Executive Licensing Panel - minutes

Centre 0258 (The Fertility Centre at Whittington Health)

Renewal Inspection Report

Tuesday, 26 March 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Dan Howard Helen Crutcher	Director of Strategy and Corporate Affairs Chief Information Officer Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Joanne Anton Danielle Vincent Yvonne Akinmodun	Licensing Manager Policy Manager Communications Manager Head of Human Resources

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 four years.

1.2. The panel noted that The Fertility Centre at Whittington Health has held a licence with the HFEA since 2007. Initially, the licence was for treatment (partner insemination), but was varied in 2016 to a treatment (insemination using partner/donor sperm) and storage licence. The centre provides basic fertility services.

1.3. The panel noted that, in the 12 months to 30 November 2018, the centre provided 11 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

1.4. The panel noted that, in the 12 months to 31 August 2018, the centre reported four cycles of donor insemination, with one pregnancy, which was not a multiple. This represents a clinical pregnancy rate which is in line with the national average.

1.5. The panel noted that, in 2018, the centre provided 12 cycles of partner inseminations, with one pregnancy and this is in line with the national average; this one pregnancy was not a multiple.

1.6. An inspection was carried out at the centre on the 15 January 2019.

1.7. The panel noted that at the time of the inspection, there were two major areas of non-compliance concerning the Quality Management System (QMS) and Third Party Agreements (TPA's) and four 'other' areas of non-compliance regarding consent to legal parenthood, disclosure of information held on the HFEA Register, for use in research, the storage of gametes, and record keeping and document control. Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendation regarding the storage of gametes. The PR has given a commitment to fully implement the recommendations made in the report in relation to the QMS, TPA's, disclosure of information held on the HFEA Register for use in research, and record keeping and document control.

1.8. The panel noted that there are some ongoing questions relating to the consents taken concerning legal parenthood. The executive will continue to liaise with the centre regarding this non-compliance but does not consider this on-going process to impact on the consideration of the centre's licence renewal.

1.9. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a 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 the renewal report's recommendations within the required timescales.

1.10. The panel noted that the inspection team recommended the renewal of the centre's treatment (insemination using partner/donor sperm) 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.

1.11. The panel noted that The HF&E Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018 (the '2018 Regulations'), 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. Centre 0258 has not

been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

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 endorsed the inspectorate's recommendation to renew the centre's treatment (insemination using partner/donor sperm) 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.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

2 April 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: 15 January 2019

Purpose of inspection: Renewal of a licence to carry out Treatment (Insemination using partner/donor sperm) 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: Mhairi West and Julie Katsaros

Date of Executive Licensing Panel: 26 March 2019

Centre name	The Fertility Centre at Whittington Health
Centre number	0258
Licence number	L/0258/4/e
Centre address	Clinic 4C, Whittington Hospital, Magdala Avenue, London, N19 5NF, United Kingdom
Person Responsible	Mr Gidon Lieberman
Licence Holder	Gurjit Mahil
Date licence issued	1 July 2015
Licence expiry date	30 June 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Fertility Centre at Whittington Health has held a licence with the HFEA since 2007. This initially was a Treatment (Partner Insemination) Licence but was varied in 2016 to a Treatment (Insemination using partner/donor sperm) and Storage licence. The centre provides basic fertility services.

The centre provided 11 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 November 2018. In relation to activity levels this is a small centre.

This current licence has been varied to reflect the following changes:

- Variation of the centre's licence type from Treatment (insemination using partner sperm) to Treatment (insemination using partner/donor sperm) and Storage;
- A change of centre name;
- The appointment of a new licence holder;
- A change of postal address.

The centre has also recently submitted an application to change the licence holder again. This will be considered by the licensing officer.

The Person Responsible (PR) has submitted an application to renew a licence for treatment and storage. He has confirmed that this is an error and that he wishes to renew the centre's licence to carry out treatment (insemination using partner/donor sperm) and storage.

Pregnancy outcomes[1]

In the 12 months to 31 August 2018, the centre reported four cycles of donor insemination with one pregnancy. This represents a clinical pregnancy rate which is in line with the national average.

In 2018, the centre reported 12 cycles of partner insemination with one pregnancy, which is in line with the national average.

Multiple births

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

The one pregnancy following donor insemination treatment in the 12 months to 31 August 2018 was not a multiple pregnancy.

In 2018, the one pregnancy following partner insemination treatment was not a multiple pregnancy.

[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 $p \leq 0.002$.

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 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 two major and four 'other' areas of non compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendation:

'Other' areas of non compliance:

- The PR should review the process for managing the storage of donor gametes that are transported in from other centres, to ensure that they will be stored with effective consent.

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

Major areas of non compliance:

- The PR should ensure that an audit of assessment of welfare of the child is performed and any corrective actions carried out, including consideration of staff competency to carry out this assessment if appropriate.
- The PR should establish a TPA with the laboratories that supply a blood screening service.

'Other' areas of non compliance:

- The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the HFEA accurately reflects that given and recorded on disclosure consent forms.
- The PR should ensure that verification of patient identification is documented.

The PR has challenged the following recommendation:

'Other' areas of non compliance:

- The PR should ensure that any woman being treated with donated gametes, and her partner if appropriate, have been given information about legal parenthood which is relevant to their marital status.

The executive will continue to liaise with the centre about this recommendation, but does not consider this on-going process impacts on the consideration of the centre's licence renewal.

Recommendation to the Executive Licensing Panel

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

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 (Insemination using partner/donor sperm) 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.

The HF&E Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018 (the '2018 Regulations'), to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments3' (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. Centre 0258 has not been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

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) 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 the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.

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
Payments for donors
Donor assisted conception

What the centre does well

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

The centre's criteria for donor selection are compliant with HFEA requirements.

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. 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 from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes 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
Nothing identified at this inspection.

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
Transport and distribution of gametes
Receipt of gametes
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 laboratories conducting tests that impact on the quality and safety of gametes (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes 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, or any material removed from them, are compliant with HFEA requirements for 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 is providing only insemination treatments and therefore this area of practice was not relevant to this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The centre is providing only insemination treatments, but such treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. The single biggest risk of fertility treatment is a multiple pregnancy and birth. Thus it is important for centres providing insemination treatments to have a multiple births minimisation strategy. The centre's procedures are compliant with HFEA requirements to have a multiple births minimisation strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

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

- document the justification for the use of the patient's 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 (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes are compliant with HFEA requirements. This is important to ensure that all gametes 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;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes (Guidance note15)
The centre's procedures for the receipt of gametes are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes 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 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 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. The centre has not been allocated an ITE import certificate and imports of gametes from third country suppliers (TCS) outside the EU/EEA have not been made since the introduction of the ITE import certification scheme on 1 April 2018. 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 during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes;
- to identify any person who has carried out any activity in relation to particular gametes; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes 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 partially compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any transport or satellite arrangements and therefore this area of practice was not relevant to this inspection.

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 clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre has not experienced any adverse incidents. The inspection team was confident after discussion with the quality manager that procedures are in place to ensure that staff are aware of how to report an incident and investigate it should the need arise.

Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Quality management system (QMS) (Guidance note 23)
An audit of assessment of welfare of the child has not been performed since 2015, against the requirements of the centre's own audit schedule. It is noted that the centre's welfare of the child assessment practices were reviewed on inspection and considered to be compliant.

SLC T36; see recommendation 1.

The inspection team noted that the centre does not hold a formal QMS management review to assess how well the system is working and improvements that can be made. It is acknowledged that the system is working well at the moment and the minutes from the monthly multi-disciplinary meetings are comprehensive, the only area of concern being around audit. The centre currently treats very small numbers of patients and the QMS is currently manageable, with any dips in quality indicators being immediately obvious. However, the centre is exploring various avenues of service development that would potentially increase patient numbers significantly. The inspection team was concerned that the quality manager has responsibility for all aspects of the QMS, as well as being the only member of staff working in the laboratory. She is employed part-time, on a temporary contract, and there did not appear to be any contingency plan for her absence.

The inspection team is of the opinion that the management of the QMS and its review should be developed, in anticipation of increased patient numbers and development of new services. It is not considered that a recommendation is required in relation to this area of practice. The executive will evaluate progress at the centre's next inspection.

Third Party Agreements (TPAs) (Guidance note 24)
The centre does not have a TPA with the Pathology Laboratory in the Whittington Hospital, who provide a blood screening service to the centre.

SLC T111; see recommendation 2.

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 is licenced for partner/donor insemination and storage therefore this area of practice was not relevant 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. Eight patients have provided feedback in the last 12 months, giving an average five star rating to the centre. Considering the low numbers of patients attending this centre for treatment, this suggests that the majority of patients provide feedback to the HFEA.

The website also gives the ability for patients to comment on the cost of treatment. All patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting the laboratory and nursing staff at the centre.

The centre's own most recent patient survey responses were also reviewed. Feedback was comparable to that provided to the HFEA.

No patients were available to speak to during this visit.

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 and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not undertake egg and sperm sharing arrangements and therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not provide surrogacy treatments and therefore this area of practice is not applicable to this inspection.

Complaints (Guidance note 28)
The centre has never received any complaints.

The inspection team was confident after discussion with the quality manager that procedures are in place to ensure that staff are aware of how to be responsive to patient complaints should the need arise. The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

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

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

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 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 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.

While the focus on legal parenthood consenting has been in place since 2014, this centre has only been providing treatment using donor sperm since 2017. The centre's proposed legal parenthood consenting practices were considered compliant at the time their licence was varied.

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 the centre's legal parenthood consenting audit. Four 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 broadly 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

Consent to Legal Parenthood (Guidance note 6)
The centre does not ascertain the marital status of couples attending for treatment with donor sperm. All couples complete HFEA WP and PP consent forms, regardless of their marital status. The inspection team was confident that the centre understands that these forms are not required if couples having treatment using donor sperm are married or in a civil partnership; they are erring on the side of caution by completing the forms for everyone. However, the inspection team considers that asking patients to complete consent forms that are not relevant to them could be confusing.

Guidance Note 6.7, SLC T60; see recommendation 3.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
One discrepancy was found during an audit of nine records of completed patient/partner

consent in patient records and the related consent data submitted for inclusion on the register. The patient had not consented to contact research, but the data submitted to the HFEA indicated that the patient had.

General Direction 0005; see recommendation 4.

3. The protection of gametes

Respect for the special status of the embryo

What the centre does well
The centre does not create embryos therefore this area of practice is not applicable to this inspection.

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

Screening of patients and Storage of gametes

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes.

Storage of gametes (Guidance note 17)
The centre's procedures for storing gametes are broadly compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes in accordance with the consent of the gamete providers. The storage of gametes 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.

What the centre could do better

Storage of gametes (Guidance note 17)
The centre has only been storing gametes since 2017 and has not had to manage any cases where the consented storage period has come to an end. They do have a robust 'bring forward' system, which is linked to their patient database. However, information about donor sperm which has been brought in from other centres in the UK is not entered onto the database and therefore would not be identified in the 'bring forward' system when the consented storage period is ending. The inspection team acknowledges that a very small number of samples are brought in from other centres and are usually used relatively quickly, but a documented system to manage their storage to ensure that they do not remain in storage outwith the consented period is required.

Schedule 3, 8(1) HF&E Act 1990 (as amended); see recommendation 5.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre is licenced for partner/donor insemination and storage only therefore this area of practice is not applicable to this inspection.

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 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 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 found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register, apart from that related to consent to disclosure of information for use in research (see recommendation 6).

What the centre could do better

Record keeping and document control (Guidance note 31)
The centre does not document verification of patient identification on first attendance at the clinic. It is acknowledged that a copy of photographic ID is taken, and asked for at each appointment, but the independent verification of that ID on first production confirming that it matches the patient attending, is not explicitly documented.

SLC T46; see recommendation 6.

The centre is almost paper-free and very dependent on data input into their electronic patient database. Completed consent forms are scanned to attach to electronic patient records, with the paper versions discarded. The inspection team was impressed by the completeness and accessibility of records, and the quality manager performs regular informal audit to ensure accuracy. The team saw no anomalies on inspection but, as activities in the centre potentially increase, the centre is encouraged to consider a documented audit of patient records to ensure the current processes are effective, e.g. that the correct forms are attached to the correct patient record. It is not considered that a recommendation is required in relation to this area of practice. The executive will evaluate progress at the centre's next inspection.

Section 3: Monitoring of the centre's performance

Following a desk-based assessment and scheduled inspection after an application to vary the centre's licence in 2016, recommendations for improvement were made in relation to four areas of major non compliance and one 'other' area of non compliance. ELP instructed that the centre should be inspected by a site visit 12 months from the initial assessment. At that inspection, recommendations for improvement were made in relation to one area of major non compliance and one 'other' area 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

This centre has not been issued with any performance alerts since the last inspection.

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, 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 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
1. **Quality management system (QMS)** An audit of assessment of welfare of the child has not been performed in the last two years, against the requirements of the centre's own audit schedule. SLC T36.	The PR should ensure that an audit of assessment of welfare of the child is performed and any corrective actions carried out, including consideration of staff competency to carry out this assessment if appropriate. The PR should provide the centre's inspector with the audit along with any findings and corrective actions, by 15 July 2019.	A Welfare of the Child audit will be carried out in Feb 2019. This will be sent to the inspector immediately upon completion.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required other than the submission of the audit of assessment of welfare of the child.
2. TPAs The centre does not have a TPA with the Pathology Laboratory in the Whittington Hospital, who provide a blood	The PR should establish a TPA with the laboratories that supply a blood screening service.	A TPA with the pathology laboratroy at Whittington is being drafted. A signed agreement will be sent to the inspector by March 2019.	The Executive acknowledges the PR's response and commitment to implementing this recommendation.

screening service to the centre. It is acknowledged that the centre is aware of this and is in the process of arranging. SLC T111.	The PR should provide the centre's inspector with a copy of the agreement by 15 April 2019.		Further action required.

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
3. Consent to Legal Parenthood The centre does not ascertain the marital status of couples attending for treatment with donor sperm. All couples complete both WP and PP forms, regardless of their marital status. Guidance Note 6.7, SLC T60.	The PR should ensure that any woman, being treated with donated gametes, and her partner if appropriate have been given information about legal parenthood which is relevant to their marital status. The PR should ensure that the marital status of patients being treated with donor gametes is documented and the appropriate consent forms related to legal parenthood are completed. The PR should ensure that any further audit of legal parenthood takes into account assessment of marital status of couples receiving treatment with donor sperm.	Centre staff are not experts in assessing the validity of marriage certificates, nor do they have knowledge of the legality of marriages carried out in other countries. As such, while it is understood that in some cases completion of WP and PP is unnecessary, the decision was taken to err on the side of caution, and ask all couples using donor sperm to sign the WP and PP forms, regardless of marital status. These forms do not take long to complete, and the centre has never received any complaints from patients who are married or in a civil partnership and have been asked to complete them.	The Executive acknowledges the PR's response to this recommendation. The concerns of the executive are not related to patients being unduly detained at the clinic to fill in these forms. The executive is concerned that the text, for example, at the beginning of the HFEA PP consent form states that the patient should fill in the form if they are **not** married or in a civil partnership, and this could create some confusion for patients who are married but are asked to complete these forms anyway. It is extremely important that the issues around legal parenthood and the implications of marital

	The PR should review the centre's processes and supply a copy of their revised procedures by 15 April 2019. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the revisions to the process have been followed through in practice. A summary of the audit should be provided to the centre's inspector by 15 October 2019.	In the opinion of centre staff, actively obtaining consent for legal parenthood from everyone represents the lesser of two evils in this circumstance, in terms of welfare of the patients and of any resulting children.	status on that are clearly understood by both the centre and the patients. The executive acknowledges the difficulties of assessing the status of patients who have married in another country but this is more straightforward for couples married in this country. The centre should determine which methods they deem acceptable as evidence of legal marriage or civil partnership; where it is clear that patients are married, then WP and PP forms are not required. The PR is asked to consider the points described here. The executive will continue to liaise with the centre about this non compliance, but does not consider this on-going process impacts on the consideration of the centre's licence renewal. Further action required.
4. Disclosure of information, held on the HFEA Register, for use in	The PR should review procedures and take appropriate corrective actions	A single data entry error was made in this instance. A review will be carried out in	The executive acknowledges the PR's response and commitment to implementing

research One discrepancy was found during an audit of nine records of completed patient/partner consent in patient records and the related consent data submitted for inclusion on the register. The patient had not consented to contact research, but the data submitted to the HFEA indicated that the patient had. General Direction 0005.	to ensure that the disclosure consent information supplied to the HFEA accurately reflects that given and recorded on disclosure consent forms. A summary of this review should be submitted to the centre's inspector by 15 April 2019. The PR should correct the submission that has been identified as being incorrect and confirm this has been completed when responding to this report. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the centre's inspector by 15 October 2019.	March and a report sent to the inspector immediately upon completion. An audit will be carried out in October following the implementation of any corrective actions. (Please can you tell us the patient number so we can confirm this has been rectified?)	this recommendation. The submission that was identified as being incorrect has now been corrected. Further action required, including submission of a review of procedures by 15 April 2019, and an audit after implementation of any corrective measures, by 15 October 2019.
5. Storage of Gametes Donor sperm brought in from other centres is not managed through the bring forward system. There is a risk that	The PR should ensure that effective consent is in place for all gametes that are in storage.	All sperm brought in from other centres will now be added to IDEAS, and therefore will automatically be on the bring forward system. The	The Executive acknowledges the PR's response. No further action required.

sperm could remain in storage outwith their consented storage period. Schedule 3, 8(1) HF&E Act 1990 (as amended).	The PR should audit the consented storage periods of any sperm that is not managed within the bring forward system to ensure that effective consent is in place, and provide the centre's inspector with the audit with any corrective actions. The PR should review the process for managing the storage of donor gametes that are transported in from other centres, to ensure that they will be stored with effective consent. The audit, along with the process review and any required revisions, should be submitted to the centre's inspector by 15 April 2019.	relevant SOPs have been amended and are attached. An audit has not specifically been carried out, as the centre currently has only one set of samples in storage which originated from another clinic. The storage consent is valid, and these sample have been entered into IDEAS.	
6. Record Keeping and document control The centre does not document verification of patient identification on first attendance at the clinic. It is acknowledged that a copy of photographic ID is taken, and asked for at each appointment,	The PR should ensure that verification of patient identification is documented. The PR should review the processes around verification of patient identity and submit these, with any required revisions, to the centre's inspector by 15 April 2019.	The procedures for checking and storing copies of photogrpahic ID will be reviewed, and updated SOPs/checklists (which will include the need to sign to confirm a likeness) will be send to the inspector by 15th April.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action further than submission of revised procedure by 15 April 2019.

but the independent verification of that ID on first production confirming that it matches the patient attending, is not explicitly documented. SLC T46.			

Reponses from the Person Responsible to this inspection report
Thank you for a pleasant inspection and helpful feedback.