Executive Licensing Panel Minutes

Centre 0196 (Jessop Fertility)

Renewal Inspection Report

Date:	29 June 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Richard Sydee (Chair) Yvonne Akinmodun Kathleen Sarsfield- Watson	Director of Finance and Resources Head of Human Resources 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 Jessop Fertility is located in Sheffield and has held a licence with the HFEA since 2001. The centre provides a full range of fertility services.

1.3. The panel noted that, in the 12 months to 31 March 2021, the centre provided 637 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers during 2020.

1.4. The panel noted that HFEA register data for the period 1 January 2020 to 31 December 2020 shows the centre's success rates for IVF and ICSI are in line with the national averages.

1.5. The panel noted that, in 2020, the centre reported 95 cycle of partner insemination, with nineteen pregnancies. This represents a clinical pregnancy rate of 20%, which is comparable to the national average.

1.6. The panel noted that HFEA register data between 1 January 2020 and 31 December 2020, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is likely to be statistically lower than the 10% multiple live birth rate target for this period.

1.7. The panel noted that the centre followed professional body guidance to suspend all non-essential treatments in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services.

1.8. The panel noted that the centre was due a renewal of licence inspection during the period of suspension of fertility treatments due to Covid-19. In June 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. The centre's current licence was issued for a period of four years, and following the grant of the licence variation the licence duration was extended to five years.

1.9. The panel noted that, the centre's interim inspection occurred in May 2018 and a renewal inspection was scheduled to be undertaken by May 2021. However, due to the Covid-19 pandemic, a Desk Based Assessment and Risk Based Approach (DBA/RBA), was conducted. Following this, it was established that any items of concern identified were of relatively low risk and could be reviewed effectively using virtual technology, rather than an on-site inspection. This process 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.

1.10. The panel noted that following a DBA, a virtual inspection was conducted on 13 April 2021, which included videoconferencing with key members of staff.

1.11. The panel noted that, at the time of the inspection, there were four major areas of non-compliance concerning payment for donors, medicines management, pre-operative assessment and the surgical pathway and the storage of gametes and embryos. There was also one 'other' non-compliance regarding the Quality Management System (QMS). Since the virtual inspection, the PR has given a commitment to fully implementing all the recommendations made in the report.

1.12. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients. The inspector will continue to monitor the centre's performance and the implementation of the report's recommendations within the required timescales.

1.13. The panel noted that the centre is well led and provides a good level of patient support.

1.14. The panel noted that, as a result of the UK's departure from the European Union (EU) a relicensing exercise is currently under way. This follows approval by the Licence Committee of a variation without application on 4 March 2021. This means that new offer licences are being sent to all clinics, incorporating changes to some of the standard licence conditions. The varied licences will all come into effect on 1 July 2021, after the transition period ends on 30 June 2021.

1.15. The panel noted that this renewal is being considered during that relicensing period. However, since this renewal licence (if approved) will begin on 1 October 2021, which is after 1 July 2021, the renewal licence will simply follow on in the normal way from the centre's current active licence, which by that date will be the new, varied, licence.

1.16. 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 in the report being implemented in the prescribed timescales.

1.17. 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 particularly noted the non-compliance concerning payment for donors, acknowledging that the import of embryos from Sweden, which were created with donor eggs, would be considered at the Statutory Approvals Committee (SAC) on 29 July 2021; a Special Direction will be requested to simultaneously export the embryos to Sweden and re-import them to the United Kingdom. The panel was satisfied that the audit of imports and summary report would be submitted to the inspectorate by 13 October 2021.

2.5. The panel also noted that outstanding actions, regarding the non-compliances related to medicines management, pre-operative assessment and the surgical pathway, alongside storage of gametes and embryos, are due for receipt by 13 July 2021; the panel requested

confirmation, in due course, from the inspectorate that all the required documentation had been submitted and was satisfactory.

2.6. 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 the report being implemented within the prescribed timescales. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

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

3. Chair's signature

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

Signature

Name

Richard Sydee

Date

5 July 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: 13 April 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 desk-based assessment, videoconference meeting 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 May 2018; therefore an on-site inspection should usually be conducted by May 2020. 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 DBA followed by a virtual inspection, which included videoconferencing with key members of centre staff.

Inspectors: Nicola Lawrence (lead), Sara Parlett and Sandrine Oakes.

Date of Executive Licensing Panel: 29 June 2021

Centre name	Jessop Fertility
Centre number	0196
Licence number	L/0196/9/d
Centre address	Sheffield Teaching Hospitals NHS Foundation Trust, Jessop Wing, Tree Root Walk, Sheffield, S10 2SF, United Kingdom
Person Responsible	Dr Helen Clarke
Licence Holder	Sheffield Teaching Hospitals NHS Foundation Trust
Date licence issued	1 October 2016
Licence expiry date	30 September 2021
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Jessop Fertility is located in Sheffield and has held a licence with the HFEA since 2001. The centre provides a full range of fertility services.

The centre provided 637 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2021. In relation to activity levels this is a medium sized centre.

The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers during 2020.

The centre was due a renewal of licence inspection during the period of suspension of fertility treatments. In June 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. The centre's current licence was issued for a period of four years, and following the grant of the licence variation, the centre's licence duration was extended to five years. The centre also varied their licence in September 2018 to reflect a change in the activities of the centre to include embryo testing and in October 2019 to reflect a change of PR.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 January 2020 to 31 December 2020 show the centre's success rates are in line with national averages.

In 2020 the centre reported 95 cycles of partner insemination with 19 pregnancies. This represents a clinical pregnancy rate of 20%, which is in line with the national average.

Multiple births[2]

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

Between 1 January 2020 and 31 December 2020, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is likely to be statistically 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 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 (with the exceptions noted in this report);
- 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 this report makes recommendations for improvement in relation to four major areas of non compliance and one 'other' area of non compliance.

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

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 sedation practices at the centre are compliant with professional guidance and best practice requirements and ensure that learning from guidance provided by the HFEA and/or other sources is implemented.
- The PR must ensure that there is effective consent to storage for all cryopreserved gametes and embryos.

'Other' area that requires improvement:

- The PR should ensure that the Quality Management System (QMS) is robust and fit for purpose.

Recommendation to the Executive Licensing Panel

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

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 (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 0196 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

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

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are 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 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 0001)
The centre imported four embryos created with donor eggs from Sweden in December 2020. Information was provided following the inspection that the donor was compensated the national rate of an equivalent of approximately £476, which is calculated by the Swedish health service as being reasonable compensation whilst maintaining the altruistic status of the donor. Excess expenses were not claimed by the donor. Additional information provided stated that Swedish law dictates that gamete donation be altruistic.

The inspection team acknowledges that this approach appears consistent with the UK's fundamental principle that donation must be altruistic in nature. However, the inspection team considers that the information provided by the PR demonstrates that the donor was compensated a flat fee irrespective of whether she actually incurred any expenses or loss of earnings. This is not compliant with General Direction 0001, and therefore the import of these embryos was not compliant with General Direction 0006.

The PR was not aware that requirements for compensating overseas donors is different to the requirements for compensating UK donors, which was highlighted in Clinic Focus articles in May 2018 and September 2020.

With respect to the import of embryos from Sweden which were created with donor eggs, the executive has taken account of the likely impact on patients were they to be prevented from using the embryos. The executive therefore recommends that, to regularise the status of those embryos and enable their lawful use in the UK, the PR be directed to make a simultaneous application to export those embryos to Sweden and re-import them into the UK before any of those embryos can lawfully be used in treatment in the UK.

General Direction 0001, paragraphs 12 and 13.

General Direction 0006 (version 7 in place at the time of the import)

Clinic Focus May 2018, September 2020.

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third-party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be 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)
It is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively. The centre has policies and procedures in place that are partially

compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway.

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; and
- 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, with the exception noted under the section 'Payments for donors' above.

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 this requirement of General Direction 0006 in relation to these requirements.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements, with the exception noted under the section 'Quality management system' below. 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 establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services. The centre has a QMS that is broadly compliant with HFEA requirements.

Third party agreements (Guidance note 24)
The centre's third-party agreements, including those associated with ITE/TCS import certificates, are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage 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/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

Medicines management (Guidance Note 25)
As part of the DBA process the centre was requested to submit six pages of their controlled drug (CD) register. In those six pages (numbers 46-51) the following issues were noted:

- In several entries, the name and strength of the drug is recorded at the top of the page as Fentanyl 100mcg/2mls. However, several anomalies were noted:
    - Two entries recorded the amount of drug given as 100mg (milligrams) instead of 100mcg (micrograms);
    - One entry recorded the amount of drug given as 50mg instead of 50mcg.
    - One entry recorded the amount of drug given as 50mg instead of 50mcg and 50mcg wasted.
    - One entry did not record the strength of the drug given and wasted.
    - One entry recorded the amount given but it was illegible.
- In one entry, the amount given was not recorded but was signed and witnessed.
- In one entry, the amount given was not signed by the practitioner who gave the drug.
- In several entries, the carry-over of stock is not documented.
- In two entries, the 'amount given' was recorded in the signature column and the signature of the practitioner has been recorded in the 'amount given' column.

Additionally, the centre is using a CD register which does not have space to record two patient identifiers and does not have a section to document the supply, administration and discard of a CD, which is a best practice requirement.

The inspection team noted that the centre's audit of medicines did not cover the time period of the pages of the CD register reviewed as part of the DBA and is assured that these would have been identified by the centre at the time of the next audit which is due after May 2021.

See recommendation 2.

SLC T2.

The Misuse of Drugs Regulations 2001.

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'.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre uses a care model in which a nurse administers sedation under the supervision of a clinician. It is therefore essential that these staff members are trained as per 'Safe sedation practice for healthcare procedures' professional guidance. It is

expected that any deviation to professional guidance should be risk-assessed and the rationale for not following professional guidance is clearly documented.

Staff stated they follow the NHS Trust sedation policy and have received Basic Life Support (BLS) training but were not aware of any other specific requirements related to sedation practices training and were unable to demonstrate that they had received formal accredited competency-based training. The Trust sedation policy was requested but not provided.

The inspection acknowledges that training in BLS is in line with professional Academy of Medical Royal Colleges (AoMRC) guidance recently published on 25 February 2021. The inspection team would like to clarify that this AoMRC update does not replace the 2013 publication, which indicates 'Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended'. Therefore, the PR should reassure herself that all practitioners involved in sedation practices are able to rescue patients whose level of sedation becomes deeper than initially intended.

The centre has also not implemented learning issued by the HFEA in September 2019 and January 2021 on 'Safe sedation practice for healthcare procedures' with regards to training requirements for all practitioners involved in sedation techniques.

Whilst these findings demonstrate that sedation practices are not in line with best practice, the inspection team considered that there does not appear to be a direct risk to patients because the centre is situated within an NHS Trust where a dedicated resuscitation team is available. No patient incidents relating to sedation have occurred at the centre. In addition, staff sedation practices are observed annually via peer reviews.

See recommendation 3.

SLCs T2, T12.

AoMRC, Safe sedation practice for healthcare procedures - an update (February 2021)

AoMRC, Safe sedation practice for healthcare procedures - standards and guidance (October 2013) (pages 2, 9, 12, 24, 27, 35, 36)

Clinic Focus September 2019, January 2021.

Quality management system (QMS) (Guidance note 23)
The following issues were noted with the centre's QMS:

- Some of the centre's audits lacked robustness:
    - In the audit of ICSI operators a non-conformance was identified, and a corrective action listed, but the report stated that re-audit was not required. The inspection team considered that re-audit should have been planned to demonstrate that corrective actions implemented had been effective.
    - In the audit of consents for patients starting treatment, the inspection team considered that the root cause analysis was not robust enough as it did not identify the reason why consents were not being checked thoroughly. The inspection team considered that it is essential to understand the reasons why

the issues have been identified before determining appropriate corrective and/or preventative actions.
    - In the audit of traceability of products used in the laboratory, a check was not included that documented whether the media/consumables being used are accurately recorded as in use on the centre's electronic record system (IDEAS). The inspection team considered that this audit does not provide assurance of the robustness of the centre's traceability systems.
- In two of the centre's audits (embryo donation & surrogacy), non-conformances were identified but there were no corrective actions documented
- In the audit of gametes and embryos in storage beyond the statutory storage period (see 'Storage of gametes and embryos' section of this report), corrective actions did not include a review of the cases identified where valid Medical Practitioners Statements (MPS) were not in place.
- Timeframes for implementation of corrective action are not documented.
- The centre's most recent version of their standard operating procedure (SOP) for host surrogacy (revised November 2019) does not reference Department of Health and Social Care (DHSC) guidance which was issued in February 2018; 'Care in Surrogacy: Guidance for the care of surrogates and intended parents in surrogate births in England and Wales', and 'The Surrogacy Pathway; surrogacy and the legal process for intended parents and surrogates in England and Wales'. The HFEA also published guidance via Clinic Focus in September 2018 and March 2021.
- The centre's process for implementing learning from HFEA guidance does not appear to be effective because, in addition to the issues already noted in relation to surrogacy above, the centre has not incorporated guidance into their practices and policies in relation to payment for donors (Clinic Focus May 2018 and September 2020), medicines management (Clinic Focus February 2020) and extension of storage (Clinic Focus September 2018)

See recommendation 5.

SLCs T32, T36.

CoP 23.27 and 23.28.

Clinic Focus May 2018, September 2018, February 2020, September 2020, March 2021.

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 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. Only one patient has provided feedback in the last 12 months, giving a 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 is 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 patient survey results were reviewed. The centre is currently collating the data for 2020, so the inspection team reviewed patient feedback provided in 2019. A total of 238 patients provided feedback to the centre, the majority of which was positive.

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 sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

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

Surrogacy (Guidance note 14)
It is important to protect the surrogate and any children born as a result of the treatment. The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements with the exceptions noted in the 'QMS' section of this report.

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 / 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)
It is important that patients and donors have provided all relevant consents before carrying out any licensed activity. The centre's procedures for obtaining consent are compliant with HFEA requirements with the exception noted in the 'QMS' section of this report

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 last 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

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)

It is important that the gametes and embryos are stored appropriately to maintain their quality and safety and that 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.

The centre's procedures for storing gametes and embryos are partially compliant with HFEA requirements.

What the centre could do better

Storage of gametes and embryos (Guidance note 17)

The centre's audit of stored gametes and embryos in storage beyond the statutory storage period was reviewed as part of the DBA. The centre identified that four patients had extended storage beyond the statutory storage period of ten years but did not have a valid Medical Practitioners Statement (MPS) signed within the 'relevant period'. The MPS confirms that the patient or their partner has met the medical criteria for premature infertility and is required in order to satisfy the requirements of the Human Fertilisation and

Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 to permit extension of storage beyond the statutory storage period.

Following discussions with the PR, the inspection team is assured that a robust system is now in place to ensure MPSs are documented within the relevant period in order to ensure compliance with the relevant requirements.

See recommendation 4.

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009.

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 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 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 has not received any risk tool alerts relating to success rates in the last two years.

Areas of practice requiring action

The section sets out matters which the inspection team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, General Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical 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 partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. Payments for donors The centre imported four embryos created with donor eggs from Sweden in December 2020. Information was provided following the inspection that the donor was compensated the national rate of an equivalent of approximately £476, which is calculated by the Swedish health service as being reasonable compensation whilst maintaining the altruistic status of the donor. Excess expenses were not claimed by the donor. Additional	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 review the centre's procedures to ensure compliance with General Direction 0001 and General 0006(GB), in particular with respect to compensation given to donors of gametes or embryos created with donated gametes procured outside the UK and then imported into the UK.	The following measures are underway: • preparation of Special Directions to virtually export and import embryos to and from Sweden • preparation of new checklist for imported or exported gametes/embryos • review and update of SOP for import/export of gametes and embryos, with a subsequent report for submission to HFEA	The executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required.

information provided stated that Swedish law dictates that gamete donation be altruistic. The inspection team acknowledges that this approach appears consistent with the UK's fundamental principle that donation must be altruistic in nature. However, the inspection team considers that the information provided by the PR demonstrates that the donor was compensated a flat fee irrespective of whether she actually incurred any expenses or loss of earnings. This is not compliant with General Direction 0001, and therefore the import of these embryos was not compliant with General Direction 0006. The PR was not aware that requirements for compensating overseas donors is different to the requirements for compensating UK donors, which was highlighted in Clinic Focus articles in May 2018 and September 2020.	The PR should provide a summary report of this review, including but not limited to corrective actions taken to address the inspection findings, confirmation that the PR fully understands the requirements, staff training that has been identified and/or provided, to the centre's inspector by 13 July 2021. With respect to the import of embryos from Sweden which were created with donor eggs, the PR should apply to the HFEA for a Special Direction to simultaneously export those embryos to Sweden and re-import them into the UK before any of the embryos can lawfully be used in treatment in the UK. The PR should provide an update on progress with this when responding to the report. The PR should audit all other imports since the last inspection in May 2018 to confirm if they are compliant with General Direction 0001	• audit of other imports of gametes/embryos since May 2018	

With respect to the import of embryos from Sweden which were created with donor eggs, the executive has taken account of the likely impact on patients were they to be prevented from using the embryos. The executive therefore recommends that, to regularise the status of those embryos and enable their lawful use in the UK, the PR be directed to make a simultaneous application to export those embryos to Sweden and re-import them into the UK before any of those embryos can lawfully be used in treatment in the UK. General Direction 0001, paragraphs 12 and 13. General Direction 0006. (version 7 in place at the time of the import) Clinic Focus May 2018, September 2020.	and General Direction 0006. A summary report of this audit should be provided to the centre's inspector by 13 October 2021.		
2. Medicines management	The PR should ensure that medicines management	• New "theatres CD book" has been introduced	The executive acknowledges the PR's response and

Several issues related to medicines management were noted by the inspection team. These are described in the main body of the report. SLC T2. The Misuse of Drugs Regulations 2001. 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'.	practices are compliant with regulatory and best practice requirements. The PR should review medicines management practices and procedures including staff training requirements. The PR should 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 13 July 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 13 October 2021.	which includes extra columns as outlined in this report • Further staff training planned • Review and update of medicines management SOP planned • Further audit planned for July 2021	commitment to implementing this recommendation. Further action required.
3. Pre-operative assessment and the surgical pathway	The PR should ensure that sedation practices at the centre are compliant with professional guidance and	Centre sedation practices are subject to Trust (and therefore CQC) and professional guidance.	The executive notes the PR's response.

Several issues related to sedation practice and procedures were noted by the inspection team. These are described in the main body of the report. SLCs T2, T12. AoMRC, Safe sedation practice for healthcare procedures - an update (February 2021). AoMRC, Safe sedation practice for healthcare procedures - standards and guidance (October 2013) (pages 2, 9, 12, 24, 27, 35, 36). Clinic Focus September 2019, January 2021.	best practice requirements and ensure that learning from guidance provided by the HFEA and/or other sources is implemented. The PR should ensure that adequate clinical supervision by fully trained staff is in place at all times. The PR should provide evidence that either all relevant staff involved in sedation techniques are able to demonstrate formal competency training in sedation practice (including assessing the level of life support training relevant to their practice) or provide the rationale for any deviations from the relevant HFEA and professional guidance, by 13 July 2021. The PR should review sedation practices in relation to the non-compliance identified during the inspection, including a root cause analysis into the circumstances which led to the failure to identify safe sedation practices training	There is a current Trust Sedation Policy (which can be provided on request) but it is in the process of being reviewed alongside current professional guidance. One of our consultants is involved in development of the new Trust policy and it is expected to be rolled out, alongside Trust training, in the near future. In the meantime all staff administering mild sedation are fully I-V trained and attend annual mandatory resuscitation training. Any patient identified as potentially being adversely susceptible to sedation have their procedure carried out in main hospital theatres with an anaesthetist present. There has not been a sedation-related incident in our clinic since we opened 20 years ago and there is an ALS-trained crash team available 24/7 if required.	Evidence of competency assessment in sedation practice and a summary report of the root cause analysis required by 13 July 2021. Further action required.

	requirements and conduct a risk-assessment against the AoMRC professional guidance. A summary report of the root cause analysis, findings of this review, including timescales for implementation of corrective actions identified, staff training requirements, should be provided to the centre's inspector by 13 July 2021. Three months after this review the PR should audit sedation practices to ensure that corrective actions implemented have been effective in achieving and maintaining compliance. An audit report should be provided to the centre's inspector by 13 October 2021.		
4. Storage of gametes and embryos The centre's audit of stored gametes and embryos in storage beyond the statutory storage period was reviewed as part of the DBA. The centre identified that four patients	The PR must ensure that there is effective consent to storage for all cryopreserved gametes and embryos. The PR should provide a report for the four patients for whom material is in store without appropriate records to	All patients with gametes and embryos in storage were reviewed last year and this is how the four patients were identified. The 4 patients' notes are currently being reviewed:	The executive acknowledges the PR's response and commitment to implementing this recommendation. The executive awaits receipt of details of the outcomes for patients one and three due by 13 July 2021.

had extended storage beyond the statutory storage period of ten years but did not have a valid Medical Practitioners Statement (MPS) signed within the 'relevant period'. The MPS confirms that the patient or their partner has met the medical criteria for premature infertility and is required in order to satisfy the requirements of the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 to permit extension of storage beyond the statutory storage period. Following discussions with the PR, the inspection team is assured that a robust system is now in place to ensure MPSs are documented within the relevant period in order to ensure compliance with the relevant requirements. It is noted that the HFEA's assessment framework recommends classification of this non compliance as 'critical' however in	support lawful storage including, for each sample, a summary of the consent documents available and an explanation why storage is likely to be unlawful. The review should also include any other medical notes/records that may relate to a statement of premature infertility during the relevant period. The PR should provide an update on progress with this when responding to the report. In the cases where there has been a failure to comply with the statutory storage regulations, the PR must seek independent legal advice from a legal representative conversant with the HF&E Act 1990 (as amended), the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009, and The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020, on how to proceed.	Patient 1: has been contacted and is considering withdrawing consent. If they would like to continue storage then their notes will be further reviewed and legal advice sought if needed. Patient 2: has withdrawn consent. Patient 3: would like to withdraw consent. Awaiting receipt of WC form. Patient 4: there is evidence in the patient's notes that the patient was prematurely infertile during the period 14-1-13 to 17-7-16 not covered by MPS. Independent specialist legal advice will be sought if required.	Further action required.

consideration that the centre had identified this issue in their audit of all stored samples with extended storage and as a result have made changes to their processes to ensure that this issue will not reoccur, this has been graded as a major non compliance. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 Paragraph 4.	Legal advice should guide the development of a documented action plan, with timescales for implementation, to ensure all samples are lawfully stored. If lawful storage cannot be assured or reconciled, actions must be taken to advise the gamete providers of the situation and of the options available to them. The PR should provide an update on progress with this when responding to the report. It is expected that the PR will provide a copy of the requested action plan to the centre's inspector by 13 July 2021.		

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
5. Quality management system (QMS) Several issues related to the QMS were noted by the inspection team. These are described in the main body of the report. SLCs T32, T36. CoP 23.27 and 23.28. Clinic Focus May 2018, September 2018, February 2020, September 2020, March 2021.	The PR should ensure that the QMS is robust and fit for purpose. The PR must ensure that all audit findings are investigated thoroughly, and effective corrective and preventive actions to address the issues identified are documented and implemented. The PR should conduct a review of the centre's QMS including, but not limited to, the issues identified in this report. A summary report of this review should be provided to the centre's inspector by 13 July 2021. The PR should ensure all relevant guidance issued from	The QMS is in the process of review. The audit report form template has been redesigned to include more space to document findings, corrective actions, root cause analysis, re-audit details and time frames for the above. For some audits, corrective actions were carried out but not documented fully in the audit reports. The new version of the audit report form should address this issue. The PR will ensure all relevant guidance is disseminated to the team as required.	The executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required.

	the HFEA and other bodies is incorporated into centre practice. A revised copy of the centre's surrogacy SOP should be provided to the centre's inspector by 13 July 2021.	The surrogacy SOP and patient information are being reviewed to address the issue raised in this report.	

Reponses from the Person Responsible to this inspection report