Executive Licensing Panel Minutes

Centre 0007 (Hewitt Fertility Centre)

Renewal Inspection Report

Date:	24 August 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Joanne Anton Kathleen Sarsfield-Watson	Director of Strategy and Corporate Affairs Head of Policy (Job-share) Communications Manager
Executive:	Bernice Ash	Secretary
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 the Hewitt Fertility Centre has held a treatment (including embryo testing) and storage licence with the HFEA since 1992 and provides a full range of fertility services including embryo testing.

1.3. The panel noted that, in the 12 months to 31 May 2021, the centre provided 2,282 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a large sized centre.

1.4. The panel noted that, HFEA register data, for the period April 2020 to March 2021, show the centre's success rates for IVF and ICSI are in line with the national averages, with the following exceptions:

- Success rates following IVF treatment in women under 38 years old are lower than average at a statistically significant level.

- Success rates following ICSI treatment in women under 38 years old are lower than average at a statistically significant level.

1.5. The panel noted that, in 2020, the centre reported 17 cycles of partner insemination with no pregnancies. This is in line with the national average.

1.6. The panel noted that HFEA data, between April 2020 and March 2021, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 4%. This represents performance that is significantly lower than the 10% multiple live birth rate target for this period.

1.7. The panel noted that In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented. These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non-compliances, identified during DBA, if not adequately investigated

1.8. The panel noted that HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

1.9. The panel noted that the centre was due a renewal inspection during the period of suspension of fertility treatments related to the Covid-19 pandemic. In July 2020, the Person Responsible (PR) applied for a variation to extend the duration of the centre's current treatment (including embryo testing) and storage licence by one year. Following the grant of the licence variation, the centre's licence duration was extended to five years.

1.10. The panel noted that the centre was last inspected in June 2018; therefore, an on-site inspection should usually have been conducted by June 2021. Following the DBA/RBA for this clinic, it was concluded that any items of concern identified during the DBA were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site inspection. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic

1.11. The panel noted that a DBA, followed by a virtual inspection was conducted on 20 May 2021, which included videoconferencing with key members of centre staff.

1.12. The panel noted that, at time of the inspection, there were seven major areas of non-compliance relating to payment for donors, laboratory accreditation, medicines management, the Quality Management System (QMS), consent to a posthumous birth registration (PBR), storage of gametes and embryos and pregnancy success rates. There was also one 'other' non-compliance regarding the centre's website.

1.13. The panel noted that, since the renewal inspection, the PR has participated in discussions with the inspection team, questioning the basis of most of the non-compliances. However, the PR has provided evidence that actions are planned or are being taken to implement the recommendations made in the report, addressing all the non-compliances, and has committed, where required, to audit the effectiveness of the actions within the required timescales.

1.14. The panel noted that the centre has no critical areas of concern but does have seven major areas of non-compliance. The inspection team noted the success rates for IVF and ICSI treatments, between April 2020 to March 2021, in patients less than 38 years of age are below the national average; however, the overall multiple pregnancy rate in the same timeframe was 4%, representing performance that is significantly lower than the 10% multiple live birth rate target.

1.15. The panel noted that significant improvement is required in order for the centre to reflect suitable practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided.

1.16. The panel noted that the centre provides a good level of patient support.

1.17. 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.

1.18. The panel noted that the inspection team recommends the renewal of the centre's treatment (including embryo testing) and storage licence, for a period of four years, without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

1.19. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to section 24(4AD). Such certificates are generally synchronised to the centre's HFEA licence. The executive 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 licensed activity.

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 noted the PR's engagement, with the inspectorate, to address all the recommendations made in the report, particularly identifying actions taken to improve success rates at the centre.

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

2.6. The panel agreed that, should any of the recommendations made in the renewal report, not be addressed to the satisfaction of the inspectorate within the next 12 months, an executive update should be submitted to the Executive Licensing Panel (ELP) for consideration.

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

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

31 August 2021

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 report provides information on the centre's application to renew its existing licence. Licensed centres usually receive a licence to operate for up to four years, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law).

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: 20 May 2021

Purpose of inspection: Renewal of a licence to carry out Treatment (including embryo testing) and Storage.

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection and communications received from the centre.

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

This centre was last inspected in June 2018, therefore an on-site inspection should usually be conducted by June 2021. However, following the DBA/RBA for this clinic, it was concluded that any items of concern identified during the DBA were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site inspection. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

This inspection was therefore carried out by desk-based assessment followed by a virtual inspection, which included videoconferencing with key members of centre staff.

Inspectors: Grace Lyndon (lead), Louise Winstone (scientific inspector), Nicola Lawrence (clinical inspector), Karen Campbell (HFEA scientific observer) and Sarah Steadman (HFEA clinical observer)

Date of Executive Licensing Panel: 24 August 2021

Centre name	Hewitt Fertility Centre
Centre number	0007
Licence number	L/0007/17/d
Centre address	Liverpool Women's Hospital, Crown Street, Liverpool, L8 7SS, United Kingdom
Person Responsible	Dr Rachel Gregoire
Licence Holder	Liverpool Women's NHS Foundation Trust
Date licence issued	1 November 2016
Licence expiry date	31 October 2021
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Hewitt Fertility Centre has held a Treatment (including embryo testing) and Storage licence with the HFEA since 1992 and provides a full range of fertility services including embryo testing.

The centre provided 2,282 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2021. In relation to activity levels this is a large centre.

The centre's licence has been varied to reflect the following:

24 March 2017 – change of Person Responsible (PR)
17 November 2017 – change of PR
4 March 2021 – All centres: variation of all licences without application (European Union (EU) Exit requirements).

This centre was due a renewal inspection during the period of suspension of fertility treatments related to the Covid-19 pandemic. In July 2020, the PR applied for a variation to extend the duration of the centre's current Treatment (including embryo testing) and Storage licence by one year. Following the grant of the licence variation, the centre's licence duration was extended to five years.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period April 2020 to March 2021 show the centre's success rates are in line with national averages with the following exceptions:

- success rates following IVF treatment in women under 38 years old are lower than average at a statistically significant level.
- success rates following ICSI treatment in women under 38 years old are lower than average at a statistically significant level.

See recommendation 7.

In 2020, the centre reported 17 cycles of partner insemination with no pregnancies. This is likely to represent a clinical pregnancy rate which is in line with the national average.

Multiple births[2]

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

Between April 2020 and March 2021, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 4%. This represents performance that is significantly lower than the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP) 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;
- 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, comprising seven major and one 'other' areas of non compliance.

Since the inspection, the PR has had discussions with the inspection team and has questioned the basis of most of the non compliances. She has however provided evidence that actions are planned or are being taken to implement the following recommendations to address all the non compliances and has committed, where required, to audit the effectiveness of the actions within the required timescales:

Major areas of non compliance:

- The PR should ensure that imports of donor gametes, or embryos created with donor gametes, are compliant with General Direction 0001 and General Direction 0006(GB).
- The PR should ensure that medicines management practices are compliant with regulatory and best practice requirements.
- The PR should ensure that laboratories performing diagnostic tests, or the tests themselves, are appropriately accredited by UKAS or another accreditation body recognised as accrediting to an equivalent standard.
- The PR should ensure that the centre's QMS is effective.
- The PR should ensure that the appropriate consent forms related to legal parenthood are completed prior to treatment.
- The PR must ensure that there is effective consent to storage for all cryopreserved gametes and embryos.
- The PR should seek to improve the pregnancy success rates for IVF and ICSI treatments involving fresh embryos in women under 38 years old.

'Other' areas of non compliance:

- The PR should take appropriate action to ensure that the centre's website is compliant with requirements.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have seven major areas of non compliance. The inspection team notes the success rates for IVF and ICSI treatments between 1 April 2020 to 31 March 2021 in patients less than 38 years of age are below the national average; however, the overall multiple pregnancy rate in the same timeframe was 4%, representing performance that is significantly lower than the 10% multiple live birth rate target.

Significant improvement is required in order for the centre to reflect suitable 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.

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 (including embryo testing) and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Centre 0007 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 executive recommends the centre's import certificate is renewed in line with the HFEA licence.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

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

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are 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 embryos.

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

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor

and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

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

What the centre could do better

Payments for donors (Guidance note 13; General Direction (GD) 0001)
The centre imports donated sperm from an overseas sperm bank under the terms of an import agreement and under the authorisation provided by an ITE import certificate. The import agreement includes specific confirmation that the donors are compensated in accordance with HFEA requirements, i.e. GD0001. However, documents provided by the overseas sperm bank to the centre in evidence of the compensation given to two sperm donors, showed that the compensation was not compliant with GD0001. The inspection team was concerned that the centre has failed to recognise that the compensation was not compliant with GD0001 or in accordance with the relevant terms within the import agreement between the centre and the overseas sperm bank.

GD0001 and GD0006(GB). See recommendation 1.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.
The premises of the centre's satellite and laboratories conducting tests that impact on the quality and safety of gametes and embryos (relevant third parties) are suitable.

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are partially 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.

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 partially compliant with guidance.

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

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

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

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes/embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements, notwithstanding the issues discussed above in 'Payments for donors'.

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 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 import certificates, are compliant with HFEA requirements.

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

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

Laboratory accreditation (Guidance note 25)
The centre undertakes diagnostic AMH testing in-house however, the laboratory is not 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.

SLC T21. See recommendation 2.

Medicines Management (Guidance note 25)
As part of the pre-inspection DBA process the centre was requested to submit six pages of their controlled drug (CD) register. They supplied eight pages. In those eight pages (numbers 91-98) the following issues were noted:

- In numerous entries there was no record of the time of administration of the drug, only the drug supply section had a time in it.
- The dose of drug administered was illegible in numerous entries and was not recorded in several cases.
- In one entry, there was no date of administration of drug recorded.

- On all pages, the carry-over of stock from one page to the next was not signed or witnessed.

SLC T2; Association of Anaesthetists 'Controlled drugs in perioperative care 2019: Good practice for controlled drugs administered directly by registered healthcare professionals in the theatre environment'; NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'; The Misuse of Drugs Regulations 2001.

See recommendation 3.

Quality Management System (Guidance note 23)
The following non compliances within the QMS were identified during the inspection:

- Some audits were unclear in relation to their methodology. For example, the sample size was not always noted (e.g. Welfare of the Child (WoC) audit and the Import and Export audit).
- The dates were not routinely documented on the audits.
- The centre does not have an SOP for the provision of information.
- The corrective actions implemented to address non conformances were not described in some audits (eg. 'Case note consent audit' and 'WoC audit').

SLC T33. See recommendation 4.

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
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 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 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's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA;
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons;
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a significant risk of having a series genetic condition.

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

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

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. 176 patients have provided feedback in the last 12 months, giving an average five-star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to.

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 inspectors during this virtual inspection.

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;
- treats patients with empathy and understanding.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Patient support
Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff 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 sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg and/or sperm providers donating for benefits in kind;
- egg and/or sperm providers are fully assessed and medically suitable; and
- the benefit offered is the most suitable for the egg or sperm provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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

Confidentiality and privacy (Guidance note 30)
The centre's procedures are 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)
The centre's procedures for providing information to patients and donors are broadly compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Information (Guidance note 4)

On review of the centre's website, the following information has not been provided for patients:

- The live birth rate per embryo transferred.
- Information was not provided on the centres website which clearly states that information on success rates is of limited value in comparing centres.

CoP Guidance 4.8. See recommendation 8.

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

What the centre does well

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

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the inspection in May 2021, 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. Seven 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 partially 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

Legal parenthood (Guidance note 6)
During the virtual inspection, seven randomly selected sets of records were reviewed in circumstances where consent to legal parenthood was required, and the following issues were noted:

- In two cases, a posthumous birth registration (PBR) consent form had been completed by couples who were having donor insemination treatment. A PBR form is for use in treatment where embryos are created in vitro and is not appropriate for use in donor insemination treatment.
- In another case, an unmarried couple had completed a PBR consent form when it was not appropriate to do so.

Whilst these inappropriate completions of the PBR form are unlikely to have any negative impact on patients, the inspection team were concerned that the correct consent forms had not been completed, as this may reflect misunderstanding of the role of the PBR forms specifically, and legal parenthood consent forms generally.

Human Fertilisation and Embryology Act 1990 (as amended); SLCs T2, T12, T60.
See recommendation 5.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

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

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are partially compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Storage of gametes and embryos (Guidance note 17)

The centre has one sperm sample in storage where there is some doubt as to the validity of the consent. A sperm sample was frozen in December 2009 and was eligible for an extension of storage from December 2019, however, the Medical Practitioner's Statement (MPS) form required as a legal requirement for extension of the statutory storage period, was not signed until June 2020, i.e. outside of the initial 10 year storage period required for the MPS to be legally active. This was identified during one of the centre's own audits however, the inspection team was concerned that no further action was taken.

The centre acknowledges that an error in the bring-forward system spreadsheet led to the requirement for the completion of an MPS not being identified in a timely manner. The centre has since reviewed their processes and appropriate corrective actions are now in place to ensure that the information in the bring-forward system is accurate.

Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009; SLCs T79, T80, and T82**.**

See recommendation 6.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

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

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are 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 evidence of 11 cases relating to the timeliness and accuracy of the centre's submission of data to the Register. These cases are historical donor treatments dating from 2000, 2002 and 2005 and are visible on the centres missing donor treatments report. No further recommendation is being made in relation to this issue; however, the PR is encouraged to continue to liaise with the HFEA's register team and their inspector to ensure a complete resolution of all cases.

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

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

On-going monitoring of centre success rates

The centre's success rates for IVF and ICSI treatments involving fresh embryos in women under 38 years old are lower than the national average at a statistically significant level.

Success rates for ICSI treatments in this group of women was identified as an area of concern at the previous inspection in 2018. Since the time of the last inspection and in response to the success rate risk tool alerts received, the PR has investigated the low success rates and performed analyses several times. Despite these interventions, success rates in this group of patients have continued to remain lower than the national average for a significant period of time. It is noted that the data collected by the HFEA that informs our inspection process is pregnancy rate per treatment cycle started. The PR described that the centre treats a higher-than-normal proportion of patients with 'freeze-all' cycles which do not progress to embryo transfer in the same cycle. The PR provided information on inspection that currently approximately 30-40% of women under the age of 38 undergo elective frozen embryo transfer and that there is a good cumulative clinical pregnancy rate for this group of patients. However, as fresh embryo transfer is still indicated for some patients, the PR is urged to monitor and continue to strive to improve success rates for those patients. The PR has taken steps to introduce changes to improve success rates overall and specifically in this group of patients and has reiterated her commitment to keeping these success rates under review.

SLC T2. See recommendation 7.

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 areas 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 areas 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. Payments for donors The centre imports donated sperm from an overseas sperm bank under the terms of an import agreement and under the authorisation provided by an ITE import certificate. The import agreement includes specific confirmation that donors are compensated in accordance with HFEA requirements, i.e. GD0001 paragraphs 12 and 13. However, a document provided by the overseas sperm bank to the centre in evidence of the compensation given to the sperm donors,	The PR should ensure that imports of donor gametes, or embryos created with donor gametes, are compliant with GD0001 paragraphs 12 and 13, and GD0006(GB). The PR should audit the compensation reports provided for each donor whose sperm has been imported since the ITE certificate with the donor bank was approved in April 2019, ensuring that the compensation received are compliant with GD0001(GB). A summary of the audit should	The PR is aware of the payments made to the donors imported from the overseas donor bank and had been satisfied that these payments were compliant with GD 0001. GD0001 details the definition of a 'clinic visit' and a 'cycle of egg donation' under section 17. Section 17 does not define a 'cycle of sperm donation' and therefore the PR had interpreted that the definition of 'cycle of sperm donation' as the time from initial consultation to the time of donation as defined with egg	The executive acknowledges the PR's response and the lack of definition of a cycle of sperm donation in GD0001. However, the executive also notes that Direction 2006/1 regarding donor compensation, which preceded GD0001, defined a course of sperm donation as: 'the period beginning at the first consultation and ending once the sample has been released for use in treatment'. This was the common definition of 'course of sperm donation' across the sector and remains the definition

showed that the compensation was not compliant with GD0001. The inspection team was concerned that the centre failed to recognise that the compensation was not compliant with GD0001 or in accordance with the relevant terms within the import agreement between the centre and the overseas sperm bank. GD0001 and GD0006(GB).	be provided to the centre's inspector by 20 August 2021. The PR should review the centre's processes to consider what further actions need to be put in place to ensure compliance with GD0001 for future imports of donated gametes from overseas donor banks, including auditing compliance of the TCS with the terms of the import agreements. A summary report of this review should be provided to the centre's inspector by 20 August 2021.	donation. The PR has since raised this with the donor bank involved and this has also been their interpretation of GD0001 without a definition stipulated by the HFEA. See attached correspondence with the overseas donor bank. When considering the PR's interpretation of GD0001 with compensation reports of the donors used at centre 0007 against the SLA and ITE, and following correspondence with the donor bank involved, the PR would consider the payments as compliant with payment not exceeding £250 per cycle of donation. The PR will seek independent legal advice regarding this issue before any further imports from overseas donor banks take place, and will use this legal guidance in a review of centre processes when importing donor gametes. The PR will provide a copy of the review and the legal guidance to the centre's inspector. The ITE and SLA in place will be	used by the executive. Against this definition, the compensation provided to the donor reviewed was not compliant with the requirements of GD0001. The executive acknowledges the PR's right to seek legal advice regarding the interpretation of 'course of sperm donation' and her commitments to implement the recommendations detailed in the 'Action required and timescale for action' table in accordance with that advice. The executive reminds the PR that, in accordance with SLC T36, the compliance of donor bank services provided to the centre should be audited against the terms of the relevant import agreements within the centre's audit schedule. No further action is required beyond the audit report, which should be provided no later than 20 October 2021.

		audited against this legal guidance and the findings from the audit also provided to the centre's inspector.	
2. Laboratory accreditation The centre undertakes diagnostic AMH testing in-house however, the laboratory is not 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. SLC T21.	The PR should ensure that laboratories performing diagnostic tests, or the tests themselves, are appropriately accredited by UKAS or another accreditation body recognised as accrediting to an equivalent standard. The PR should provide a report of their response regarding the laboratory accreditation with planned actions and timescales for implementation, to the centre's inspector by 20 August 2021.	The PR acknowledges that diagnostic AMH testing is performed within centre 0007 without UKAS accreditation. Centre 0007 has risk assessed the use of a laboratory with UKAS accredited QMS and Diagnostic Andrology service but no accreditation for AMH testing specifically. Risk assessment is attached with evidence embedded for suitable practice for equivalence to UKAS accredited AMH testing. Staff training, iQC, calibration, blood analysing protocol, and servicing PPM all follow manufacturers instructions as followed in UKAS accredited services. Data validation studies have confirmed no difference when in-house data is compared to that of a UKAS accredited laboratory.	The executive acknowledges the response given by the PR and confirmation that the diagnostic AMH testing is performed at the centre without appropriate accreditation. The executive has reviewed the additional documentation provided by the PR and notes the steps the centre has taken. SLC T21 discusses 'If the centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, these laboratories must be *accredited* to conduct the relevant test(s) by UKAS, the national accreditation body for the UK, or another *accreditation body* recognised as accrediting to an equivalent standard'.

		The Quality Manager has requested a change to scope meeting with UKAS assessors later in 2021 where addition of AMH testing to scope will be considered. The PR has initiated a service evaluation study for in-house non-UKAS testing v UKAS accredited AMH testing to verify the use of in-house testing for algorithm based dosing of stimulation. Approval expected late 2021.	It is evident from the documentation provided, that the testing service is not accredited by UKAS or another accreditation body recognised as accrediting to an equivalent standard. As such, the use of the in-house AMH testing service is non compliant with SLC T21, and can only be compliant when the service obtains suitable accreditation. The executive notes the centre proposes to meet with UKAS to seek a change in scope to add AMH testing to the accreditation provided by UKAS for the centre's semen assessment service. The PR should provide by 20 October 2021, an action plan with timescales for implementation, to develop the service to ensure UKAS accreditation of the AMH testing service is achieved in a timely manner.

			The executive notes the risk assessment provided for the testing service, which indicates it can be safely continued until UKAS accreditation is obtained. The executive also notes the requirements of SLC T21 discussed above, and that the PR has a legal duty to ensure the centre operates in compliance with its licence conditions. The PR should take appropriate actions to ensure this occurs and should advise the centre's inspector of the actions planned and taken. Once the in-house AMH testing service is suitably accredited, the PR should forward the accreditation to the centre's inspector. Further action required.
3. Medicines Management Several issues were identified as detailed in the main body of the report.	The PR should ensure that medicines management practices are compliant with regulatory and best practice requirements.	The PR submitted evidence to the Lead Inspector ahead of the desk based inspection on 20.05.2021. The evidence included photographic evidence of the Controlled	The executive acknowledges the PR's response. During the inspection, a selection of pages from the centre's current CD register were reviewed, not just the most

Association of Anaesthetists 'Controlled drugs in perioperative care 2019: Good practice for controlled drugs administered directly by registered healthcare professionals in the theatre environment'. NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'. The Misuse of Drugs Regulations 2001. SLC T2.	The PR should review medicines management practices and procedures including staff training requirements, and provide a summary report of this review, including any corrective actions and staff training requirements, with timescales for implementation to the centre's inspector by 20 August 2021. Three months after the review the PR should audit medicines management practice and procedures to ensure that any corrective actions implemented have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 20 November 2021.	Drug book including pages from March 2021 and an audit performed on 25.01.21 (both attached for your reference). With the photographs there was also narrative provided to explain and acknowledge the errors highlighted during the audit and which have been noted in the body of this inspection report. The errors in the Controlled Drug book were attributed to the fact that within the general theatre setting of the Trust, the time of administrating the drug is not routinely recorded. A period of education followed which entailed working specifically with the theatre practitioners. There was significant improvement following training and this was acknowledged when further evidence was reviewed by the clinical inspector on the 20.05.2021. On the day of inspection, the last two full pages of the Controlled Drug book were reviewed and the clinical inspector acknowledged that significant improvement had	recent pages. It is accepted that there have been recent improvements in the completion of the CD register but numerous issues were observed in the CD register pages provided pre-inspection. Non conformances in CD register completion identified at this inspection were also identified as a 'major' non compliance during the centre's last inspection in June 2018. The inspection team considered escalating this non compliance to critical because of its repetitive nature, but decided that recent improvements in CD register completion meant a 'major' grading was appropriate. The inspection team expects the improvements in CD register completion to be maintained. The PR should provide the review discussed in the recommendation to the centre's inspector by 20 August 2021, and the

		been made. There were no errors noted. The improvement and significant change to practice was also noted by the inspector at the informal feedback session on the day of inspection. The Lead Nurse is liaising with the Clinical Director of Anaesthetics to review training of theatre staff. This review will be provided to the centre's inspector. All Trust clinical staff must complete medicine management mandatory training every two years. Compliance for the clinics staff is attached. Work continues to improve the management of medicines and documentation in the Controlled Drug book, and further developing and improving the pre, peri and post -operative documentation.	summary report of the check audit by 20 November 2021. Further actions required.

		Staff, at the end of every list check the controlled drug book with anaesthetic colleagues to ensure all entries are legible. In addition, a Controlled Drug competency will be developed which will ensure competence and knowledge of the areas highlighted within the body of this report. This will not replace medicine management Trust training but will provide additional assurance within the clinic.	
4. QMS Several issues were identified as detailed in the main body of the report. SLC T33.	The PR should ensure that the centre's QMS is effective. The executive acknowledges the vast overhaul of audits and SOPs currently being undertaken at the centre, however, the PR should ensure that actions are taken to address the issues noted in this report and provide a summary of these when responding to this report. The SOP described should be provided to the centre's inspector by 20 August 2021.	The PR is unclear of the evidence to suggest that the QMS is ineffective. No discussion took place before, during or after the licence renewal inspection with the PR to consider any potential findings with the QMS. Had this discussion taken place the PR expects this major non-compliance would not have been raised. In the body of this report (page 12) it states that audits are unclear in their methodology and refers to	The executive cannot reconcile the comments made by the PR given the interactions with the PR and centre staff during the inspection process and the feedback provided to them. All non conformances within the QMS were highlighted to the centre's team and discussions were held during the inspection process, feedback session and in additional correspondence after the inspection.

		sample size not noted on the audits provided for Welfare of the Child and Import and Export. WoC audit and non-conformance reports were sent to the inspector pre-inspection on 13.04.21. Sample size, date of audit and corrective actions were all documented in these reports. The PR has attached these documents again for consideration. Import and Export audit paperwork was also emailed to the inspector ahead of the inspection date on 13.04.21. The audit paperwork again lists corrective actions and the date of audit is detailed at the top of the first page. The sample size is clear with patients listed 1-5. In the body of this report (page 12) it states that corrective actions implemented were not routinely described in audits and refers to WOC audit and 'case note consent audit'. The PR is unclear which audit the	The executive urges the PR to continue to review their QMS documentation and to implement actions to address the issues noted in this report. A summary of the actions taken should be provided to the centre's inspector, no later than 20 August 2021. Further actions required.

		second is referring to but has attached to this response the WOC audit that was emailed to the inspector on 13.04.21 with the non-conformance response detailing actions taken. The PR has also attached a copy of a 'case note' audit and 'consent' audit, both also submitted to the inspector on 13.04.21 and both detailing corrective actions. In the body of this report (page 12) it is stated that centre 0007 does not have an SOP for Provision of Information. The PR can confirm that centre 0007 does have an SOP for Provision of Information (QMS-SOP-16) and attaches the current version (version 11) to this draft report as evidence to support this. This SOP details the provision of written information. The provision of verbal information is detailed in each relevant, separate procedural SOP to ensure the most current, up to date verbal information is provided to	

		patients as procedures are reviewed. The PR has attached a selection of SOPs as evidence to support this: SCI-EMB-SOP-11, -19, -33. NURSE-SOP-2, -4, -9. Based on the detail provided above, the PR strongly diagrees that this non-conformance was raised.	
5. Consent to PBR. As discussed in the main body of the report, in three cases, PBR consent forms were completed by patients when it was not appropriate for them to do so given their marital status or the treatment provided. This may reflect misunderstanding of the role of the PBR forms specifically, and legal parenthood consent forms generally. Human Fertilisation and Embryology Act 1990 (as amended). SLC T2, T12, T60.	The PR should ensure that the appropriate consent forms related to posthumous birth registration and legal parenthood are completed prior to treatment. The PR should complete an investigation and root cause analysis (RCA) to understand the reasons why the consent documentation and checking processes have failed on this occasion. A copy of the investigation report and RCA should be submitted to the centre's inspector by 20 August 2021. The PR should ensure all relevant staff are competent to collect posthumous birth	The PR will perform an RCA and submit evidence of staff training and competency in legal parenthood consenting and consent checks by 20th August. The PR is satisfied that a robust process is in place with the counselling team for consenting to legal parenthood, with a clear understanding of the forms required for treatment. There is also a robust process in place immediately prior to treatment to confirm the correct forms are in place to confirm valid consent. However, this check does not currently include a check for	The executive acknowledges the PR's response. No further action is required beyond the submission of the RCA and the evidence of staff training and competency, no later than 20 August 2021.

	registration and legal parenthood consents from patients. Further training should be provided. Evidence of staff training, and competence assessment should be provided to the centre's inspector by 20 August 2021.	the incorrect completion of additional forms. The PR is satisfied that a robust LP audit is in place to confirm informed valid consent to legal parenthood is gained prior to treatment. However the scope of the audit should be widened to cover the completion of additional incorrect forms. The PR recognises that the further training is required for staff who are less familiar with legal parenthood forms, to ensure that additional forms are not requested by staff unnecessarily. Specifically this includes the use of PBR forms only when required. The scope of the legal parenthood workshop provided by the Lead Counsellor and the competency assessment completed following the workshop (both attached in their current version to this response), should be widened to provide more detail	

		regarding the use of the PBR form. The scope of the LP audit now covers inappropriate completion of forms (SOP attached). The case note review SOP (attached) now also details actions to be taken if inappropriate LP forms are found at case note review prior to treatment. The LP consent taking SOP now explains the PBR form in more detail and its appropriate use (SOP attached).	
6. Storage of gametes and embryos The centre has one sperm sample in storage where there is some doubt as to the validity of the consent. A sperm sample was frozen in December 2009 and was eligible for an extension of storage from December 2019, however, the Medical Practitioner's Statement (MPS) form required as a legal requirement for extension of the statutory storage period, was not signed until June	The PR must ensure that there is effective consent to storage for all cryopreserved gametes and embryos. In cases where there has been a failure to comply with the storage regulations, the PR must seek independent legal advice, with a legal representative who is conversant with the HF&E Act 1990 (as amended) and the HFEA statutory storage regulations, on how to proceed, including whether	The PR acknowledges that in this case there was lack of consent for a period of 6-7 months for this particular patient.The PR has sought legal advice from the Trust legal representative (with extensive knowledge of HFE Act 1990 as amended). Following this legal advice the PR will continue to store the sperm samples under the new regulations: the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes)	The executive acknowledges the PR's response. The executive acknowledges the number of notes that may be required to be reviewed for this process to be undertaken effectively. The executive extends until 20 October 2021, the deadline for the summary to be provided to the centre's inspector. No further action required beyond submission of the

2020, i.e. outside of the initial 10 year storage period required for the MPS to be legally active. Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009. Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020 SLCs T79, T80, and T82**.**	affected patients should be informed. The PR must provide a detailed summary report of the findings of the legal opinion demonstrating why (where applicable) the samples may continue to be lawfully stored. The PR should audit all samples that have been in storage for over 10 years to ensure that a valid MPS is in place. A summary of the audit should be provided to the centre's inspector by 20 August 2021.	(Coronavirus) Regulations 2020 ("the 2020 Regulations"), As the "2020 Regulations" do not stipulate that gametes or embryos must be lawfully in storage in order to be eligible for the extension, the PR has contacted the patient and requested him to complete an HFEA CVS form to consent to a further two years in storage. This will allow the samples to lawfully remain in storage until an MPS form can be completed prior to the extended storage expiry date. The PR has provided a report detailing the legal opinion. The PR has initiated an audit of all samples in storage over 10 years and will feedback to the inspector once complete. The PR requests that the HFEA consider the time taken to perform this audit with centre 0007 being classed as a large centre with a significant number of historical samples in cryostorage.	summary of the audit by 20 October 2021.
7. Pregnancy success rates	The PR should seek to improve the pregnancy	The PR understands that centre 0007 success rates per	The executive notes that the low success rate for ICSI

The centre's success rates for IVF and ICSI treatments involving fresh embryos in women under 38 years old are lower than the national average at a statistically significant level. SLC T2.	success rates for IVF and ICSI treatments involving fresh embryos in women under 38 years old. The PR should commission an independent review of all clinical and laboratory practices and procedures that can have an impact on the pregnancy success rates for IVF and ICSI treatments involving fresh embryos in women under 38 years. The review should include an action plan for addressing the success rates, a schedule for implementation and review of any corrective actions identified. The PR should provide the centres' inspector with a plan for commissioning an independent review by 20 August 2021. A summary of the independent review and action plan for the implementation of any recommendations to address the success rates should be	cycle started are lower then the national average. It is worth noting that in 2020 at centre 0007 ~35% of fresh cycles resulted in a 'freeze all' cycle, therefore no embryo was transferred and therefore no expectation of a clinical pregnancy in that fresh cycle. The high ratio of 'freeze all' cycles is due to conservative management of OHSS at centre 0007. On 18.01.21 an independent fertility expert (Peter Humaidan) presented clinical advice regarding stimulation protocols to the medical, nursing and scientific teams at the centre. This was a Q&A session and initiated a series of internal clinical review meetings to consider changes to stimulation protocols to further improve pregnancy rates for those receiving a fresh embryo transfer. The initial series of change ran from 01.02.21 to 30.04.21, followed by a lag period to	treatments in patients under 38, was also identified as a major non compliance at the last inspection in 2018; hence the significant concern and recommendation made in this inspection report in response to the low success rates. The executive appreciates the PR's detailed response, which documents the significant actions taken and planned by the centre to address low success rates. The executive also acknowledges that a high 'freeze all' rate can drive down success rates for fresh cycles, if the 'freeze all' cycles are not elective and reported to the HFEA as such. An independent review of stimulation practice had already been undertaken in February 2021 before this inspection. The impact of the resulting practice changes initially is said to be positive. Further changes are planned from 1 September 2021. It is correct to allow time for the

	provided to the centre's inspector by 20 February 2022.	collate all pregnancy outcomes for patients treated within these dates. A clinical meeting involving nursing, medical and scientific staff was held on 26.07.21 to review the clinical and laboratory data from 01.02.21 to 30.04.21 in more detail and to consider further changes in response to the data. On review of the data, the change in stimulation and timing of trigger based on follicular response reduced the 'freeze all' rate from 38% in 2020 to 28% between 01.02.21-30.04.21 (statistically significant). This positive outcome will continue to be monitored. The review also indicated an upward trend for positive and clinical pregnancy rates in all fresh cycles but not yet showing signficance. This positive outcome will continue to be monitored. Further changes to stimulation, trigger, and luteal	impact of these changes to be properly analysed. It is possible that if actions already taken improve success rates to a significant extent, the recommended wide-ranging independent review of the centre's practices may not be needed. Review of treatment data by the centre (notably in March 2022) and by the HFEA will be undertaken. The centre's data analyses, and minutes of their consideration should be provided to the centre's inspector in a timely manner. The PR should liaise with the centre's inspector in early April 2022, after the planned report in March 2022, to discuss and decide whether the further wide-ranging independent review of the centre's practices is still needed. If the executive considers the review is still needed, a summary of the independent review and action plan should be produced and provided to the HFEA by 20 June 2022.

		support in fresh cycles were agreed, and will be implemented on 01.09.21 to allow for clear communication with the wider clinical team and to allow changes to SOPs ahead of implementation. The impact of these changes will be assessed in March 2022 and reviewed at a further clinical meeting. The data review from 26.07.21 clinical meeting and the agreed action plan from the meeting is attached for review. No RBAT has been received for centre 0007 since January 2021 and the PR continues to monitor the quality indicators closely. The PR has also recently updated the HFEA website (see 'other' non-compliance raised below) based on calculations of live birth for all ages February 2019-February 2020. This data shows a current live birth rate per embryo transferred for centre 0007 as 27%, above the national average of 23%.	No further actions required beyond the submission of treatment monitoring and success rate reports to the HFEA, notably on 31 March 2022, and, if considered necessary, the submission of the independent review of the centre's practices and the action plan in response to the review, on 20 June 2022.

		The PR also continues to update the HFEA inspector for centre 0007 on a regular basis regarding changes to clinical processes. The PR acknowledges and agrees with the benefit of commissioning an independent review. However, the PR is conscious that the internal review initiated in February 2021 is ongoing and first review has shown a positive outcome, with a further action plan in place. The true outcome of this internal action plan cannot be reviewed until March 2022, and implementation of further changes in the interim will invalidate the monitoring of impact. The PR therefore requests that the timeline for inititating an independent review is reconsidered and the internal review of data in March 2022 allowed to take place before initiating an independent review. Data will be assessed in the interim and the PR/Scientific Director and Clinical Director	

		will contact UK colleagues to commission the independent review in preparation (if still needed).	

Other areas of practice that require improvement

'Other' areas of practice that require improvement are any areas of practice which cannot be classified as either a critical or major area of non compliance, but which indicate 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
8. Website The centre's website is non-compliant with requirements as detailed in the main body of the report. CoP Guidance 4.8.	The PR should take appropriate action to ensure that the centre's website is compliant with requirements. The PR should audit the content of the centre's website against the requirements of CoP Guidance 4.8 and provide a report of the audit, including plans for corrective actions, to the centre's inspector by 20 August 2021.	On page 17 of this draft report it states that the Hewitt Centre website does not provide the following information for patients: '…information on success rates is of limited value in comparing clinics'. This reported finding is incorrect. The Hewitt Fertility Centre website/success rates clearly states '…it must be noted that success rates are of limited value when comparing centres…' and has done so for several years. The PR concludes that this statement is inaccurate. The Hewitt Fertility Centre website details success rates per embryo transfer and not embryo transferred. As 87% of	During the feedback session with the PR and centre staff, excerpts from the centre's website were shared and discussed, showing the absence of the information highlighted in this non compliance. At no time were the inspection team directed to the information at other locations. The executive acknowledges that recent checks of the centre's website indicated that the following sentence was present on the success rates page: 'It must be noted that success rates are of limited value when comparing centres and choosing where to seek treatment.'

		patients receive a single embryo transfer (as is detailed on the website for patient information), and guidance 4.8 only 'encourages' clinics to display data per 'embryo transferred' the PR did not view this information as a non-compliance. The website has now been updated to include success rates per 'embryo transferred'. Please refer to screen shots provided with this report.	No further action is required beyond the submission of the audit plan with corrective actions by 20 August 2021.

Responses from the Person Responsible to this inspection report

I am disappointed with the content of this report. I do not agree that this report, the detail of the findings in the body of this report, or the severity of the actions suggested, are a true reflection of the inspection or the compliance of our service. The report presented here is a misrepresentation of the inspection itself and the level of compliance within our service.

Routine licence renewal inspections allow time for the PR and the inspectors to discuss the possible non-compliances raised and consider the evidence available to reflect compliance before the draft report is issued. The desk based inspection of centre 0007 on 20.05.21 did not provide the PR with any/adequate time to discuss the non-compliances raised in this report with the inspectors. The Lead Inspector on the day of the inspection stated that they were happy with the evidence provided pre-inspection and that an on-site visit was not necessary.On reflection, reading this report, I object to that decision and believe an on-site inspection would have allowed me to provide evidence of compliance in several areas noted in this report. One major non-compliance in particular had never been discussed with me until reading this draft report, which I have never experienced in the 5 previous inspections I have been involved with as PR with three different clinic inspectors.

Below I have listed some detail that I believe should have been included in the description of the non-compliances raised to accurately reflect the findings and current practice at centre 0007:

Major non-compliance 3 Medicines Management:
I would like it noted that on the day of inspection the Clinical Inspector commented that the Lead Nurse had already identifed concerns with the CD book and had already initiated change to process. The current entries in the CD book had shown significant improvement.

Major non-compliance 4 QMS:
I was shocked to see this major non-compliance in this report. This had not been discussed with me prior to receiving this report. The suggested findings detailed in the body of this report (page 12) are factually incorrect. I believe this non-compliance should be revoked. Please see my response above.

Major non-compliance 5 Legal Parenthood:
I acknowledge that improvements need to be made regarding the appropriate use of the PBR form, however I think it is important that it is noted in the body of this report that valid consent to legal parenthood was in place for all patients. The consent process and consent check that takes place is thorough and effective. The only gap in this process was that clinic staff did not highlight and remove unnecessary forms that had been completed.

Major non-compliance 7 Success Rates:
I acknowlege that improvements could be made with the clinic success rates, however the action required does not ackowledge the ongoing communication between myself and the clinics inspector who is already aware of our focused work over the last 6 months to tackle this. I request that the Lead Inspector for this inspection liaises with our clinic inspector to confirm if they are in agreement with my response detailed above. An independent review can be commissioned if still appropriate in March/April 2022, following further review of clinical outcomes.

Other non-compliance 8 Website:
One of the two findings listed in the body of this report is inaccurate. The centre website does state that the information on success rates is of limited value when comparing centres.

R Gregoire HFEA Person Responsible for centre 0007
30.07.2021

The inspection team thanks the PR for the comments provided in the body of the report and in this section 'the response from the PR to this inspection report'.

The executive is saddened by the PR's disappointment at the content of the inspection report findings but notes there are a number of areas where the executive is unable to reconcile our perception of the inspection process and its findings, with comments made by the PR within the report. The executive will continue to liaise with the PR regarding the inspection findings but is confident those findings are correct and of the evidence base to support them.

The executive thanks the PR and her team for their work supporting the inspection process and wishes the centre every success for the future.