relevant patient and partner numbers so that the data can be reviewed and corrected.

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:

- 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 and
- 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 identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

The centre's procedures for screening patients 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.

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. 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.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)
What the centre does well **Use of embryos for training staff (Guidance note 22)** The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are 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; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are partially compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The following issues were identified relating to the accuracy and timeliness of the centre's submission of data to the HFEA Register (recommendation 7):

- One egg donor, whose donated eggs used to create embryos which have been imported into the centre, has not been registered with the HFEA (SLC T9e).
- At the time of inspection, the centre had reported four treatments with the gametes of unregistered donors (General Direction 0005, SLC T41).
- At the time of the inspection 5% (6/133) of the IVF treatments reviewed had been reported to the HFEA outside the time period required by General Direction 0005.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2014, recommendations for improvement were made in relation to two areas of major non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented.

On-going monitoring of centre success rates

In 2015, the centre was asked to review procedures for the provision of ICSI treatment. The PR responded to the request and during discussions at the time of the inspection, provided a commitment to keep success rates in this group of patients under review. The centre's current success rates are in line with national averages.

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, General Direction 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. The records of two egg donors were reviewed on inspection. In both cases the donor's blood samples for screening were obtained at the time of donation, but this blood had not been screened for Hepatitis B surface antigen, Hepatitis B core antibody, Hepatitis C virus, or syphilis at this time. SLC T52(b) and SLC T 53(b).	The PR should ensure that gamete donors are screened in accordance with regulatory requirements and professional body guidelines. The PR should provide the centre's inspector confirmation of revised screening practices, a copy of the updated donor screening SOP and evidence of relevant staff training when responding to this report. The PR should conduct an audit of the centre's screening practices and procedures for	The PR can confirm that all egg donors are now screened in accordance with regulatory requirements and professional body guidelines and the revised SOP to reflect the changes has been sent to the centre's inpsector (NURSE-SOP-60). The PR can confirm that all potential egg donors in the system (two) will be screened in accordance with the revised SOP. An audit will be performed within 3 months of the revised	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The Executive has received the revised SOP and will continue to liaise with the PR to ensure it describes compliant practices. Upon completion of the SOP, the Executive will seek the requested evidence of staff training. The audit and root cause

	gamete donors (including sperm donors) to ensure that they are compliant with regulatory requirements and professional body guidelines. The audit should also include a root cause analysis to identify why the centre's processes for screening egg donors were not compliant with regulatory requirements. The PR should provide the centre's inspector with a copy of this audit report, including corrective actions identified, by 15 September 2016. Within three months of the implementation of revised practices, the centre should carry out an audit of gamete donor screening to ensure that the corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 15 November 2016. The PR should seek the advice of an expert virologist to assess the risk to patients who	protocol being introduced and the PR will provide a summary of this audit to the centre's inspector by the 15th September 2016. The PR is seeking expert advice from Ian Hart (Consulatnt Virologist) at the Royal Liverpool Hospital. The PR will provide the advice to the centre's inspector when it becomes available. The PR will review the centre's screening procedures for all gamete donors to ensure that they are compliant with regulatory and professional body guidelines and provide a RCA to identify why this was absent from the SOP - this will be sent to the centre's inspector by the 15th September 2016.	analysis is due to be provided by 15 September 2016. The Executive also requested a time line for obtaining advice from the expert virologist. The timeline should be received no later than 15 September 2016. Further action required.

	have received treatment with eggs or embryos created with donated eggs, from donors where the screening has not been compliant with regulatory requirements. The PR should inform the centre's inspector of the timeline for obtaining this expert advice when responding to this report.		

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
2. Several non-compliances were noted in the QMS: • an audit of counselling did not include a summary of findings or documentation of corrective actions; • an audit of donor recruitment, selection and screening has not been conducted within the last two years; • the SOP to direct the process for egg and embryo donation, and egg donor recruitment had not been audited against compliance with regulatory requirements as it does not include all screening tests required	The PR should review the SOP directing the process of donor selection and screening to ensure that it is compliant with regulatory requirements. The PR should review the centre's audit process to ensure that they include an audit against regulatory requirements and centre's activities and that audits are documented in a consistent manner. Audit reports should also include a summary of findings and corrective actions where applicable. The PR should provide the centre's inspector with a copy of the review and an action plan for implementation of this	The PR can confirm that the screening protocol for donors has been revised to include the regulatory requirements - a copy of the revised SOP has been past to the centre's inspector (NURSE-SOP-60). The PR can confirm that the centre's audit process is being reviewed to ensure that all audits are appropriately documented to include a summary and corrective actions where applicable. This review will then be sent to the centre's inspector with an action plan for implementation of recommendations. The PR can confirm that the missing/incomplete audits	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. A copy of the review of the centre's audit process and resulting action plan should have been submitted with the response to the inspection report however the Executive acknowledges the actions taken to date and will accept this being submitted in addition to copies of the incomplete and missing audits by 15 September 2016. Further action required.

at the time of donation. SLC T36.	recommendation when responding to this report. The PR should provide copies of the incomplete and missing audits identified in this report to the centre's inspector by 15 September 2016.	identified during the inspection are will be provided to the cnetre's inspector by the 15th September 2016.	
3. The centre undertakes procurement by way of surgical sperm retrievals at unlicensed premises and has not established written agreements to cover these activities SLC T111.	The PR should ensure that third party agreements are in place with third party premises where surgical sperm retrievals are performed. The PR should provide the centre's inspector with copies of these agreements by 15 September 2016.	The PR can confirm that the centre's Business Manager and Quality Manager are sending the third party agreements for surgical sperm retrievals to the external sites. The PR will then provide copies for the centre's inspector by the 15th September 2016.	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. Copies of third party agreements to be received by 15 September 2016. Further action required.
4. The following medical devices used by the centre are not CE marked: containers used for semen sample collection; serological pipettes. SLC T30.	The PR should ensure that CE marked medical devices are used wherever possible. The PR should ensure the implementation of this recommendation by 15 December 2016.	The PR can confirm that the protocols are being revised and CE marked products are being sourced to ensure compliance by the 15th December 2016.	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. Confirmation of compliance with this recommendation to be received by 15 December 2016. Further action required.

5. A review of the centre's incident log on inspection identified two adverse incidents which had not been reported to the HFEA. SLC T120.	The PR should ensure that all relevant adverse incidents are reported to the HFEA. The PR should review the incidents identified on inspection to consider why they had not been reported to the HFEA. The PR should ensure that all staff are aware of their responsibility to report serious adverse events and serious adverse reactions to the HFEA. The PR should provide a summary report of the actions taken to meet these regulatory requirements to the centre's inspector by 15 September 2016.	The PR can confirm that there is a system in place where every incident report is passed to her and she forwards these onto the HFEA. There are deputies in her absence. All staff understand that PR (or deputies in her absence) must be made aware of all incidents immediately, however on the two occasions identified in the inspection it was the PR that failed to send the completed reports to the HFEA due to confusion with incidents that had been reported. An identification system for reports send to the HFEA has now been agreed with the HFEA Governance Lead to help to avoid this occurring again. The PR can confirm that the reporting system will be reviewed and a summary report will be sent to the centre's inspector by the 15th September.	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. A summary of the review of the reporting system to be received by 15 September 2016. Further action required.
6. At the time of the inspection discrepancies were found between four completed	The PR should review procedures and take appropriate corrective actions	The PR can confirm that a review of the CD consent form information submission to the	The Executive acknowledges the PR's response and her commitment to fully

patient/partner disclosure consents on patient files (15 checked in total) and the related consent data submitted for inclusion on the register. CH(10)05 and General Direction 0005. It is noted that this was also identified as a non-compliance at the interim inspection in 2014 and has therefore been classified as a major non-compliance.	to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms. The PR should also correct the submissions that have been identified as being incorrect and confirm this has been completed when responding to this report. The PR should conduct an audit six months after the implementation of corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the centre's inspector by 15 December 2016.	HFEA is underway and a six month audit will be performed and submitted to the centre's inspector by 15th December. The four discrepancies that were identified during the audit will be identified and corrected.	implementing this recommendation. Audit summary to be received by 15 December 2016. Further action required.
7. The following issues were identified relating to the accuracy and timeliness of the centre's submission of data to the HFEA Register. • One egg donor, whose donated eggs were used to create embryos which have been imported into to the centre, has not been registered with the	The PR should ensure the accuracy and timeliness of the centre's submission of data to the HFEA. The PR should register the egg provider identified on inspection as a donor with the HFEA and confirm that this has been completed when responding to this report.	The PR has confirmed that this donor has now been registered. The PR has met with the embryology team and reminded them to select 'partner' from the drop down box in the IDEAS database when preparing the semen sample as the four occasions	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR is advised to discuss the specific cases identified on inspection with the HFEA registry team. The Executive should receive clarification that

HFEA. • The centre reported four treatments with the gametes of unregistered donors. • At the time of the inspection 5% (6/133) of the IVF treatments reviewed had been reported to the HFEA outside the time period required by General Direction 0005. General Direction 0005, SLC T41, SLCT9e. It is noted that delays in data submission to the HFEA was identified as a critical non-compliance at the renewal inspection performed in 2013. The centre improved their processes and there were no related issues identified at the interim inspection in 2014. This has therefore been classified as a major non-compliance in accordance with the HFEA's assessment framework.	The PR should review the centre's processes for registering donors and completion of donor details in patent's treatment forms and review all donors in use at the centre to confirm that they have been registered as a donor with the HFEA. The PR should provide the centre's inspector with a copy of this review including corrective actions identified and evidence of staff training by 15 September 2016. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for poor quality submissions. The PR should provide the centre's inspector with a copy of the review and an action plan for improving the time frame for reporting treatments when responding to this report. The PR should conduct an audit six months after implementing any corrective actions, to confirm that they	identified on the inspection as use in treatment of unregistered donors were data input errors. Further details of this will be provided by 15 September 2016. The PR can confirm that the process for data submission is being reviewed and training will be provided where necessary. The details of the review and an action plan will be sent to the inspector once completed. The PR can confirm that an audit and action plan of corrective actions will be provided to the centre's inspector by 15 December 2016.	this has been addressed in the summary of the review of the centre's processes for registering donors and completion of donor details in patient's treatment forms which is to be received by 15 September 2016. The Executive awaits a copy of the review of procedures used to submit licensed treatment data to the HFEA which should have been submitted with the response to the report. The Executive accepts that the review may not have been completed and therefore extends the date for receipt of the review to 15 September 2016. A summary of the audit to be received by 15 December 2016. Further action required.

	have been effective. A summary of the audit should be provided to the centre's inspector by 15 December 2016.		

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. An audit of patient records performed on inspection identified an instance where the time of administration of a controlled drug was not documented in the patient's record. SLC T2.	The PR should with immediate effect ensure that the details of controlled drugs including the time of administration are clearly documented in the patient record. The PR should perform an audit of patient records to ensure that the details and time of administration of any controlled drugs administered to the patients are clearly documented. The PR should provide the centre's inspector with a summary of the audit findings including corrective actions identified by 15 September 2016.	The PR can confirm that the anaesthetic department has been contacted and made aware that the full details including date and time of drug administration must be clearly documented in the patient's notes (copies of emails available on request). An audit of patient records will be completed and a summary report will be sent to the centre's inspector by 15th September.	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. Summary of audit to be received by 15 September 2016. Further action required.
9. The centre has not documented the validation of the suction pumps used for egg collection. It is noted that the HFEA's	The PR should ensure that the validation of all critical equipment is completed and documented. The PR should ensure the	The PR can confirm that the process of validation of all critical equipment is being reviewed and the validation documentation will be sent to the centre's inspector by the	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation.

assessment framework recommends classification as a major non compliance but in consideration that the centre had undertaken the relevant testing prior to installation, and that regular servicing had been performed this has been classified as an 'other' non compliance. SLC T24.	validation of the egg collection suction pumps are documented and a copy provided to the centre's inspector by 15 September 2016.	15th Septmenber.	Copy of validation document to be received by 15 September 2016. Further action required.

Reponses from the Person Responsible to this inspection report
The PR would like to thank the HFEA for their constructive and encouraging advice during the inspection process.