# Executive Licensing Panel - minutes

## Centre 0017 (Newcastle Fertility Centre at Life)

## Renewal Inspection Report

Friday, 25 May 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

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| Panel members | Caylin Joski-Jethi (Chair)<br>Dan Howard<br>Kathleen Sarsfield Watson | Head of Intelligence<br>Chief Information Officer<br>Communications Manager |
| Members of the Executive | Bernice Ash | Secretary |
| External adviser | | |
| Observers | Catherine Burwood<br>Mhairi West | Senior Governance Manager<br>Inspector |

## 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 Newcastle Fertility Centre at Life has held a HFEA licence since 1992 and provides a full range of fertility services.

**1.3.** The panel noted that other licensed activities at the centre include the storage of gametes and embryos and embryo testing and pronuclear transfer related to the avoidance of mitochondrial disease.

**1.4.** The panel noted that the centre varied their treatment (with embryo testing) and storage licence in 2017 to also include Mitochondrial Donation (PNT), with an approved PNT embryologist named on the licence. The centre also holds a licence for research project R0152 'Towards improving assisted reproductive technologies for the treatment of infertility and prevention of disease' under which their research into mitochondrial donation techniques has taken place.

**1.5.** The panel noted that, in the 12 months to 30 November 2017, the centre has provided 917 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium sized centre.

**1.6.** The panel noted that HFEA held register data, between 1 November 2016 and 31 October 2017, shows the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is likely to meet the 10% multiple live birth rate target. The centre had not submitted any data for IUI treatments for 2015 or 2016.

**1.7.** The panel noted that for IVF and ICSI, HFEA held register data for the period 1 November 2016 to 31 October 2017 show the centre's success rates are in line with the national average, with the exception of clinical pregnancy rates following frozen embryo transfer (FET) in patients aged less than 40 years are lower than average at a statistically significant level.

**1.8.** An inspection was carried out at the centre on the 6 and 7 February 2018.

**1.9.** The panel noted that at the time of the inspection, there were nine major areas of non-compliance regarding success rates, screening of patients and donors, traceability, the Quality Management System (QMS), equipment and materials, confidentiality, consent, counselling and legal parenthood. There was also five 'other' non-compliance concerning information, premises and facilities, record keeping, data submission and disclosure of information. The panel noted that since the inspection, the recommendations with regards to traceability, confidentiality and premises and facilities had been fully implemented.

**1.10.** The panel noted that the Person Responsible (PR) had given a commitment to fully implementing the outstanding major areas of non-compliance regarding screening of patients and donors, the QMS, equipment and materials, consent, counselling and legal parenthood alongside the 'other' areas of non-compliance surrounding information, data submission and disclosure of information.

**1.11.** The panel noted that the Executive and PR will continue to liaise to ensure that the recommendation concerning the centre's success rate for FET in women under 40 years old is appropriately implemented. The centre's multiple clinical pregnancy rate meets the target.

**1.12.** The panel noted that significant improvement is required in order for the centre to reflect suitable practices. The PR is encouraged to correct, then use the QMS to best effect to monitor and improve their success rates, therefore impacting on the quality of the service offered to patients.

**1.13.** The panel noted that the inspector will continue to monitor the centre's performance and the implementation of the report's recommendations within the required timescales. Failure to implement the recommendations within the prescribed timescales will result in the submission of a

further report to the ELP with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

**1.14.** The panel noted the inspectorate recommendation to renew the centre's treatment (including embryo testing and Mitochondrial Donation (PNT)) and storage licence for a period of four years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales.

## 2. Decision

**2.1.** The panel decided to defer the decision on the renewal of the centre's licence until assurance is received that a majority of the recommendations made in the report are completed, particularly with regards to the QMS and legal parenthood. The panel also wished to continue to assess the level of the PR's engagement with the inspectorate to ensure that patients are provided with a high-quality service.

**2.2.** The panel noted that further actions and reports, regarding the recommendations relating to the screening of patients, equipment and materials, consent, counselling and information are due for receipt by 7 June 2018. Further actions regarding the QMS and legal parenthood are due by 20 July 2018. The panel requested to receive an update report, after the 20 July 2018, to reconsider the renewal of the centre's treatment (including embryo testing and Mitochondrial Donation (PNT)) and storage licence.

**2.3.** The panel agreed to issue a Special Direction under Section 24 (5A)(b) of the HF&E Act 1990 (as amended), to permit the continuation of the centre's treatment (including embryo testing and Mitochondrial Donation (PNT)) and storage licence from 1 August to 30 November 2018 to allow time for assurances to be provided that the non-compliances, identified in the report, are being addressed and for the administrative process of licence renewal to be completed within the usual timeframe.

## 3. Chair's signature

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

### Signature

### Name

Caylin Joski-Jethi

### Date

4 June 2018

# 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:** 6 and 7 February 2018

**Purpose of inspection:** Renewal of a licence to carry out Treatment and Storage including Embryo Testing and Mitochondrial Donation (PNT).

**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:** Lesley Brown, Sharon Fensome-Rimmer, Janet Kirkland and Karen Conyers.

**Date of Executive Licensing Panel:** 25 May 2018

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| **Centre name** | Newcastle Fertility Centre at Life |
| **Centre number** | 0017 |
| **Licence number** | L/0017/15/b |
| **Centre address** | International Centre for Life, Bioscience Centre, Times Square, Newcastle upon Tyne, NE1 4EP, United Kingdom |
| **Person Responsible** | Dr Jane Stewart |
| **Licence Holder** | Professor Mary Herbert |
| **Approved PNT Embryologist** | Dr Louise Hyslop |
| **Date licence issued** | 1 August 2014 |
| **Licence expiry date** | 31 July 2018 |
| **Additional conditions applied to this licence** | None |

# Contents

# Section 1: Summary report

### Brief description of the centre and its licensing history:

Newcastle Fertility Centre has held a HFEA licence since 1992 and provides a full range of fertility services.

The centre provided 917 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 November 2017. In relation to activity levels this is a medium centre.

Other licensed activities at the centre include the storage of gametes and embryos and embryo testing and pronuclear transfer related to the avoidance of mitochondrial disease.

The centre varied their Treatment (with Embryo Testing) and Storage licence in 2017 to also include Mitochondrial Donation (PNT), with an approved PNT embryologist named on the licence.

The centre also holds a licence for research project R0152 'Towards improving assisted reproductive technologies for the treatment of infertility and prevention of disease' under which their research into mitochondrial donation techniques has taken place.

All sections of this report, where relevant, also reflect the inspection team's assessment of regulatory requirements as they apply to mitochondrial donation techniques in use at the centre

### Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 November 2016 to 31 October 2017 show the centre's success rates are in line with national averages with the following exception:

- clinical pregnancy rates following frozen embryo transfer (FET) in patients aged less than 40 years are lower than average at a statistically significant level (recommendation 1).

The centre has not submitted data for IUI treatments for 2015 or 2016 (recommendation 13).

### Multiple births[2]

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

Between 1 November 2016 and 31 October 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is likely to meet 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 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 the centre's 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 nine major and five 'other' areas of non-compliance.

Since the inspection visit, the following recommendations have been fully implemented:
Major areas of non-compliance:

- The PR should ensure that all containers used in the course of procurement, processing, use and storage of gametes and embryos are labelled and traceable.
- The PR should ensure that all areas where confidential identifying information can be accessed are secure at all times.

Other' areas of non-compliance:

- The PR should ensure that medical gas cylinders are properly stored.

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

Major areas of non-compliance:

- The PR should ensure that the risks of Ebola and Zika infection are considered prior to any donor or patient being treated and that patient screening is performed within the time frame specified by the authority.
- The PR should ensure that audit findings and incidents are robustly investigated and addressed, that HFEA guidance is embedded into centre's practices and the documents are effectively controlled.
- The PR should ensure appropriately CE marked medical devices are used where available.
- The PR should ensure that all patient consents are clear and that any alterations are appropriately made.
- The PR should ensure that the centre's counsellor is appropriately accredited.
- The PR should ensure that relevant staff are trained and competent to inform patients about legal parenthood consent, and to assist patients in providing and documenting such consents effectively.

'Other' areas of non-compliance:

- The PR should ensure that patients and donors are provided with all necessary information, for example regarding the use of embryos in training and Zika/Ebola virus infection risk assessment.
- The PR should ensure that the identity of those treated is reliably confirmed and that this check is documented, along with the identity of the staff member performing the check.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the required timeframe.
- The PR should ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms.

The executive and PR will continue to liaise to ensure that the following recommendation is appropriately implemented:

Major areas of non-compliance:

- The centre's success rate for FET in women under 40 years old is significantly lower than the national average.

The executive is confident that this can be resolved satisfactorily and does not consider that the on-going discussion of this non compliance affects the recommendation below.

## Recommendation to the Executive Licensing Panel

**The centre has more than five major areas of concern.**

The inspection team notes the success rates for FET in women under 40 years old are below the national average and their multiple clinical pregnancy rate meets the target. The PR should ensure that the quality management system (QMS) is used to best effect to monitor and improve their success rates so as to improve the quality of the service offered to patients.

Significant improvement is required in order for the centre to reflect suitable practices. The PR is encouraged to correct and then use the QMS to best effect to monitor and improve the service provided.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales. Failure to implement the recommendations within the prescribed timescales will result in the submission of a further report to the ELP with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

The inspection team recommends the renewal of the centre's Treatment and Storage including Embryo Testing and Mitochondrial Donation (PNT) 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
Mitochondrial donation

**What the centre does well**

**Screening of donors (Guidance notes 11 and 33)**
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. The centre's procedures for screening donors are partially compliant with HFEA requirements.

The centre's procedures for screening the donors of gametes for use in PNT for pathogenic mitochondrial DNA mutations are compliant with HFEA requirements.

**Payments for donors (Guidance notes 13 and 33, 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)**

It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non-identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

**Mitochondrial Donation (Guidance note 33)**
In the case of treatment involving mitochondrial donation, the centre's procedures are compliant in ensuring that it only carries out the process of PNT for a particular named patient once the Authority has issued a determination that:

- there is a particular risk that any egg extracted from the ovaries of the named woman, or any embryo created by the fertilisation of an egg extracted from the ovaries of the named woman, may have mitochondrial abnormalities cause by mitochondrial DNA, and
- there is a significant risk that a person with those abnormalities will have or develop a serious mitochondrial disease.

**What the centre could do better**

**Screening of donors (Guidance note 11)**
The inspection team was not assured that the centre has a robust procedure in place to assess the risks of Ebola and Zika infection for potential donors prior to treatment (SLC T52h; recommendation 2). Concerns about the information provided to donors about Ebola and Zika virus infection assessment are discussed below in 'Information' (recommendation 10).

**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 notes 25 and 33)**
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 premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

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

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

The centre has processes in place that ensure compliance with requirements to ensure PNT is only undertaken on premises licensed to undertake mitochondrial donation.

**Laboratory accreditation (Guidance note 25)**
The centre's laboratories and 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 to be accredited by Clinical Pathology Accreditation (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

**Infection control (Guidance Note 25)**
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

**Medicines management (Guidance Note 25)**
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

**Prescription of intralipid 'off label' (Guidance Note 25)**
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

**Pre-operative assessment and the surgical pathway (Guidance Note 25)**
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;
- where the 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 note15)**
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 they 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 partially 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;
- to 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.

**Quality management system (QMS) (Guidance note 23)**
The centre has a QMS 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 compliant with HFEA requirements.

**Transport and satellite agreements (Guidance note 24; General Direction 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 partially compliant with HFEA requirements. Some of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

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 partially compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred, however the inspection team has concerns about the robustness of these investigations (see QMS and recommendation 4). 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**

**Safety and suitability of premises and facilities (Guidance note 25)**
One medical gas cylinder stored in the basement of the centre was not secured and was at risk of falling over. This issue was addressed by centre staff immediately. Although the centre has risk assessed the safety of their own gas store, the basement houses gases and liquid nitrogen belonging to other tenants within the building and a health and safety assessment of the basement has not been performed by the building owners (SLC T17; recommendation 11).

**Traceability (Guidance note 19)**
Unlabelled dishes are used to hold, for a short period, embryos selected for transfer prior to them being loading into a transfer catheter. The unlabelled dish is returned to an incubator next to the workstation until the transfer procedure is undertaken. The centre noted this non compliance as an issue in its own audit of practice and had concluded that no changes were necessary as 'risk deemed minimal', even though a documented risk assessment was not performed (SLC T101; recommendation 3).

**QMS (Guidance note 23)**
A review of the centre's own audits and incident reports highlighted that there is, in some cases, no evidence to show that robust investigation has taken place (e.g. a proportionate

root cause analysis) or that corrective and preventative actions are effectively implemented.

The centre has not followed their own procedures for approving and releasing documents as a review of the centre's document management system showed documents had been activated without being approved by the listed approvers.

The centre has not fully implemented guidance issued by the HFEA, as detailed elsewhere in this report (for example see 'Screening of donors' and 'Legal parenthood' sections).

(SLCs T32, T33b and T36; CoP guidance 23.27 and 23.28; recommendation 4).

**Equipment and materials (Guidance note 26)**
The following items are not appropriately CE marked for IVF use: 1ml and 10 ml serological pipettes, 5ml and 15ml tubes, semen sample containers. The centre had completed an audit that identified these non-CE marked products and noted that CE marked alternatives were available. However, the centre was not using CE marked medical devices as they had failed the centre's validation process. The inspection team advised the PR that if they had concerns regarding the suitability of CE marked medical devices for their intended purposes, this should be reported to the MHRA (SLC T30; CoP guidance 27.8; recommendation 5)

## 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 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.

**Staff (Guidance notes 2 and 33)**
The centre is partially 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.

The centre has processes in place to ensure only those embryologists assessed as competent by the Authority, and named on the licence, undertake PNT.

**What the centre could do better**

**Staff (Guidance notes 2 and 33)**

The counsellor is a member of the British Association for Counselling and Psychotherapy (BACP) but is not accredited by this organisation, nor is the counsellor accredited by the British Infertility Counselling Association (BICA). Unfortunately, the counsellor was not available on the inspection, so evidence for the equivalence of the counsellor's qualifications, experience and training, with that provided by BICA accreditation, could not be easily reviewed. Telephone discussion with the counsellor after the inspection did not provide the inspection team with reassurance of equivalent accreditation.

During the 2014 renewal inspection the counsellor was working towards BACP accreditation, however the counsellor confirmed that this has not yet been achieved, nor currently worked towards. At that time the PR was asked to review the counselling service in accordance with professional guidance, taking into account continuing profession development needs. The PR has failed to fully implement this recommendation. (SLC T12; CoP Guidance 2.12; Clinic Focus February 2013; recommendation 8).

## 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 before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

**Safeguarding (Guidance Note 25)**
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'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 the statutory tests are met i.e. that the embryos is at a significant risk of having a series 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, genetic counsellors and infertility 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 the inspectors were unable to speak to any patients to provide feedback on their experiences. The centre's own patient feedback report was reviewed on inspection. Overall patient feedback was positive, with many comments praising staff. The report recognised that some feedback highlighted areas for investigation and development, and detailed actions taken to encourage patients to provide feedback directly to NHS Choices and the HFEA.

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 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 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, notwithstanding the concerns related to the counsellor's accreditation discussed in 'Staff' above. 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 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 partially 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**

**Confidentiality and privacy (Guidance note 30)**
The centre stores notes in a room with a lockable door however this door was unlocked during the inspection. Discussions with centre staff revealed that it is normal practice for this door to be unlocked during working hours. The doors of both the cryostore and laboratory are not locked. The dewars contained within the cryostore are individually locked but records containing patient identifying information are attached to the tanks and are unsecured. Both rooms are accessed down a corridor, through an unsecured door from the main reception area. The inspection team was not assured that access to patient identifying information is effectively restricted to those persons authorised by the PR (SLC T44, HF&E Act 1990 (as amended) Section 33A; recommendation 6).

## 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 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; Chair's Letter CH(11)02)**
Patients and donors considering donating embryos for use in training are provided with written information but it does not include all relevant requirements. Patients and donors are not provided with information about the assessment of Ebola virus infection risk and information about Zika virus is also out of date (SLC T58; SLC T97, CoP guidance 22.10; Clinic Focus February 2016, March 2016 and April 2017; recommendation 10).

## Consent

### Consent to legal parenthood and
### Consent to disclosure of information, held on the HFEA Register, for use in researc

**What the centre does well**

**Consent (Guidance notes 5 and 6)**
The centre's procedures for obtaining consent are partially 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 is 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 the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the interim inspection in January 2016, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff. The centre's own audit of legal parenthood consent was reviewed, and a further three sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required, were audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are partially compliant with HFEA requirements.

**Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)**
The HFEA Register is a rich source of information about treatment using assisted reproductive technologies (ART). It can be used by researchers and linked to other health registers to improve knowledge about the health of patients who have undergone ART and those born following ART treatment. The HFEA is permitted to disclose non-identifying information to researchers but can only provide patient identifying information with the consent of the patient. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA.

The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

**What the centre could do better**

**Consent (Guidance notes 5 and 6)**
During an audit of records, one set of consent forms had amendments that were not initialled and another had changes that were unclear and that the inspection team considered raised doubt over the patient's intentions (SLC T57 and T47; recommendation 7).

**Legal parenthood (Guidance note 6)**
In April 2017 the HFEA released the PBR consent form, to allow married or civil partners of patients undergoing treatment using embryos created with donor sperm, to consent to becoming the legal parent posthumously, without having to complete unnecessary legal parenthood consents in a PP form. The centre does not yet use the PBR form, so all patients using donor sperm complete WP and PP legal parenthood consent forms, regardless of their partnership status. At the time of the inspection, staff indicated that they were still undergoing training in this area and the required changes had not yet been implemented.

The centre's audit of legal parenthood included a review of records of couples who were married or in a civil partnership. The inspection team was concerned that centre staff did not fully understand who should complete consent to legal parenthood, as the centre continues to have couples who are married or in a civil partnership complete consent to legal parenthood forms, when such consents are not applicable or required. Such practice may carry risks but also suggests that staff training is needed.

SLCs T2 and T12; Clinic Focus April 2017; recommendation 9.

**Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)**
One discrepancy was found between the 10 completed patient disclosure consents reviewed in patient files and the related consent data submitted for inclusion on the register. The failing identified leads to a risk that the HFEA will withhold the release of patient data contrary to the patient's consent (Chair's letter CH(10)05; General Direction 0005; recommendation 14).

## 3. The protection of gametes and embryos

### Respect for the special status of the embryo

**What the centre does well**

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

- 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.
- No alterations are made to the nuclear or mitochondrial DNA of an embryo created by means of the application of PNT.
- No cell is added to an embryo created by the means of the application of PNT, other than by the division of the embryo's own cells.

**What the centre could do better**

Nothing identified at this inspection.

### Screening of patients and Storage of gametes and embryos

**What the centre does well**

**Screening of patients (Guidance note 17)**

The centre's procedures for screening patients are partially 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 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**

**Screening of patients (Guidance note 17)**
The inspection team was not assured that the centre has a robust procedure in place to assess the risks of Ebola and Zika infection in patients prior to treatment.
(SLC T50d; recommendation 2).

Concerns about the information provided to patients about Ebola and Zika virus infection assessment are discussed above in 'Information' (recommendation 10).

## Use of embryos for training staff

**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**
Information provided to patients or donors considering donating their embryos for use in training does not include all relevant requirements, as is discussed in 'Information' above and in recommendation 10.

## 4. Information management

**Record keeping and 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 broadly compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

**Obligations and reporting requirements (Guidance note 32; General Direction 0005)**
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information, about licensed activities to the Authority are broadly 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**

**Record keeping and document control (Guidance note 31)**
The centre does not maintain a record of how, and by whom, the patient/donor has been reliably identified and the centre accepts a GP referral letter as a means of patient identification. The inspection team does not consider this a reliable method of identification (SLC T46b; recommendation 12).

**Obligations and reporting requirements (Guidance note 32; General Direction 0005)**
Three percent (3/106) of the IVF, and two percent (1/46) of the DI treatments reviewed following inspection had not been reported to the HFEA.

Seven percent (7/103) of the IVF and 42% (19/45) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005.

At the time of inspection there were also a small number of donor registration issues that were unresolved. These issues have the potential to impact the HFEA's ability to fulfil statutory obligations to donors and the donor conceived.

The centre has not submitted data for IUI treatments for 2015 or 2016.

(SLC T41; General Direction 0005; recommendation 13).

## Section 3: Monitoring of the centre's performance

Following the interim inspection in 2016, recommendations for improvement were made in relation to one 'other' area of non-compliance.

The PR provided information and addressed concerns to the satisfaction of the executive.

### On-going monitoring of centre success rates

The clinical pregnancy rate following FET in patients aged less than 40 years is significantly lower than the national average for treatments in the year to 31 October 2017 (recommendation 1). The PR is aware of the low pregnancy rate in some FET cycles and has reviewed practices and is monitoring the FET treatment outcomes. Centre staff advised that the reduction may be due to a move to more single rather than double blastocyst transfers in FET cycles. In the last year, the centre has not been sent any HFEA risk tool alerts related to success rates. The inspection team reviewed the data and it appears that the centre should have received an alert email towards the end of the period in 2017 when the risk tool monitoring system was not operational.

The inspection team considered that the centre was effectively engaged in monitoring its outcomes and taking action, when appropriate, to improve them.

## 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 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.

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
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| 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.

A major area of non-compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
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| **1. Success rates**<br>The centre's success rates for FET in women under 40 years old are lower than the national average at a statistically significant level.<br><br>SLC T2. | The PR should review practice and take appropriate action to improve the success rate for FET in patients less than 40 years old.<br><br>The PR should provide the centre's inspector with a copy of the review, with proposed corrective actions and timescales for implementation, when responding to the report.<br><br>Following this, the PR should monitor the success of the actions taken, and take further actions as appropriate, to improve the success rate for | In 2016 the Centre updated its eSET policy to reduce multiple births in line with national strategy. The new policy stated that "Patients with more than one frozen blastocyst in storage will be recommended and expected to have a single blastocyst FET." Following the introduction of the policy the multiple pregnancy rate (per pregnant patient) decreased from 26% to 5%. Our modelled data demonstrates that overall pregnancy rate per freeze remains similar to our previous eSET policy. | The executive acknowledges the PR's response and receipt of the requested review.<br><br>Although the PR has provided assurance that there has been no significant worsening of success rates for FET in women under 40 years old, since updating the eSET policy, the PR is reminded of the requirement to continuously improve the quality and effectiveness of the service provided (SLC T32). |

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| | FET in patients aged less than 40. Thereafter, quarterly updates on the monitoring and actions taken should be provided to the centre's inspector, with a goal to normalise this success rate by 7 February 2019. | As pregnancy rate per freeze has not been impacted by the new eSET policy (see review attached) and multiple pregnancy rate significantly reduced, NFC does not believe this should be recorded as a non-compliance. | The PR has stated that the centre's clinical pregnancy rate, per freeze event, remains similar to that at the centre before 2016. However, HFEA sector analysis currently looks at clinical pregnancy rate per frozen embryo transfer. This analysis demonstrates that the centre is significantly below the national average. We do not believe that this is because the majority of other centres have a policy of double blastocyst transfers and therefore consider that a review of the centre's policies and procedures is still important.<br><br>The executive would also like to acknowledge the PR's accomplishment in significantly reducing the centre's multiple pregnancy rate. In response to the review, the HFEA would not recommend attempting to improve success rates by abandoning the effective eSET policy. |

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| | | | Further action required by 20 July 2018. |
| 2. **Screening of patients and donors**<br>The centre does not have robust procedures in place to assess the risks of Ebola and Zika infection in potential donors or patients prior to treatment.<br><br>SLCs T50d and T52h. | The PR should ensure that the risks of Ebola and Zika virus infection are assessed prior to donor or patient treatment in all cases and that the assessment is documented in the records.<br><br>The PR should review the centre's processes for assessing Ebola and Zika virus risk to ensure they are robust. The PR should consider as part of the review, with expert advice if necessary, if there is any risk resulting from any past failure to perform Ebola and Zika assessment. If risk is present, appropriate risk control measures should be implemented.<br><br>A summary of the findings of the review, including corrective actions and the timescales for implementation, should be provided to the centre's inspector when responding to this report. It is expected that compliance with | At the time of the inspection seven different patient checklists (to cover a range of donor and treatment scenarios) had been updated to include travel. Whilst the checklist was not deemed explicit enough by inspectors to cover Ebola and Zika, it was a conscious decision by NFC staff to keep them broad as there are several other areas of travel that also impact treatment (e.g. antimalarial drugs and travel vaccination etc.) that need to be considered.<br><br>In light of the inspection NFC will review SOPs and all relevant checklists and will make them more explicit about Zika and Ebola.<br><br>As with the checklists, at the time of the inspection all relevant patient information had been updated to include a section on general travel. We have now included explicit information about Ebola and | The executive acknowledges the PR's response and her commitment to implement the recommendation.<br><br>The executive requests a copy of the amended SOP, checklist and patient information to be provided by 7 June 2018.<br><br>Further action required by 7 June 2018. |

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| | this requirement will be in effect by 7 June 2018.<br><br>The centre should ensure that up-to-date information is provided to patients regarding Zika and Ebola viruses, and confirm this has been completed when responding to this report.<br><br>The PR should conduct an audit three months after implementing any corrective actions, to ensure that those actions have been effective. A summary report of the findings of the audit should be provided to the centre's inspector by 7 September 2018. | Zika in these patient information documents.<br><br>At the time of the inspection there were posters in the waiting room highlighting specific risks associated with Zika. | |
| **3. Traceability**<br>The centre uses an unlabelled dish for a short time, to hold an embryo selected for transfer prior to it being loaded into a transfer catheter.<br><br>SLC T101. | The PR should ensure that all containers of gametes and embryos are labelled with the patient's/donor's full name and a further identifier.<br><br>The PR should review the centre's processes to identify if any further unlabelled tubes or dishes are used, and should take appropriate | This had already been considered and part of an audit submitted to the HFEA prior to the inspection (NFC/Depart/1) - see attached.<br><br>Use of unlabelled dishes were assessed during the audit and the only used when risk deemed low; following the | The executive acknowledges receipt of the submitted audit and the PR's assurance that this recommendation has been fully implemented.<br><br>No further action. |

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| | actions to ensure that all containers are appropriately labelled and that the practices used are safe.<br><br>A copy of the review, including corrective and preventative actions and timescales for implementation, should be provided to the centre's inspector by 7 June 2018. | inspection we now label the embryo transfer dishes. | |
| **4. QMS**<br>A review of the centre's audits and incident reports highlighted that in some cases, robust investigation of non conformances and adverse events has not been documented.<br><br>The procedure for approving and releasing documents in the QMS is not consistently applied.<br><br>The PR has failed to take action to implement guidance from the HFEA concerning CE marking, assessing Ebola and Zika virus infection risks and changes to consent forms. | The PR should ensure that the centre's QMS has effective processes for:<br>• thorough investigation of all non conformances and adverse events, including root cause analysis where appropriate, so that corrective and preventative actions are devised, documented and implemented that are robust and effective;<br>• incorporating regulatory changes into the centre's documented procedures and practices;<br>• approving and releasing documents in the QMS. | i) Investigation of non-conformances: Newcastle Fertility Centre uses the Q-Pulse and the Datix system to report all incidents as detailed in (NFC/SOP/QA/9). A proportional approach is taken to investigate each incident. All Datix are discussed at the monthly quality management meeting. In cases of adverse events, case review or audits are performed. In accordance with Direction 0011 - all adverse events have been submitted and closed by the HFEA. We feel we have investigated all non-conformances but in light of the inspectors comments we will update our SOP and Q- | The executive acknowledges the PR's response, and commitment to implement the recommendation and provide the requested audits three months after implementation of corrective actions.<br><br>Further action required by 20 July 2018. |

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| SLCs T2, T32, T36; CoP guidance 23.27, 23.28; Clinic Focus articles from February 2016, March 2016, Clinic Focus April 2017. | The PR should ensure that these processes are consistently applied.<br><br>The actions taken to implement this recommendation should be documented in the PR's response to this report.<br><br>Three months after the implementation of corrective actions, the PR should audit the QMS to determine the effectiveness of the actions taken. A summary report of this audit should be provided to the centre's inspector by 7 June 2018. | pulse, where appropriate, to include remedial action, root cause analysis and corrective and preventative action (currently recorded as "corrective and preventative" action in Q-Pulse and "Action and lessons learned" in Datix). An audit will be performed three months after submission of this report.<br><br>ii) Regulatory change: The PR has not failed to take action concerning CE marked products and Ebola and Zika (see section 2 and 5 of this document). New regulatory processes are discussed at the monthly management meeting (Clinic Focus). In light of the inspection we will perform an audit to determine if we have missed any new regulatory changes from the past two years.<br><br>iii) Document Control: All documents that have changes that directly impact patient treatment are approved by a senior member of staff (consultant, nurse or | |

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| | | embryologist) prior to being made active as detailed in NFC/SOP/QA/6. In some cases e.g. the QM manual or documents where spelling and grammar have been updated, and there is no direct impact on treatment, the documents are made active prior to senior staff approval. We will now update the NFC/SOP/QA/9 to remove approval of staff for these minor changes. An audit will be performed to ensure that only approved documents are active. | |
| **5. Equipment and materials**<br>The following items are not appropriately CE marked for IVF use; 1ml serological pipette, 10ml serological pipette, 5ml tubes, 15ml centrifuge tubes, semen sample containers.<br><br>SLC T30, CoP guidance 27.8 | The PR should ensure appropriately CE marked medical devices are used where available.<br><br>The PR should review the validation documents for the CE marked products that failed the centre's validation process. If the validation data shows a problem with the medical device, the PR should report this to the MHRA, via the yellow card scheme, and to the HFEA via the incident reporting procedure. | NFC regularly audits the use of non CE marked products (NFC/Laboratory-Audit/7 - last audit January 2018).<br><br>We have processes in place to replace non CE marked products with CE marked products when availiable. We will send the HFEA and an update of the audit by 07th of June 2018.<br><br>We have reported the 5ml tubes to the MHRA (Ref: 2018/004/011/401/014) and the HFEA (Ref: IN05941) and | The executive acknowledges the PR's response and commitment to implement the recommendations.<br><br>Further action required by 7 June 2018. |

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| | A summary of this review and confirmation of incident reporting should be provided when responding to this report.<br><br>For the remainder of non-CE marked products, that can be appropriately validated, we would not recommend the implementation of precipitous changes that might impact on the quality of treatment. In consideration of this, the PR should identify suitable CE marked alternatives and should provide the centre's inspector, by 7 June 2018, with confirmation of the products to be used and with a plan and timeline for their introduction.<br><br>The PR should aim to be fully compliant no later than 7 September 2018. | will continue to report products that have failed the validation test; our SOPs will be updated to reflect this practise. | |
| **6. Confidentiality**<br>Access to areas where confidential identifying information can be seen or obtained is not fully or | The PR should ensure that all areas where confidential information is held are secure at all times. | Previous inspectors acknowledged we have appropriate measures to restrict people from entering the fertility centre, this has also been risk assessed. In | The executive acknowledges the PR's response and assurance that this recommendation has been implemented. |

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| reliably restricted to people authorised by the PR.<br><br>The HF&E Act 1990 (as amended) section 33A, SLC T45. | The centre's inspector should be informed of action taken to implement this recommendation when responding to this report. | light of the current inspection comments we have installed swipe card access to the door between the patient waiting area and the main corridor. | No further action. |
| **7. Consent**<br>During an audit of records, one set of consent forms had amendments that were not initialled and another had changes that the inspection team considered raised doubt over the patient's intentions.<br><br>SLC T57 and T47. | The PR should ensure that all consents are clear and readable, and are protected from unauthorised amendment.<br><br>The PR should undertake a review of the processes for checking consent forms and for making amendments to them. The review should include the assessment of staff competence in this area of practice.<br><br>A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 7 June 2018.<br><br>Within three months, the centre should carry out an audit of consent forms to ensure that the proposed | The Centre acknowledges the findings of the inspection team. In light of their findings a further audit of notes will be undertaken to establish the nature and frequency of such amendments. As part of the Centre's Clinical Update this area will be highlighted to the team to ensure that there is no doubt about the importance of accuracy in checking and/or amending forms. PR will undertake a review of the process and report to the HFEA by the 07th of June. | The executive acknowledges the PR's response and commitment to fully implement this recommendation.<br><br>Further action required by 7 June 2018. |

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| | 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 7 September 2018. | | |
| **8. Counselling**<br>The centre's counsellor is not accredited by BICA and could not demonstrate the equivalence of her qualifications, accredited membership of a recognised counselling body, training and experience, to that provided by BICA accreditation.<br><br>SLC T12; CoP guidance 2.12, Clinic Focus February 2013. | The PR should ensure a full training and development plan is drawn up for the counsellor.<br><br>The training plan should aim for the counsellor to achieve BICA accreditation or equivalent within two years.<br><br>The counsellor should also be able to provide evidence of regular mentoring and / or supervision by a counsellor holding BICA accreditation (or equivalent) during this development period.<br><br>The plan should be provided to the centre's inspector by 7 June 2018.<br><br>The PR should provide quarterly updates to the HFEA on progress in implementing the proposed actions. | Unfortunately our counsellor was on leave at the time of the inspection. It was agreed that a phone call with her at a later date would suffice and there was little further discussion about this at the time of the inspection. Our counselling practices have been questioned and notably approved at every inspection we have had. Importantly our Counsellor's credentials were specifically scrutinised in detail by the HFEA in relation to the mitochondrial transfer programme within the last six months and confirmed to be compliant.<br><br>Whilst our Counsellor undergoes appraisal as a Trust Employee we acknowledge that since we consider her to be | The executive acknowledges the PR's response. Although the counsellor could demonstrate compliance at previous inspections, she is not currently working towards BICA accreditation, and is not an accredited member of alternative recognised counselling body.<br><br>The executive is assured that the PR will be more proactive in guiding the counsellor's personal development plan (PDP) in relation to her fertility work.<br><br>The executive acknowledges the PR's commitment to provide detail of the CPD activities identified by the 7 June 2018, and commitment to provide the requested quarterly updates. |

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| | | "independent" of the unit we do not separately appraise her and do not therefore draw up her PDP. Given the inspectors' comments and prior discussion the PR will undertake to be more proactive in guiding her PDP. The PR will meet with the Counsellor and her line manager to put an appropriate PDP in place in relation to her fertility work and notify the HFEA of the result before 7th June 2018. The PR will provide updates as requested thereafter. | Further action required by 7 June 2018. |
| **9. Legal parenthood**<br>All patients using donor sperm at the centre, complete WP and PP legal parenthood consent forms, regardless of their partnership status. This is because the centre does not use the PBR consent form.<br><br>The centre's audit of consent to legal parenthood included couples regardless of their partnership status. The | The PR should ensure that the PBR consent form is introduced into the centre's practice and that staff are trained to assist patients to use the PBR, WP and PP consent forms appropriately.<br><br>The actions taken to implement this recommendation and relevant evidence should be provided to the centre's inspector by 7 June 2018. | It is regrettable that this was not discussed with the PR at the time of the inspection. The inspectors' assertion that the "centre does not use the PBR forms" is inaccurate.<br>Because of need to ensure WP and PP forms are in place for unmarried etc. couples we have indeed asked all couples undertaking donor treatment to complete them whether married or not. Following the form changes last year we have made the transition over to the PBR form but there are | The executive acknowledges the PR's response. The PR is reminded that the HFEA issued guidance in April 2017, advising that WP and PP forms should only be completed when a women is receiving treatment with donor sperm, and is not married to, or in a civil partnership with her partner (Consent Forms, A Guide For Clinic Staff. Version 3. Revised April 2017).<br><br>The executive acknowledges the PR's commitment to re- |

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| inspection team was concerned that centre staff did not fully understand who should complete consent to legal parenthood forms and that patient couples may be consenting to legal parenthood when not required.<br><br>Sections 37(1) and 44(1) of Part 2 of the HF&E Act 2008; CH(17)01. | | very few couples for whom it is relevant - those married or in a civil partnership undertaking IVF/embryo storage.<br>Since it is clear that the impression that we were not using the forms must have come from staff interview the PR acknowledges that the team need to be re-appraised of the use of the forms. We will add this to our clinical teaching and ensure that relevant staff members understand the form's use.<br>We have in addition since the inspection, undertaken a full audit of all of the embryo storage for couples who would be eligible to sign a PBR form. Of the nine sets of embryos in store all but two of the couples had signed V2 or V4 of the WP/PP form prior to the introduction of PBR. Those forms specifically make the same provision as the PBR now - namely the potential for posthumous storage and birth certification for married/civil partnership couples. Since none of those couples have withdrawn that consent we | appraise the use of the WP, PP and PBR forms. The executive requests that the PR then carries out an audit of consent forms for all patients who have undertaken treatment using donor sperm, to ensure that the correct use of all forms has been imbedded into practice. This audit should be submitted to the centre's inspector by 20 July 2018.<br><br>Further action required by 20 July 2018. |

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| | | believe it remains valid albeit that the forms have now become obsolete for new use. Of the two who did not complete WP/PP earlier versions, the embryos had been stored in 2013 and 2015 prior to the form change and the patients although remaining in touch, have not been seen in the clinic since. The PR will now write to these couples to offer PBR consent. We do not therefore have embryos in store where posthumous storage and birth certification has not been addressed. Because of the apparent staff uncertainty we will undertake a prospective audit to ensure that all relevant couples have PBR in place prior to embryo storage. We are undertaking a review of documents to ensure that equivalent checkpoints are in place for this form as for other key consents in the IVF process. | |

## 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.

An 'other' area of non compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
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| **10. Information**<br>Patients and donors considering donating embryos for use in training are provided written information but this does not include all relevant requirements.<br><br>SLC T97, CoP guidance 22.10.<br><br>Patient and donors are not provided with information about the assessment of Ebola virus infection risk and information about Zika virus is out of date.<br><br>SLC T58; Clinic Focus February 2016, Clinic Focus March 2016, Clinic Focus April 2017. | The PR should ensure that patients or donors are provided with current and complete information about all aspect of their treatment and use of their gametes, notably regarding the use of embryos in training and Zika and Ebola virus infection assessments.<br><br>The PR should review the information provided to patients and donors to ensure it is compliant with requirements. A summary of the findings of the review including corrective actions and the timescales for implementation, should be provided to the centre's inspector by 7 June 2018. | The patient information documents have been updated to reflect training information (NFC/PID/59).<br><br>With regards to Ebola and Zika, please see Section 2 above. | The executive acknowledges the PR's response and commitment to fully implement the recommendation. A copy of the updated information should be submitted to the centre's inspector for review.<br><br>Further action required by 7 June 2018. |

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| 11. **Premises and facilities**<br>A safety assessment for the basement area, which is used to store gases and liquid nitrogen by multiple tenants, has not been performed.<br><br>One medical gas cylinder stored in the basement by the centre was not secured and was at risk of falling over.<br><br>SLC T17. | The PR should ensure that medical gas cylinders are properly stored and provide confirmation of this to the centre's inspector when responding to this report.<br><br>The PR should ensure a safety assessment of the basement area used by the centre for gas and liquid nitrogen storage, is performed and documented. A copy of this assessment should be provided to the centre's inspector by 7 June 2018. | The one small medical gas cylinder has been secured. A risk assessment has been performed and submitted with this response. | The executive acknowledges the PR's response and receipt of the requested risk assessment.<br><br>No further action required. |
| **12. Record keeping**<br>It is not documented in the records how, and by whom, patients and donors have been reliably identified and it was reported on inspection that the centre accepts a GP referral letter as a means of patient identification.<br><br>SLCs T46b and T47. | The PR should ensure that patients and donors are reliably identified and that the staff member performing the identity check documents their own identity in the records when noting that the check has been performed.<br><br>The centre's inspector should be informed of the actions taken to implement this recommendation by 7 June 2018. | Our processes for identifying patients have been considered and approved by previous inspections. All of our patients come via referral - we do not accept self-referral and since we are an NHS institution, all are cross checked through the e-record system. Moreover the majority of our patients have come through our fertility clinics and are therefore known to the Centre before undertaking licenced treatment. In order to undertake closer ID checks we | The executive acknowledges the PR's response and commitment to implementing this recommendation.<br><br>During the inspection it wasn't clear what evidence the centre were using to reliably verify the identity of patients at the assessment stage, and there was no record of this identity check documented in the patient record.<br><br>For examples of suitable methods of identification |

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| | Within three months of the implementation of actions, the centre should carry out an audit of records to ensure that the 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 7 September 2018. | would need to include all patients attending the centre for the first time. It would be most helpful to understand from the Licence Committee what methods of ID check have been approved for other centres since any increase in reception work will require significant investment. The PR will take advice from the Trust in the meantime but if we are to change this process it would be helpful to have more explicit advice. | checking, the PR is reminded of CoP guidance 18.18 *Centres should establish procedures to ensure patients, donors, and their gametes and embryos are accurately identified. At the assessment stage, centres should use appropriate evidence to verify the identity of donors and self-referred patients seeking treatment (eg, passport or photocard driving licence).*<br><br>Further action required by 7 September 2018. |
| **13. Data submission**<br>Three percent (3/106) of the IVF, and two percent (1/46) of the DI treatments reviewed following inspection had not been reported to the HFEA.<br><br>Seven percent (7/103) of the IVF and 42% (19/45) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005. | The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.<br><br>The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for non-reporting and delayed submissions. This recommendation should be implemented, and the inspector informed of the results of the review and | Discrepancies in reporting of data to the HFEA are identified during the verification of data for the CAFC website - we have not recently had an opportunity to complete this.<br><br>We are aware of the late reporting of data as it is a KPI at our monthly QM meeting. This has been due to staff shortages that have now been addressed. However we have challenged and do so again the need for such tight deadlines when we cannot | The executive acknowledges the PR's response.<br>Although the PR has attempted to submit the IUI data, the submission has not been received by the executive, due to HFEA technical difficulties. The executive will work with the PR to ensure the data is resubmitted once the technical difficulties are resolved.<br><br>The executive acknowledges receipt of an email dated 22 February 2018, correcting |

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| At the time of inspection there were also a small number of donor registration issues that were unresolved<br><br>The centre has not submitted data for IUI treatments for 2015 or 2016.<br><br>SLC T42, General Direction 0005. | actions taken, when responding to this report.<br><br>The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the inspector.<br><br>The PR should review the causes of the donor registration issues identified and if they are not the result of simple data entry errors take appropriate corrective actions to prevent recurrence.<br><br>The PR should ensure that the IUI data for treatments in 2015 and 2016 is submitted to the HFEA by the time of responding to this report. | verify submissions and the information is not used contemporaneously. Within the next six months we will be introducing paperless records (Capture Fertility). Capture Fertility will automatically download data to EDI although we are awaiting the new data dictionary from the HFEA.<br><br>We have resolved outstanding donor registration issues; these were due to simple data entry errors.<br><br>2015 IUI data was submitted on the 10 Feb 2016. There were difficulties submitting the IUI data in 2017 due to the new portal. All IUI data has now been resubmitted on the portal. | data submission and donor registration errors.<br><br>Further action required by 7 September 2018. |
| **14. Disclosure of information**<br>One discrepancy was found between the 10 completed patient disclosure consents reviewed on patient files and the related consent | The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and | This is already part of an biannual audit. Staff submitting EDI data have been reminded of the importance of ensuring data submitted to the register correctly reflects the | The executive acknowledges receipt of an email dated 22 February 2018, correcting disclosure consent information. |

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| data submitted for inclusion on the register.<br><br>Chair's letter CH(10)05; General Direction 0005. | recorded on disclosure consent forms. The PR should also correct the submission identified as being incorrect.<br><br>These recommendations should be implemented and the inspector informed of the results of the review and actions taken, when responding to this report.<br><br>The PR should conduct an audit six months after implementing any corrective actions, to confirm that they have been effective. A summary of the audit should be provided to the centre's inspector. | disclosure on the consent forms. We have highlighted before that the transfer of tick box consent in this way is a point of risk. We will be interested to hear how this will be addressed in the new data collection system.<br><br>We plan to implement paperless records (Capture Fertility) over the next six months. If paperless records has not been implemented within this timeframe another notes audit will be performed. If paperless records have been implemented validation of the software will be performed. | Further action required by 7 September 2018. |

| Reponses from the Person Responsible to this inspection report |
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| The PR thanks the Inspection team for their diligence and advice during the inspection.<br><br>We are pleased to see many areas of good practice noted.<br>Whilst we acknowledge the areas of concern raised we have answered to and challenged some of them in the responses above and attached documents. We do not believe that some of those constitute major non-compliance issues and would be grateful if they were reviewed in light of the responses and downgraded or removed. Specifically: 1,2,4,6,8,9.<br><br>We will as indicated provide further information by the dates requested. |