Executive Licensing Panel - minutes

Centre 0144 (Nuffield Health Woking Hospital)

Renewal Inspection Report

Tuesday, 23 July 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Kathleen Sarsfield-Watson Howard Ryan	Director of Strategy and Corporate Affairs Communications Manager Data Analyst
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Moya Berry	Licensing Manager Committee Officer

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:

- 9th 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 five years.

1.2. The panel noted that Nuffield Health Woking Hospital has held a treatment and storage licence with the HFEA since 1994 and provides a full range of fertility services. Other licensed activities at the centre include the storage of gametes and embryos.

1.3. The panel noted that the centre's interim inspection report of May 2017 was considered by the Licence Committee (LC), rather than the Executive Licensing Panel (ELP), because a report of a Grade A incident (a serious adverse reaction or event) at the centre was also presented. The LC endorsed the continuation of the centre's licence.

1.4. The panel noted that, in the 12 months to 28 February 2019, the centre provided 1329 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large sized centre.

1.5. The panel noted that HFEA register data, between 1 February 2018 and 31 January 2019, show the centre's pregnancy outcomes for IVF and ICSI success rates, in terms of clinical pregnancy outcomes, are in line with the national averages.

1.6. The panel noted that, in 2018, the centre provided 27 cycles of partner insemination, with three pregnancies, and this is in line with the national average.

1.7. The panel noted that, between 1 February 2018 and 31 January 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represents performance that is not likely to produce a multiple live birth rate statistically different from the 10% multiple live birth rate target.

1.8. An inspection was carried out at the centre on the 16 and 17 April 2019.

1.9. The panel noted that at the time of the inspection, there were three major areas of non-compliance concerning the screening of donors, confidentiality and privacy, alongside record keeping and document control. There was also one 'other' non-compliance regarding disclosure of information held on the HFEA Register for use in research (General Direction 0005). Since the inspection visit, the Person Responsible (PR) has implemented all the recommendations made in the report. Where required, and by the dates specified, the PR will provide an update or summary of audits conducted to ensure corrective actions have been effective.

1.10. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a Quality Management System (QMS) and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients.

1.11. The panel noted that the inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

1.12. The panel noted that, the inspection team recommends the renewal of the centre's treatment 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.

1.13. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018; these certificates are generally synchronised to the centre's HFEA licence. The inspection team recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

2. Decision

2.1. 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.

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

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

2.4. The panel expressed particular concern, with regards to the centre's implementation of actions concerning record keeping and document control, following the Grade A incident. The panel noted the inspection team's statement that they were 'not assured that the PR has established robust processes to prevent a similar incident occurring again'. The panel requested the inspectorate to provide a further update on this issue, within the next six months, and by close of December 2019.

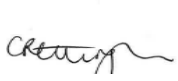
2.5. The panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

2.6. The panel endorsed the inspectorate's recommendation to renew the centre's ITE import certificate, in line with the centre's licence.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

30 July 2019

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: 16 and 17 April 2019.

Purpose of inspection: Renewal of a licence to carry out 'Treatment 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: Julie Katsaros, Louise Winstone and Kathryn Mangold. Chris Hall and Rosie O'Grady from the HFEA Registry team attended on day one.

Date of Executive Licensing Panel: 23 July 2019.

Centre name	Nuffield Health Woking Hospital
Centre number	0144
Licence number	L/0144/13/a
Centre address	Victoria Wing Assisted Conception Services, Shores Road, Woking, Surrey, GU21 4BY, United Kingdom.
Person Responsible	Mr Andrew Riddle
Licence Holder	Mrs Caroline Lewis
Date licence issued	1 October 2015
Licence expiry date	30 September 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Nuffield Health Woking Hospital has held a Treatment and Storage licence with the HFEA since 1994 and provides a full range of fertility services.

The centre provided 1329 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2019. In relation to activity levels this is a large centre.

Other licensed activities at the centre include the storage of gametes and embryos.

The interim inspection report of May 2017 was considered by the Licence Committee (LC) rather than the ELP because a report of an incident (Grade A) at the centre was also presented. The LC endorsed the continuation of the centre's licence.

The current licence has not been varied.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 February 2018 to 31 January 2019 show the centre's success rates are in line with national averages.

In 2018, the centre reported 27 cycles of partner insemination with three pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

Multiple births[2]

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

Between 1 February 2018 and 31 January 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

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

Summary for licensing decision – pre review of draft by PR

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) and standard licence conditions (SLCs), 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 his 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 three major and one 'other' area of non-compliance.

Since the inspection visit, the following recommendations have been fully implemented. Where required and by the dates specified the PR will provide an update or summary of audits conducted to ensure the corrective actions taken are effective:

Major areas of non-compliance:

- The PR should ensure that egg donors are recruited and screened in line with professional body guidance and CoP requirements.
- The PR should ensure that all patient information is kept secure and confidential and is accessible only to authorised persons.

'Other area of practice requiring improvement:

- The PR should ensure that information about consent to disclosure for research purposes provided to the HFEA register, is accurate.

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

Major area of non-compliance:

- The PR should ensure that proper records are maintained.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have three major areas of concern.

The inspection team notes the centre's success rates are comparable to the national average and their multiple clinical pregnancy/live birth rates meets the target.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system (QMS) and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

The inspection team recommends the renewal of the centre's Treatment 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.

Centre 0144 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

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

What the centre does well

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

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but, at the same time, donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
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.

What the centre could do better

Screening of donors (Guidance note 11)
The following issues were identified during the inspection:

- The blood group and rhesus factor of egg donors is not being tested, contrary to current guidance produced by the relevant professional bodies.
- A known egg donor donated at the age of 37 years but relevant professional guidelines on age limits, which should be adhered to, limits egg donor age to less than 36 years. There was no documentation in the donor or patient records to demonstrate that consideration had been given to the age of the donor and the rationale for breaching professional body guidelines.
- A congenital abnormality was identified in the family history of a donor. There was no record of a discussion having taken place with the donor in relation to the abnormality identified or to the recipients.

See recommendation 1; SLC T49, T52, CoP Guidance 11.2, 11.3, 11.15 and 11.23.

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 so that patients and staff are in safe surroundings that prevent harm.

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accreditation by UKAS, the national accreditation body for the UK, or another accreditation body recognised as 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'
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 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. The single biggest risk of fertility treatment is 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;
- 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.

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. This centre has been allocated an ITE import certificate and imports of gametes and embryos from TCSs outside the EU/EEA have been made since the introduction of the ITE import certification scheme on 1 April 2018. No imports have been made from TCS which are not specified on the centre's ITE import certificate. The centre is therefore compliant with General Direction 0006.

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;
- 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 compliant with HFEA requirements however see 'Confidentiality and privacy' and 'Record keeping and document control'. 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, including those associated with ITE/TCS import certificates, are compliant with HFEA requirements.

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

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

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 all 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
Nothing identified at this inspection.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has 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.

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

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

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

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account 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 does not undertake preimplantation genetic screening or embryo testing and sex selection, therefore this area of practice is not applicable to this inspection.

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

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only 15 patients have provided feedback in the last 12 months, giving an average four star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.

The centre's own most recent patient survey responses were also reviewed. A total of 44 patients had left feedback between January and March 2019. The majority of the feedback was positive with references to a caring and personalised approach and that the information given was helpful and well explained. There was also positive feedback regarding the staff.

During the inspection the inspectors spoke to four patients who also provided positive feedback on their experiences.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

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 requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

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

Surrogacy (Guidance note 14)
The centre does not provide treatment involving surrogacy.

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)
During the inspection it was noted that a computer had been left unattended for a significant period of time in a public thoroughfare, clearly displaying a list of patients' names. The centre staff reported that the computers do shut down after a period of inactivity, however, the timeframe is clearly not effective. The inspectors were concerned that confidential information displayed on the screen could be viewed by people other than staff.

Evidence that all staff had undergone some training in confidentiality was seen, however, it was not clear that they have undergone the necessary training in relation to the specific requirements of the HF&E Act 1990 (as amended).

The centre does not have an SOP defining the process to be used when requests are received for the release of information held at the centre. An SOP was developed by the end of the inspection, but it did not include other likely scenarios for when information may be requested, nor had it been disseminated to staff with appropriate training to ensure its effective implementation.

See recommendation 2; SLC T33b, T43, T44d and T45.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and/or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

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

▶ Consent and disclosure of information, held on the HFEA Register, for use in research

What the centre does well

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

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos 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 inspection in May 2017, 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 and reviewed the results of recent legal parenthood consenting audits. Six sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also 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 compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are broadly 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 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 (General Direction 0005)
Three discrepancies were found between completed patient/partner and donor disclosure consent decisions in patient files and the corresponding data submitted for inclusion in the Register. Whilst these failings would not lead to the risk that the HFEA may release patient identifying information to researchers, they do mean that the consent wishes of the patient may not be followed.

See recommendation 4; SLC T9(e), CH(10)05, General Direction 0005.

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.

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 15)

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

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 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 partially compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are 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 noted some minor issues with the timeliness and accuracy of the centre's submission of data to the Register but the quality of data submissions by the centre is generally good. There is a technical issue with the centre's third party treatment data submission system of which the HFEA are aware and therefore no recommendation has been made.

What the centre could do better

Record keeping and document control (Guidance note 31)
During a review of patients' records several entries by staff were identified which were illegible.

Following a grade A incident at the centre which was considered by the Licence Committee in July 2017, the PR made a commitment to implement corrective actions. The effectiveness of those actions were assessed at this inspection and were found not to be robust because:

- Chromosomal and genetic screening results to be verified and evidenced by the consultant: This action was unclear in some of the records reviewed.
- All pathology results to be reviewed and evidenced that they have been seen by a practitioner: a number of pathology results seen in the patients' records had not been signed.
- The centre uses a standardised form to document when laboratory test results have been reviewed; the inspection team noted that results were initialled, however a full name and designation had not been recorded therefore it was unclear which members of staff had reviewed the results.
- There is a section on the form to indicate that all screening results have been checked, but there is no provision for the date to be documented.
- The processes implemented by the PR were to be incorporated into the clinic's audit programme. This has not been done.

The standardised checklist for screening patients includes screening for cystic fibrosis. This section is not being fully completed by staff because:

- The form has options to indicate whether screening is required or is not applicable to a patient. This area was not completed in one of the records

reviewed, so it was unclear if screening had been overlooked by the clinician or if it was not required.

- On another screening checklist, the requirement for cystic fibrosis screening had not been indicated on the form, but the patient (male) record indicated that he did have the screening and was a carrier of cystic fibrosis. There was a record documenting that his female partner had subsequently undergone screening but the result was not present. The checklist had been signed to say that all screening results had been checked but the date of the signature was not recorded, so it was unclear if the later cystic fibrosis screening result of the female partner had been reviewed.
- In another record reviewed, in answer to the question 'Requires Cystic Fibrosis Screening', both 'Yes' and 'No' had been circled on the screening checklist; there were no details documented as to whether screening was required, so it was unclear if screening had been overlooked by the clinician or if it was not required.
- A number of records indicated that screening was not required but this had not been signed or dated by the embryologist, as is required by the form.

During discussions with the centre staff, varying accounts as to the process for the review and documentation of screening results were provided. To clarify the process a request to see the centre's SOP confirmed that there was not an SOP in place to guide the receipt and review of screening and pathology results.

At the end of the inspection, the inspectors were provided with an SOP, however this SOP did not align itself with the discussions and findings documented in patient records during the course of the inspection and therefore the document requires further consideration by the centre.

The inspection team are not assured that the PR has established robust processes to prevent a similar incident occurring again.

See recommendation 3; SLC T33, T36, T37 and T38.

For each patient/donor the centre does not record how and by whom, the patient/donor has been reliably identified.

See recommendation 3; SLC T46.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2017, 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 all of the recommendations were fully implemented within the prescribed timescales

On-going monitoring of centre success rates

Since the last interim inspection, the centre has not received any performance related risk tool alerts.

Areas of practice requiring action

This 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
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 partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Screening of donors The following issues were noted on inspection: • The blood group and rhesus factor of egg donors is not being tested, contrary to current guidance produced by the relevant professional bodies • A known egg donor donated at the age of 37 years but relevant professional guidelines on age limits, which should be adhered to, limits egg donor age to	The PR should ensure that egg donors are recruited and screened in line with professional body guidance and CoP requirements. The PR should review the centre's egg donor recruitment and screening practices and implement actions to ensure compliance with this recommendation. A summary of the findings of the review and the actions taken should be provided to the centre's inspector when responding to this report.	We have reviewed our policy, altered the egg recruitment policy to incorporate these factors, have had meetings with nurses, embryologists and doctors explaining the importance and will continue to audit. A separate file has been forwarded to the lead inspector. Further audits will continue to be performed with a summary report to be forwarded in the proposed time frame assuming there are further donors recruited by 17.9.19.	The Executive acknowledges the PR's response and actions taken to implement this recommendation. No further action beyond submission of an audit report due 17 September 2019

less than 36 years. There was no documentation in the donor or patient records to demonstrate that consideration had been given to the age of the donor and the rationale for breaching professional body guidelines. • A congenital abnormality was identified in the family history of a donor. There was no record of a discussion having taken place with the donor in relation to the abnormality identified or to the recipients. SLC T49, T52, COP 11.3 11.15 and 11.23.	Three months after the review the PR should audit donor records to ensure that the corrective actions implemented have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 17 September 2019.	Rolling audits will continue after this date. The case of a known donor's age and relevant risk to pregnancy outcome was explained to the recipient and not documented but was known to the recipient. This has been drawn to the attention of all doctors and nurses with the importance of clear documentation by doctors and egg donor recruitment nurses . The one off case of a donor recruitment with a second degree relative having a history of spina bufida occulta was we believe, given the correct clinical care but we have explained to all nurses and doctors the importance of doumenting this in notes of any donor and recipient	
2. Confidentiality and privacy A computer was left unattended for a significant period of time in a public thoroughfare, clearly displaying a list of patients'	The PR should ensure that all patient information is kept secure and confidential and is accessible only to authorised persons.	I confirm that all staff have had GDPR training prior to the inspection and will continue to do this. Further training has occurred at the weekly team meetings and will be done one to one for all staff. All	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action.

names. The inspectors were concerned that confidential information displayed on the screen could be viewed by people other than staff. Evidence that all staff had undergone some training in confidentiality was seen, however, it was not clear that they have undergone the necessary training in relation to the specific requirements of the HF&E Act 1990 (as amended). The centre does not have an SOP defining the process to be used when requests are received for the release of information held at the centre. An SOP was developed by the end of the inspection, but it did not include other likely scenarios for when information may be requested, nor had it been disseminated to staff with appropriate training to ensure its effective implementation.	The PR should review the centre's processes for maintaining confidentiality including, but not limited to, staff training in relation to the HF&E Act 1990 (as amended) requirements for confidentiality. A summary of the findings of the review including staff training undertaken since the inspection should be provided to the centre's inspector when responding to this report.	computers have been labelled as to now to screen lock. The quality manager will continue to keep a log of training. Nuffield Corporate IT department were informed that the automatic logout time appeared to have been increased to in excess of 10 minutes and this has now been reduced to 2 minutes. The quality manager will continue to audit this. The corporate IT department have been informed by the quality manager they must not alter the automatic logout time without our approval. Release of notes was discussed in detail with the inspectors and a SOP has been written, disseminated to staff via the weekly meeting but in the meantime I wish to confirm that when notes are requested those who copy notes are aware that they should discuss with the PR, Licence Holder or quality manager prior to release for any queries.	

SLC T33b, T43, T44d and T45.			
3. Record keeping and document control During a review of patients' records several entries by staff were identified which were illegible. There were a number of other issues identified during the course of the inspection documented in the main body of the report SLC T33, T36, T37 and T38. For each patient/donor the centre does not record how and by whom, the patient/donor has been reliably identified. SLC T46.	The PR should ensure that proper records are maintained. The PR should review the centre's processes and procedures for the review and documentation of screening and pathology test results. A summary report, including corrective actions and timescales for implementation should be provided to the centre's inspector when responding to this report. The PR should ensure that a record of how and by whom a patient/donor has been reliably identified, is documented in the patient's records. The PR should review the centre's processes and inform the centre's inspector of the actions taken to ensure compliance with this	Notes audits will continue and individual feedback given when needed. All staff have or will receive confirmation at the weekly meeting or on one to one basis the need to maintain contemperaneous, accurate and clear notes with signatures. We have reviewed the process for documentation of critical results. A separate report has been forwarded to the lead inspector For patient/donor ID confirmation, all staff have or will receive confirmation at the weekly meeting or on a one to one basis the need to check ID, how to perform and document. New results and demographic proformas have been developed and will be audited . Further information has been forwarded to the lead inspector. The quality manager will keep a log of	The Executive notes the PR's response, however the review of the process for documentation of critical results is not as comprehensive as would be expected. The Executive asked the PR to reconsider his response to this recommendation, further information has now been provided by the PR which provides assurance of robust systems No further action required beyond submission of the audit due by 17 September 2019.

	recommendation when responding to this report. Three months after the reviews, the PR should conduct an audit of patient records to ensure compliance with this recommendation. A summary report of this audit should be provided to the centre's inspector by 17 September 2019.	training and perform further rolling audits	

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
4. Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005) Three discrepancies were found between completed patient/partner and donor disclosure consent decisions in patient files and the corresponding data submitted for inclusion in the Register. SLC T9(e), CH(10)05, General Direction 0005.	The PR should ensure that information about consent to disclosure for research purposes, provided to the HFEA register, is accurate. The PR should correct the consent to disclosure discrepancies identified at this inspection and provide confirmation of this to the centre's inspector when responding to this report. The PR should review procedures for data submission in relation to consent to disclosure of information, and should provide a summary report of this review, including any corrective actions needed, to	Please note that the inspectors and HFEA auditors were aware there had been several weeks prior to the inspection of trying to identify several factors from the Registry which we were unable to access due to difficulties with the in house IT, Corporate IT, third party data software provider and the HFEA Registry. The IT issues have been resolved. These three cases have been identified, corrected and we have had confirmation from the HFEA Registry that all non compliances have been addressed with a report from the HFEA registry to myself already forwarded to the lead	The Executive acknowledges the PR's response and action taken to comply with this recommendation. No further action required beyond submission of an audit report due 17 October 2019.

	the centre's inspector by 17 July 2019. Six months after the review, the PR should audit data submission practice and procedure to ensure that any corrective actions implemented have been effective in ensuring compliance. A summary report of this audit should be provided to the centre's inspector by 17 October 2019.	inspector. The root cause appears to have been human errors in data transposition with all cases being readily identifiable within the unit. Further action including in house training for those who take consent and/or upload data has occurred; further audits will continue and a separate report forwarded to the lead inspector	

Responses from the Person Responsible to this inspection report
The quality manager will continue to perform internal audits and is aware to submit audits within the documented time frames