HFEA Executive Licensing Panel Meeting

30 May 2014

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

Minutes – Item 2

Centre 0017 – (Newcastle Fertility Centre at Life) – Renewal Treatment (including embryo testing) & Storage Inspection Report

Members of the Panel:	**Committee Secretary:**
Rachel Hopkins – Head of HR (Chair)	Dee Knoyle
David Moysen – Head of IT	**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 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 considered the papers, which included a completed application form, inspection report, update report from the centre and licensing minutes for the past three years.

2. The Panel noted that this is a treatment (including embryo testing) and storage centre which provides a full range of licensed treatments including embryo testing. The Panel noted that in relation to activity levels this is a medium-sized centre.

3. The Panel noted that the centre has been licensed by the HFEA since 1992 and is on a three-year licence due to expire on 31 July 2014.

4. The Panel noted that in the 12 months to 31 December 2013 the centre provided 856 cycles of treatment (excluding partner intrauterine insemination).

5. The Panel noted that for IVF and ICSI, HFEA-held register data for the period October 2012 to September 2013 show the centre's success rates are in line with national averages.

6. The Panel noted that the success rates for ICSI are similar to or below the national average.

7. The Panel noted that in 2013, the centre reported 33 cycles of partner insemination with five singleton pregnancies. HFEA analysis of results for the sector for 2013 had not been performed; therefore a comparison of the centre's results against the national average cannot be made at this time.

8. Between 1 October 2012 and 30 September 2013, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%: this represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

9. The Panel noted that the centre has a quality management system (QMS) in place to monitor and continually improve their success rates and the quality and safety of the service it provides in accordance with good practice.

10. The Panel noted that at the time of the inspection on 12 and 13 February 2014, the Inspectorate identified five 'other' areas of non-compliance. The Panel noted in particular the non-compliances in relation to a standard operating procedure for the provision of information about legal parenthood, and the process to seek such consent, and the availability of professional infertility counsellors to meet the needs of patients and donors by providing treatment, donation and legal parenthood consent implications counselling.

11. The Panel noted that that the counsellor is a member of the British Association for Counselling and Psychotherapy (BACP) and has attended a British Infertility Counselling Association (BICA) introductory course in infertility counselling but has not received any recent infertility related professional development or further specialist infertility counselling training.

12. The Panel noted that the Inspectorate had requested the Person Responsible (PR) informs them of any further actions taken following their patient survey in relation to counselling.

13. The Panel acknowledged the positive comments made by patients in relation to their experience of the centre.

14. The Panel noted that the centre demonstrates good clinical practice; has suitable premises and equipment for the treatment services offered.

15. The Panel noted 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 compliance with the recommendations made in this report being fully implemented within the prescribed timescales.

Decision

16. 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.

17. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and that she has discharged her duty under section 17 of the HF&E Act 1990 (as amended).

18. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

19. The Panel endorsed the Inspectorate's recommendation to renew the centre's Treatment (including embryo testing) and Storage licence for four years, without additional conditions.

Signed: Date: 12 June 2014
Rachel Hopkins (Chair)

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: 12 and 13 February 2014

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: Gill Walsh (Lead), Janet Kirkland MacHattie, Heidi Birch, Chris Hall, Roup Kaur and Colin Wilson (CQC)

Date of Executive Licensing Panel: 30 May 2014

Centre name	Newcastle Fertility Centre at Life
Centre number	0017
Licence number	L/0017/14/b
Centre address	International Centre for Life, Bioscience Centre, Times Square, Newcastle upon Tyne, NE1 4EP, UK
Person Responsible	Dr Jane Stewart
Licence Holder	Dr Mary Herbert
Date licence issued	01 August 2011
Licence expiry date	31 July 2014
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
The Newcastle Fertility Centre at Life has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services, including embryo testing. The inspection team is satisfied that the activities carried out at the centre are necessary in order to provide licensed treatment services.

The centre is also licensed by the HFEA for research.

The centre provided 856 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2013. In relation to activity levels this is medium sized centre.

Centre's activity levels:

Type of treatment	Number of treatment cycles for calendar year 01 Jan 2013 – 31 Dec 2013
In vitro fertilisation (IVF)	348
Intracytoplasmic sperm injection (ICSI)	240
Gamete intrafallopian transfer (GIFT)	0
Frozen embryo transfer (FET)	165
Donor insemination (DI)	103
	Number of treatment cycles for calendar year 2013
Partner insemination (IUI)	33

Other licensable activities	
Storage of gametes	✓
Storage of embryos	✓
Embryo testing	✓
Research	✓

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period October 2012 to September 2013 show the centre's success rates are in line with national averages.

In 2013 the centre reported 33 cycles of partner insemination with five singleton pregnancies. HFEA analysis of results for the sector for 2013 has not yet been performed; therefore a comparison of the centre's results against the national average cannot be made at this time.

Multiple births[2]

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

Between 1 October 2012 and 30 September 2013, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%: this represents performance that is not likely to be statistically different than the 10% multiple live birth rate target for this period.

[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. 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 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 application has been submitted in the form required;
- 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 five 'other' areas of non-compliance which have resulted in the following recommendations:

Since the inspection visit, the following recommendations have been fully implemented:

'Other' areas that requires improvement:

- The PR should review the provision of counselling to ensure that there are sufficient professional counselling resources available to meet the needs of patients and donors and to ensure that the counsellor has appropriate professional development relevant to infertility counselling.
- The PR should review procedures to ensure that patient and partner or donor disclosure consent decisions submitted to the HFEA accurately reflect the consent provider's decision recorded in the primary medical record.
- The PR must ensure that all licensed treatment activity is reported to the HFEA as required by Directions 0005; and that all information required by the HFEA to fulfil it's statutory obligations to the donor-conceived is provided to the HFEA.
- The PR should ensure there is a documented procedure to direct the information to be provided and the process for obtaining consent to legal parenthood. The PR should consider providing written information to patients and partners about legal parenthood and the provision of implications counselling.
- The PR should review the process for assessing welfare of the child and final checking of documentation to ensure that an appropriate assessment has been completed and that the documentation retained within the patient / partner record accurately reflects this.

Recommendation to the Executive Licensing Panel

The centre demonstrates good clinical practice; has suitable premises and equipment for the treatment services offered and has a quality management system (QMS) in place to continually improve the quality and safety of the service it provides in accordance with good practice.

The inspection team notes the success rates for ICSI are similar to or below the national average. The PR should ensure that the QMS is used to best effect to monitor and improve their success rates and in doing so improve the quality of the service offered to patients.

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. The centre uses an electronic witnessing system. Observation of practice and a sample audit of witnessing records conducted on inspection confirmed that where manual witnessing is required this is done and that a record of witnessing steps is maintained in the patient / donor record.

The centre uses an electronic witnessing system. Observation of practice and a sample audit of witnessing records conducted on inspection confirmed that where manual witnessing is required this is done and that a record of witnessing steps is maintained in the patient / donor record.

There is a standard operating procedure (SOP) in place to direct the manual witnessing of embryo biopsy procedures. The process was also described by an embryo biopsy practitioner.

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 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. A sample audit of donor screening records conducted on inspection showed that donor screening is compliant with standard licence condition (SLC) T52. Blood samples are obtained within the timeframes specified by the Authority and testing is conducted in a suitably accredited laboratory in accordance with SLC T53.

Payments for donors (Guidance note 13; Directions 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 when they come of age. Parents of a donor-conceived child are able to access non-identifying information about 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 broadly compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

What the centre could do better

Donor assisted conception (Guidance note 20)
An audit of donor records held at the centre compared with data held on the HFEA register showed that in four instances donor information forms submitted did not contain information that the HFEA is required to provide to donor-conceived people. See the section 'Obligations and reporting requirements' (Guidance note 32, Directions 0005) and recommendation 3)

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 laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (and 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 own laboratory responsible for conducting diagnostic semen analysis is currently working towards accreditation with the United Kingdom Accreditation Service (UKAS) for testing laboratories. The Quality Manager was able to demonstrate that the centre's processes for diagnostic semen analysis have been validated, are regularly monitored and audited and that the laboratory is working to a standard equivalent to accreditation.

All 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, including that for analysis of embryo biopsy, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard (i.e UKAS). 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 best practice and professional body guidance.

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

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; Directions 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements, 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. The single biggest risk of fertility treatment being a multiple pregnancy.

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 and;
- If the sperm sample 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; Directions 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 has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; Directions 0006)
The centre's procedures for the 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,
- to identify any person who has carried out any activity in relation to particular

gametes or embryos, and

- 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.

SLC T101 requires that all containers used in the course of procurement, processing, use and storage of gametes and embryos are labelled with the patient's / donor's full name and a further identifier. The centre does not label the tubes and dishes used to hold follicular fluid during egg collection. The risks of misidentification by not labelling these tubes and dishes have been formally assessed by the centre and actions identified to mitigate the risks have been implemented. The actions implemented to mitigate the risks of misidentification are considered by the inspectors to be robust. The inspection team is satisfied that no recommendation is required.

Quality management system (QMS) (Guidance note 23)
The centre has a comprehensive QMS in place that is broadly 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 compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; Directions 0010)
The centre does not have transport and satellite links therefore this area of practice is not applicable to this inspection.

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

SLC T30 requires that wherever possible, CE marked medical devices must be used. A small number of materials used in the procurement and processing of gametes and embryos are not CE marked, however the PR provided assurance to the inspection team of their suitability. The centre demonstrated a commitment to use CE marked dishes once new, replacement CE marked stock is available in the centre imminently. The inspection team are therefore satisfied that no recommendation is required.

The centre is 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 compliant with HFEA

requirements. The centre reports relevant 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

Quality management system (QMS) (Guidance note 23)
The centre has a comprehensive QMS which is regularly revised and updated, however it was noted that there is no documented SOP to direct the provision of information and process to be followed for obtaining consent to legal parenthood, although the process was described appropriately by staff. (See recommendation 4).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has fulfilled her responsibilities as PR and complied with HFEA requirements.

The PR has academic qualifications in the field of medicine and has more than two years of 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 (PREP number T/1013/7).

Staff (Guidance note 2)
The centre is broadly compliant with HFEA requirements.

With the exception described below, the centre has 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

Staff (Guidance note 2)
In discussion with the counsellor and staff on inspection it became apparent that the availability of independent counselling to centre patients and donors is limited. The counsellor is available for 18.75 hours per week and during that time provides a service across the Women's Health Directorate which includes gynaecology, maternity, foetal medicine and bereavement counselling. The counsellor described that she provides therapeutic counselling to centre patients but does not provide treatment / donation or legal parenthood consent implications counselling as this is provided by the senior nursing team. There is currently a waiting time of two to three weeks for independent

counselling appointments. (See recommendation 1) (SLC T12).

The counsellor is a member of the British Association for Counselling and Psychotherapy (BACP) and was able to describe recent professional development in counselling supervision and having completed a diploma in bereavement counselling. The counsellor has attended a British Infertility Counselling Association (BICA) introductory course in infertility counselling but has not received any recent infertility related professional development or further specialist infertility counselling training. (See recommendation 1) (SLC T15).

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures for taking into account the welfare of the child are broadly compliant with HFEA requirements. This is important 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.

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

What the centre could do better

Welfare of the child (Guidance note 8)
A sample audit of five patient/partner welfare of the child records showed that in one instance the welfare of the child forms had not been completed and in another the form was ticked to indicate that no treatment was offered but treatment had been provided. (See recommendation 5).

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'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
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons
- no embryo is tested unless it meets the statutory tests i.e. that the embryos is at a

significant risk of having a serious genetic condition. The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists and genetic counsellors where required.
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 visit the inspectors spoke to three patients who provided feedback on their experiences. A further 41 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was very positive, with 29 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 identified at this inspection.

Treating patients fairly

Counselling
Egg [and sperm] 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 the Equality Act 2010 requirements. This is important to ensure that all persons are treated fairly.

Counselling (Guidance note 3)
The centre's counselling procedures are broadly 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.

Information giving and discussions with patients and donors regarding the implications of their consent decision to donate or to receive treatment with donor gametes or embryos

and to legal parenthood is provided by the senior nursing team. The inspection team considers that the information provided by the nursing team during these implications sessions is well informed and provided in a sensitive manner but there was some concern that certain elements of these sessions may constitute implications counselling which should be provided separately from the medical decision making process by an independent infertility counsellor. Staff were however able to clearly demonstrate that all patients and donors are also offered counselling with the Trust counsellor.

The provision of implications counselling was discussed at length with the PR on inspection and whilst the inspection team considers that the information and implications discussions provided by this experienced nursing team is comprehensive, centre staff should be reminded that in accordance with CoP guidance 3.7 and 3.8, the provision of counselling should be clearly distinguished from:

a) the assessment of a person's suitability to receive treatment, or to store or donate their gametes or embryos

b) the provision of information before obtaining consent or providing treatment,

c) the normal relationship between clinical staff and patients or donors and;

that the counselling service should comply with current professional guidance on good practice in infertility counselling. Counselling should only be provided by qualified counsellors in order to provide the patient or donor the opportunity to discuss issues in a confidential environment that is independent of the provision of treatment. Further to this discussion the inspection team is satisfied that no formal recommendation relating to this point is required at this time.

In discussion with the counsellor it was noted that uptake of counselling by centre patients and donors is low. It is considered by the inspection team that the reasons for this may be two fold, firstly that patients and donors feel sufficiently well informed as to the implications of their consent decisions that no independent counselling is required and secondly that there is limited availability for infertility counselling for centre patients/donors as described in the section 'Staff' within this report. (See recommendation 1).

Egg sharing arrangements (Guidance note 12; Directions 0001)
The centre's procedures for egg sharing arrangements are 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).

It was noted on inspection that the centre also operates an arrangement whereby patients may agree to egg sharing for research. Patient information provided and discussions with the research nurse on inspection demonstrated that patients are well informed regarding the implications of consenting to donate some of their eggs to research, and that the arrangement is compliant with requirements.

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.

What the centre could do better

Counselling (Guidance note 3)
Please see section on 'staffing' and recommendation 1.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
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.

What the centre could do better

Information (Guidance note 4; CH(11)02)
Legal Parenthood (Guidance note 6)
From discussions with the PR and centre staff, the inspection team concludes that appropriate information regarding legal parenthood is provided verbally prior to consent and that reference is made to information available on the HFEA website. However, no written information is provided to patients and their partners about legal parenthood As this is a complex area for consent consideration, to provide written information to couples regarding legal parenthood may be considered good practice.

The offer of counselling was seen to be embedded in relevant donor recipient SOPs but no reference was seen in SOPs or patient information regarding independent implications counselling regarding consent to legal parenthood. (See recommendation 4).

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

What the centre does well

Consent (Guidance note 5)
The centre's procedures for obtaining consent, including that for the use of gametes and embryos in training or research, are 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 (Directions 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 assisted reproductive therapy (ART) and those born following ART treatment.

What the centre could do better

Disclosure of information, held on the HFEA Register, for use in research (Directions 0005)
The centre's procedures for taking consent to disclosure to researchers may not ensure that the HFEA holds an accurate record of the patients consent, so that it only releases the patients identifying information, to researchers, with their consent.

As part of this inspection an audit sample of 19 disclosure consent decisions recorded in patient records were compared with the disclosure consent decisions submitted by the centre for inclusion in the HFEA register. In six of the 19 records reviewed there were discrepancies between the disclosure consents recorded in the patient/partner file and the disclosure consent decision recorded on the HFEA register.

In two instances the disclosure consent forms in the patient record had been signed and dated by the patient and her partner but no boxes had been selected to indicate whether consent is being given or withheld. The inspection team were given assurance on inspection that in such instances the centre would act with caution and record for the register that consent has been withheld. The consent decision submitted to the HFEA register confirmed this in both cases. (See recommendation 2).

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, Directions 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, Directions 0005)
A comparative audit of patient records against information submitted to the HFEA showed that in a number of instances patient, partner and donor registration forms submitted to the HFEA did not include required information that was evident in the patient / partner / donor file.

In four instances donor information forms submitted did not contain information that the HFEA is required to provide to donor-conceived people. (See recommendation 3).

Section 3: Monitoring of the centre's performance

Following the interim inspection in February 2013 recommendations for improvement were made in relation to one area of major non-compliance and two 'other' areas of non-compliance.

The PR provided information and evidence that the one major and one 'other' area of non-compliance were resolved immediately following the inspection.

The following recommendation has now been implemented but was not completed within the required timescales as no patients requiring surrogacy were treated within the time frame specified for implementation:

- The PR should ensure that gamete providers in all future surrogacy arrangements are appropriately screened.

The inspection team is satisfied that additional NAT testing is available to male gamete providers where full surrogacy is planned and that this has been implemented since the last inspection.

On-going monitoring of centre success rates

The centre has been proactive in reviewing their ICSI procedures having identified an earlier dip in success rates and has provided a commitment to keep success rates in this group of patients under review.

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
None			

Major area of non compliance

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

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several “other” areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

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

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
1. Staff Counselling resources may be insufficient in order to provide a suitable infertility counselling service in accordance with professional body guidance. SLC T12 The centre's counsellor has not participated in any recent professional development specifically relevant to infertility counselling. SLC T15	The PR should undertake a review of the counselling service, to determine the level to which the counselling service meets the needs of the centre's patients and donors in accordance with professional guidance on good practice in infertility counselling This review should include an assessment of the availability of counselling and of the professional development relating to infertility counselling undertaken by the counsellor. The summary report should document any corrective actions required to ensure compliance with the requirements and the timescale for the implementation of the corrective actions.	Comments acknowledged. We will: 1. Undertake a review of service with the centre's counsellor regarding the limitations of the service, any complaints received or concerns raised, her asperations for service development and her CPD needs. 3. Commission a thorough needs-based audit/review of patients views with regard to the service and its future development. 3. Highlight the inspection report and the results of 1&2 above as undertaken to the Directorate to request support for the counselling service in line with the review. PR will provide an initial report to HFEA by 13th May 2014 which will include the	An initial report was received from the PR on 13 May 2014. The report outlines actions being implemented as a result of the service review undertaken, plans to increase available counselling hours, and plans for a survey to identify areas in which the service could be improved based on the needs of patients. The Executive acknowledges the PR's response and we request that the PR informs us of any further actions taken following their survey.

	A copy of the summary report should be provided to the HFEA by 13 May 2014.	commissioning of the audit however for a comprehensive audit it is not envisaged that this will be completed by that date but will be reported further on completion.	
2. Consent to disclosure to researchers As part of this inspection, an audit sample of 19 disclosure consent decisions recorded in patient records were compared with the disclosure consent decisions submitted by the centre for inclusion in the HFEA register. In six of the 19 records reviewed there were discrepancies between the disclosure consents recorded in the patient/partner file and the disclosure consent decision recorded on the HFEA register. In two instances the disclosure consent forms in the patient record had been signed and dated by the patient and her partner but no boxes had been	The PR should: • review procedures to ensure that all disclosure consent decisions submitted to the HFEA accurately reflect the consent providers decision recorded in the primary medical record. • correct the submissions that have been identified as being incorrect by the HFEA • ensure completed disclosure consent forms are reviewed by centre staff to ensure that the intent of the patient/partner/donor is clear in relation to whether consent is being given or withheld (i.e. obviating the need to record that it has been withheld by default as a precaution).	1. There are currently procedures in place to ensure that CD forms are completed, reviewed, reported and filed correctly. There is a defined mechanism that in the absence of correction a negative response be filed with the HFEA EDI to avoid apparent consent being given. We aspire to 100% completeness of CD forms and therefore an extra checkpoint for them will be added to the process to be applied in all cases. 2. This area is already the subject of a departmental audit and we will re-audit in 6 months as indicated. This will be reported in 6 months. 3. The "incorrect submissions report" has been reviewed and submissions corrected as appropriate.	The Executive acknowledges the PR's response and awaits the audit summary in due course.

selected to indicate whether consent is being given or withheld. Directions 0005	To be completed by 13 May 2014 The centre should conduct a sample audit six months after implementing any changes to confirm that any changes made to systems and processes are having the desired effect. The centre is to provide a summary of this audit to the HFEA once completed.		
3. Obligations and reporting requirements An audit of donor records held at the centre compared with data held on the HFEA register showed that in four instances donor information forms submitted did not contain information that the HFEA is required to provide to donor-conceived people, however this information was available in the donor file. Four DI treatments reviewed at the time of inspection had not been reported to the HFEA as required by Directions 0005.	The PR must ensure that: • all licenced treatment activity is reported to the HFEA as required by Directions 0005; and The systems and processes used for licensed treatment data submission should be reviewed to enable the reasons for the under-reporting of DI cycles to be identified and addressed. Donor records should be reviewed to identify donor registration records submitted,	1. The process for ensuring the timely (Direction 0005) reporting of donor insemination treatments is complicated by the rapid turnaround between cycles and the stringency of the reporting deadlines. We have reviewed this process and made changes which we hope will avoid missing cycles in the future. 2. Missing cycles will be added to EDI. 3. We are confident however that these would have been picked up in the bi-annual validation process and we are also confident that no	The Executive is satisfied with the PR's response and the register team report that this recommendation has been implemented. No further action required.

SLC T9(e) / T41 Directions 0005	where information the HFEA is required to provide to donor-conceived persons has been omitted. In liaison with the HFEA information team these records should be updated by 13 May 2014.	pregnancies and in particular live births have been missed. 4. This has been a process issue and donor records will be reviewed to ensure that all the required information is updated in the EDI submitted forms. The process for donor form completion will be reviewed to ensure no future omissions.	
4. Quality Management System There is no SOP in place for the provision of information about legal parenthood, and the process to seek consent to legal parenthood. SLC T33(b) No written information is provided to patients and their partners to be treated with donor gametes or embryos regarding legal parenthood. SLC T58	The PR should ensure there is a documented procedure to guide this process and inform the HFEA that this is in place by 13 May 2044. The PR should consider providing written information to patients and their partners regarding legal parenthood, and the availability of implications counselling relative to legal parenthood requirements. The PR should inform the HFEA of her rationale regarding this by 13 May 2014.	We have undertaken a gap analysis regarding this issue and will update the documents accordingly. As indicated this is already an integral part of implications discussions.	The Executive acknowledges the PR's response and implementation of this recommendation. In an up-date received 13 May 2014, the PR confirms that relevant documentation has been up-dated where appropriate. We request that any up-dated SOPs or patient information are forwarded at the PR's earliest convenience.
5. Welfare of the child A sample audit of five patient/partner welfare of the child records showed that in	The PR should review the process for assessing welfare of the child and final checking of documentation, to ensure	1. As for CD forms, there are currently procedures in place to ensure that WoC forms are completed, reviewed, reported	The Executive is satisfied with the PR's response and awaits the audit summary in due course.

one instance the welfare of the child forms had not been completed, and one form was ticked to indicate that no treatment was offered, but treatment had been provided. The PR confirmed this was a typographical error and that there were no concerns regarding welfare of the child identified. SLC T56	that an appropriate assessment has been completed and that the documentation retained within the patient / partner record accurately reflects this. The PR should inform the HFEA by 13 May that this has been done and provide a summary of findings and actions taken to prevent recurrence of this problem. Six months after the implementation of any changes, a sample audit should be conducted to ensure the changes are effective and the outcome of that audit be provided to the HFEA.	and filed correctly. We aspire to 100% completeness of WoC forms and therefore an extra checkpoint for them will be added to the process to be applied in all cases. 2. This area is already the subject of departmental audit and we will re-audit in 6 months as indicated. This will be reported in 6 months.	

Reponses from the Person Responsible to this inspection report
Thank you - it is good to see that positive features are noted in detail. The updates will be provided by 13th May as required.