Executive Licensing Panel - minutes

Centre 0293 (Andrology Solutions)

Renewal Inspection Report

Tuesday, 5 May 2020

HFEA Teleconference Meeting

Panel members	Clare Ettinghausen (Chair) Anna Coundley Yvonne Akinmodun	Director of Strategy and Corporate Affairs Policy Manager Head of Human Resources
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

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 Andrology Solutions has held a treatment (insemination using partner/ donor sperm) and storage licence with the HFEA since 2007 and provides basic fertility services. The centre shares premises with The Doctors Laboratory (TDL), a company providing diagnostic laboratory services. Other licensed activities at the centre include the storage of gametes

1.3. The panel noted that, in the 12 months to 30 September 2019, the centre provided 5 cycles of treatment (excluding partner intrauterine inseminations). In relation to activity this a small sized centre.

1.4. The panel noted that, in 2018, the centre reported 77 cycles of partner insemination, with four pregnancies, and this is in line with the national average; none of these pregnancies were a multiple pregnancy.

1.5. The panel noted that, in the 12 months to 30 September 2019, none of the donor insemination treatments resulted in a multiple pregnancy.

1.6. An inspection was carried out at the centre on the 11 December 2019

1.7. The panel noted that at the time of the inspection, there were four major area of non-compliance concerning the safety and suitability of premises and facilities, imports and exports, the quality management system (QMS) and staff. Since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations regarding the safety and suitability of premises and the QMS, and has committed, where required, to audit the effectiveness of those actions within the required timescales. The PR has provided a commitment to fully implement the recommendations surrounding imports and exports and staff.

1.8. 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 centre is well led and provides a good level of patient support.

1.9. 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.

1.10. The panel noted that 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.

1.11. 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. 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.

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 her 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, acknowledging that a number of audits are due for receipt, by the inspectorate, by 11 June 2020. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

2.5. The panel endorsed the inspectorate's recommendation to renew the centre's ITE 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

11 May 2020

Renewal 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: 11 December 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: Victoria Brown and Sandrine Oakes

Date of Executive Licensing Panel: 5 May 2020

Centre name	Andrology Solutions
Centre number	0293
Licence number	L/0293/4/a
Centre address	75, Wimpole Street, London, W1G 9RT, England
Person Responsible	Dr Sheryl Homa
Licence Holder	Miss Sara Matthews
Date licence issued	01 August 2016
Licence expiry date	31 July 2020
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Andrology Solutions has held a Treatment (Insemination using partner / donor sperm) and Storage licence with the HFEA since 2007 and provides basic fertility services. The centre shares a premises with The Doctors Laboratory (TDL), a company providing diagnostic laboratory services.

The centre provided five cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2019. In relation to activity levels this is a small centre.

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

Pregnancy outcomes[1]

In 2018, the centre reported 77 cycles of partner insemination with four pregnancies. This represents a clinical pregnancy rate of 5%, which is in line with the national average.

Multiple births[2]

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

No donor insemination treatments in the 12 months to 30 September 2019 resulted in a multiple pregnancy.

In 2018, none of the four pregnancies following partner insemination treatment were a multiple pregnancy.

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) 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 her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable with the exception noted in the main body of the report;
- 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, four major areas of non-compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

Major areas of non-compliance:

- The PR should risk assess the cryo-storage facilities in the andrology laboratory to ensure there is no health and safety risk posed to staff, patients and other personnel in the vicinity.
- The PR should ensure that the centre's quality management system (QMS) and auditing processes are effective.

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

Major areas of non-compliance:

- The PR should ensure that the import of donor gametes is compliant with General Directions 0001 and 0006.
- The PR should ensure that staff are suitably trained and competent for the tasks they perform.

Recommendation to the Executive Licensing Panel

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

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/ live birth rates are below the target.

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 this report's recommendations within the required timescales.

The centre is well led and provides a good level of patient support.

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.

Centre 0293 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 with the exception noted in the 'Staff' section of this report. 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 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 with the exception noted in the 'Imports and exports' section of this report. 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
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 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 partially 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 partially 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 laboratory 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, are compliant with HFEA requirements to be accredited 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 with the exceptions noted in the 'QMS' and 'Staff' sections of this report.

Medicines management (Guidance Note 25)
These requirements are not relevant to the centre's activities.

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)
These requirements are not relevant to the centre's activities.

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 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 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 partially 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. The centre has been allocated an ITE import certificate and imports of gametes and embryos from TCSs outside the EU/EEA have not 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 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, including those associated with ITE/TCS import certificates, are compliant with HFEA requirements, with the exceptions noted in the 'Imports and exports' and 'QMS' sections of this report.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
These requirements are not relevant to the centre's activities.

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

Safety and suitability of premises and facilities (Guidance note 25)
Several cryo-storage dewars are being stored in the main andrology laboratory in which no extraction system is in place. When filling these dewars with liquid nitrogen, the laboratory door, leading onto a corridor used by patients, staff and personnel not employed by the centre, is opened as a means of ventilation. The centre has not carried out a risk assessment of these arrangements. The inspection team could not be assured that the ventilation within the laboratory is adequate for the safe storage of cryo-storage dewars and may pose a risk of harm to staff, patients and other personnel.

SLC T17 and British Compressed Gases Association's (BCGA) (2000) Code of Practice 30 (CP30) – 'The safe use of liquid nitrogen dewars up to 50 litres'; recommendation 1.

Imports and exports (Guidance note 16; General Direction 0006)
The third-party agreements with donor sperm banks in the EU, supplying the centre, made no reference to donor compensation arrangements. The PR could not assure the inspection team that, in reference to gametes imported to the centre for use in patient treatment, the overseas donors had been compensated in line with General Direction 0001, and therefore that imports were compliant with General Direction 0006.

General Directions 0001 and 0006; recommendation 2.

Quality management system (QMS) (Guidance note 23)
On inspection, the following issues were identified:

- The centre has no quality indicators for welfare of the child or record keeping;
- The centre does not have SOPs to cover the following areas of practice: emergency procedures (including clinical) and infection control processes.

On the day of the inspection the PR confirmed that the above-mentioned services are provided to the centre by TDL, with whom the centre share a premises. Whilst the inspection team acknowledges this is acceptable, the centre should have SOPs in place which describe the services provided by TDL, to ensure staff have a clear understanding of the processes to follow.

- The centre's current protocol is to review SOPs every two years instead of the recommended 12 months. As a result of this, the centre's SOPs for the following areas of practice had not been reviewed within the required time-frame of 12 months: welfare of the child and recording of information for the HFEA.

In addition, the centre has several TPA's with courier companies that had not been reviewed within the timeframe specified in the TPA. Therefore, these SOPs and TPAS are at risk of not reflecting current best practice guidelines and regulatory requirements.

- The centre has not audited the following areas of practice in the last two years:
    - Welfare of the child
    - Procuring, processing and transporting gametes
    - Traceability
    - Record keeping
    - Infection control

SLC T33, T35, T36, T112, CoP 31.9 and Department of Health (DH), The Health and Social Care Act 2008 Code of Practice on the prevention and control of infections and related guidance (2015) sections 1.2 and 1.5); recommendation 3.

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
Staff

What the centre does well

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

Leadership
The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

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

The centre has access to a nominated registered medical practitioner and scientist, within

the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Staff (Guidance note 2)
On inspection, the following issues were identified:

- Personnel not employed by the centre but who work for TDL, another company sharing the same premises, are sometimes used for double checking the identification of gametes and the patient or donor to whom they relate. There is no evidence that these personnel have received training and assessment of competency of witnessing procedures and requirements nor the confidentiality requirements of the HF&E Act 1990 (as amended). Furthermore, the inspection team were concerned that these arrangements may not ensure compliance with the confidentiality requirements of the HF&E Act 1990 (as amended).
- The competency assessment document for "sperm preparation" of one andrologist at the centre, contained areas where it was recorded that a 'pass' had not been achieved. Despite this, the member of staff was signed off as being competent and able to practice the procedure unsupervised, without evidence of further training and re-assessment of competency.
- The centre does not employ any medical practitioners but grants medical practitioners practising privileges to perform licensed treatment under the centre's HFEA licence. These clinicians provide information to, take consent from and perform welfare of the child assessments of patients having insemination treatments. Medical practitioner competency is assessed by a retrospective patient notes audit. The inspection team considered that this is too narrow in scope to demonstrate compliance with SLC T15a and best practice guidelines.
- There was no evidence that clinicians with practising privileges at the centre had been provided with an induction to the organisational framework, quality management system and Health & Safety rules of the centre.
- There was no evidence that centre staff have received a refresher of infection control or safeguarding training for several years, since initial staff induction.

SLC T12, T15a. T15c and T43; COP 18.10, 18.12, 25.20 and 25.35; recommendation 4.

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)
These requirements are not relevant to the centre's activities.

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 two patients have provided feedback in the last 12 months, giving an average five-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 (2017-2018). Out of the five responses received, all patients were satisfied with the centre's services. The PR is encouraged to continue to conduct patient feedback surveys on a more frequent basis.

During the inspection, the inspectors spoke to one patient who also provided positive feedback on their experience.

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

Patient support
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.

Patient support (Guidance note 3)
New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

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)
These requirements are not relevant to the centre's activities.

Surrogacy (Guidance note 14)
These requirements are not relevant to the centre's activities.

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

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

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 / 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 that inspection in 2018, 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. Three 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 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
Nothing identified at this inspection.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
These requirements are not relevant to the centre's activities.

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 are 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
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)
These requirements are not relevant to the centre's activities.

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 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.

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

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2018, recommendations for improvement were made in relation to one area of major non-compliance.

The PR provided information and evidence that the recommendation was fully implemented within the prescribed timescales.

On-going monitoring of centre success rates

Since the last inspection in March 2018 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 identified.			

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.Safety and suitability of premises and facilities Several cryo-storage dewars are being stored in the main andrology laboratory in which no extraction system is in place. When filling these dewars with liquid nitrogen, the laboratory door, leading onto a corridor used by patients, staff and personnel not employed by the centre, is opened as a means of ventilation. The centre has not carried out a risk assessment of these arrangements. The inspection team could not be assured that the ventilation within the	The PR should risk assess the cryo-storage facilities in the andrology laboratory to ensure there is no health and safety risk posed to staff, patients and other personnel in the vicinity. The risk assessment should include a calculation of the ventilation requirements, given the number and capacity of dewars stored, including if a dewar was to fail, and also the safety of those who use the corridor outside the laboratory. A copy of this risk assessment,	In view of the findings from the recent inspection, a decision has been made to transfer all liquid nitrogen crystorage dewars from the laboratory to the external storage facilities where there is maintained air extraction and oxygen monitoring. The laboratory will continue to retain dry shippers for short term storage and holding flasks for the cryopreservation procedures. A risk assessment will be carried out for these processes by 11th March	The executive acknowledges the PR's response and commitment to implementing this recommendation. The PR confirmed on 16 March 2020 that the dewars stored in the andrology laboratory have now been relocated to the cryo-storage room. The PR has provided a risk assessment for the storage of dry shippers and holding flasks in the andrology laboratory. No further action required

laboratory is adequate for the safe storage of cryo-storage dewars and may pose a risk of harm to staff, patients and other personnel. SLC T17. British Compressed Gases Association's (BCGA) (2000) Code of Practice 30 (CP30) – 'The safe use of liquid nitrogen dewars up to 50 litres'.	including any corrective actions and timescales for implementation, should be provided to the centre's inspector by 11 March 2020.		
2. Imports and exports The third-party agreements with donor sperm banks in the EU supplying the centre made no reference to donor compensation arrangements. The PR could not assure the inspection team that, in reference to gametes imported to the centre for use in patient treatment, the overseas donors had been compensated in line with GD 0001, and therefore that imports were compliant with GD 0006. General Direction 0001. General Direction 0006.	The PR should ensure that the import of donor gametes is compliant with General Directions 0001 and 0006. The PR should review the third-party agreements it has in place with the overseas banks that the centre has used to import donor gametes with particular consideration to donor compensation arrangements. The PR should provide evidence of compliance with GD 0001 requirements to the centre's inspector by 11 March 2020. The PR should review the	The PR will review and update all the TPAs currently held with overseas donor sperm banks to ensure that they comply with general Directions 0001 and 0006. In particular, the PR will request copies of receipts for all payments made to sperm donors. This information will be kept on file. A review of the changes will be presented to the HFEA bey 11th March 2020.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The PR has provided the centre's inspector with copies of the updated TPAs that the centre now has in place with overseas banks. These TPA's now detail donor compensation arrangements that are compliant with GD 001. However, the PR has also provided evidence, supplied to her by the donor banks from which the centre imports. This

	centre's procedures to ensure that evidence required to demonstrate compliance with the requirements of GD 0006 is obtained and kept on file, before gametes are imported. A summary of the review and any changes implemented as a result, should be provided to the centre's inspector by 11 March 2020.		evidence shows that donors, previously imported by the centre have been compensated above the limit specified in GD 0001. The PR should note that a course of sperm donation, referred to in GD 0001, has been previously defined by the HFEA as the period beginning at the first consultation and ending once the sample has been released for use in treatment. The PR should ensure that compliance is assessed using this definition. The centre's inspector will continue to liaise with the PR to ensure ongoing compliance in this area Further action required.
3. QMS Several issues with the centres QMS were noted, as detailed in the main body of the report. SLCs T33, T35, T36 and T112. CoP 31.9.	The PR should ensure that the centre's QMS and auditing processes are effective. The PR should conduct a review of the centre's QMS including, but not exclusively, the issues identified in this	The QMS will be reviewed to correct the issues identified in the report above and to determine its effectiveness.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The PR has conducted a review of the centre's QMS and provided a copy to the centre's inspector.

DH, The Health and Social Care Act 2008 Code of Practice on the prevention and control of infections and related guidance (2015) sections 1.2 and 1.5).	report. A summary report of this review should be provided to the centre's inspector by 11 March 2020. The PR should address the issues identified with the QMS, as detailed in the main body of the report and provide copies of the reviewed SOPs and TPAs to the centre's inspector by 11 March 2020. The PR should conduct the necessary audits, as outlined in the main body of the report. A summary report of those audits should be provided to the centre's inspector by 11 June 2020. The PR should provide the centres inspector with confirmation that quality indicators have been established and implemented for the welfare of the child and record keeping by 11 March 2020. The PR should develop an SOP and/or service agreement detailing the services provided	All SOPs will be reviewed annually and revised if necessary. The SOP for document control will be updated accordingly. TPAs with courier companies and donor sperm banks will be reviewed and revised. The PR will carry out the audits as required The centre will provide quality indicators for welfare of the child and record keeping. The PR will provide an SOP for detailing emergency procedures including clinical,	The PR has provided evidence to centre's inspector that the QMS issues identified at this inspection have been addressed. An SOP detailing the services provided to the centre by TDL has been developed and copy of this has been provided to the centre's inspector. No further actions are required beyond completion of the outstanding audits as detailed in the main body of the report, due 11 June 2020.

	by TDL to the centre and provide a copy of this to the centre's inspector by 11 March 2020.	infection control processes and services provided by TDL	
4. Staff Several issues related to staffing were noted, as detailed in the main body of the report. SLC T12, T15a and T43. COP 18.10, 18.12, 25.30 and 25.35.	The PR should ensure that staff are suitably trained and competent for the tasks they perform. The PR should ensure that all staff undertaking witnessing procedures have been appropriately trained and assessed as competent. The PR should ensure that no practitioner undertakes witnessing procedures until they have been assessed as competent to do so. The PR should undertake a review of the training and competency assessment of all personnel carrying out witnessing activities with careful consideration to the confidentiality requirements of the HF&E Act 1990 (as amended). A summary report of this review along with evidence that competency assessments have been	On occasion, staff from an adjacent diagnostic laboratory have been requested to act as witness to samples when only one member of staff is avaiable from Andrology Solutions. Typically, when a request has been made for a procedure out of hours. This practice will no longer continue. The PR will ensure that only competent staff from Andrology Solutions will be undertaking witnessing procedures. All Andrology Solutions staff have been trained by the PR to witness, have read the HFEA CoP section on Witnessing procedures (signed off in their training folders) and have read and signed the clinic SOP for witnessing. In circumstances where IUI procedures are performed out	The executive acknowledges the PR's response and commitment to implementing this recommendation. The PR has confirmed that only staff employed at the centre who have been appropriately trained and competency assessed will undertake witnessing activities. The PR has clarified why areas of "failure" were included in the original competency document seen by the inspectors. She has confirmed that this particular member of staff is in fact competent to carry out the procedures in question unsupervised. She has undertaken a review of all staff competencies for lab procedures and confirmed that all staff carrying out lab procedures have been appropriately trained and assessed as being competent.

	completed should be provided to the centre's inspector by 11 March 2020. The PR should ensure that staff are competent before being permitted to practice procedures unsupervised. Where competency is not assured during a competency assessment further training should be undertaken before re-assessment. The PR should undertake a review of all staff competencies to ensure that staff are competent for the tasks they perform and that their practices are compliant with HFEA requirements, professional body and practice guidance, and the centre's own SOPs. This report should also include a review into when training and competency assessment should be repeated. A summary report of this review including timescales for completion of any required competency assessments should be provided to the centre's inspector by 11 March 2020.	of hours, from now on, two members of Andrology Solutions staff will always be present for witnessing if more than one patient sample is in the laboratory. If only one patient sample is in the laboratory, only one member of staff may be present. The male patient always confirms that his sample is labelled correctly and the recipient and doctor performing the IUI procedure confirm the details on the final preparation container with the prepared sperm. All intermediate stages are witnessed retrospectively. No additional training of staff is therefore required at this moment in time. With regard to general competency training, the document provided for Competency in Sperm Preparation for Maria Kontopyrgou contained some errors and I have attached the updated version. Please note that the PASS/FAIL annotation does not refer to competency.	The PR has confirmed that several members of staff have undertaken refresher training in safeguarding and the remaining staff members will have completed this refresher training by 11 June 2020 at the latest. The PR has confirmed that medical practitioner competency assessments will be completed. These, assessments due 11 June 2020 are awaited. The PR has confirmed that staff will be made aware of infection control procedures. However, as previously requested the PR should evaluate appropriate timescales for the delivery of this training and if following this, there are any staff outside the recommended intervals, the PR should ensure the relevant training is provided. The PR should provide an action plan with time scales for the delivery of appropriate training, to the centre's

	The PR should ensure that no practitioner undertakes procedures unsupervised until they have been assessed as competent to do so. It is expected that all required competency assessments will be completed no later than 11 June 2020. The PR should ensure that all personnel working under the centre's HFEA licence, whether they are employed by the centre or not, are suitably trained and competent for the tasks they perform. The PR should provide the centre's inspector with details of medical practitioner competency assessments when they have been completed. It is expected that these will have been completed by 11 June 2020. The PR should ensure that all staff working under the centre's HFEA licence are provided with suitable induction training and that staff receive infection control and safeguarding training at	It merely refers to a 95% confidence interval for acceptable difference for a particular parameter, which allows for discrepancies from time to time i.e. 5%. Comparisons between operators differ from time to time in any IQC or EQA programme. As long as these discrepancies fall within 95% confidence intervals and are not persistent, this is perfectly acceptable. In this particular case, twelve parameters were assessed per sample and this was repeated 3 times. In total there were 2 random discrepancies out of 36 observations, equivalent to 5.5% discordant results. Based on the data we have presented, I consider this member of staff to be fully competent. The discrepancies have been further clarified on the report in the comment section 4. Every doctor must sign a duty list before they are accepted to carry out intrauterine insemination at Andology	inspector by 11 June 2020. Further action is required.

	appropriate intervals following their induction. The PR should evaluate appropriate timescales for the delivery of this training and if following this, there are any staff outside the recommended intervals, the PR should ensure the relevant training is provided. The PR should provide an action plan with time scales for the delivery of appropriate training, to the centre's inspector by 11 March 2020.	Solutions. They are also required to provide the following information: • A recent CV • GMC number • A copy of occupational health status i.e hepatitis B immunity • A copy of DBS check • A copy of certificate of appraisal (annually) • A copy of revalidation certificate (every 5 years) • A copy of medical indemnity insurance (annually). All of this information is kept on file with the PR In addition, the PR will ensure that all doctors will receive an induction to the organisational framework, quality management system, and health and safety rules of the centre. They will also be required to become fully familiar with the HFEA CoP section and Andrology Solutions SOP for welfare of the child. All Andrology Solutions staff have undertaken Safeguarding training and have certficiates	

		of attendace for this. The staff have not had any refresher training since 2017 but this will be organised forthwith. The PR will ensure that all staff are aware of the Health and Safety Policies and Procedures for the premisis as directed by The Doctors Laboratory which includes infection control.	

Other areas of practice that requires improvement

Other areas of practice that require 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
None identified.			

Responses from the Person Responsible to this inspection report
NONE