Executive Licensing Panel Minutes

Centre 0324 (City Fertility)

Renewal Inspection Report

Date:	19 October 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Anna Coundley Kathleen Sarsfield-Watson	Director of Strategy and Corporate Affairs Policy Manager Communications Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood Victoria Askew Ana Hallgarten	Licensing Manager Policy Manager Scientific Policy Officer (Induction)

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 City Fertility is located in London and has held a treatment (including embryo testing) and storage licence with the HFEA since 2012. The centre provides a full range of fertility treatment service. Other licensed activities at the centre include the storage of gametes and embryos.

1.3. The panel noted that, in the 12 months to 31 March 2021, the centre provided 293 cycles of treatment (excluding partner intrauterine insemination). In relation to activity, this is a small sized centre. The Covid-19 pandemic has reduced treatment activity at this centre.

1.4. The panel noted that, HFEA register data, for the period March 2020 to February 2021, show 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 17 cycles of partner insemination, with one pregnancy. This represents a clinical pregnancy rate which is comparable to the national average.

1.6. The panel noted that HFEA data, between March 2020 and March 2021 (as confirmed by the Inspector; the report incorrectly states between March 2020 and February 2020), show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%. This represents performance that is not likely to be statistically different from 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 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.

1.10. The panel noted that the centre was due a renewal inspection, in 2020, during the Covid-19 pandemic. In July 2020, the Person Responsible (PR) applied for a variation to extend the centre's licence, by one year; this was granted by the Executive Licensing Panel (ELP) in August 2020, thereby extending the licence duration to five years.

1.11. The panel noted that the centre was last inspected in September 2018; an on-site inspection should have been conducted by July 2021. However, a significant DBA was undertaken for this clinic, followed by video-conferences with centre staff to clarify areas of concern. Following the

DBA, a RBA of outstanding areas, to review any remaining concerns, was conducted; this indicated that an inspector should visit the centre for one day to address these matters. This shortened onsite inspection visit minimised the risk to patients and staff, but enabled the inspection team to finalise evidence collection, thereby ensuring the compliance of the centre.

1.12. The panel noted that following the DBA/RBA, the onsite inspection of the centre was conducted on 23 June 2021.

1.13. The panel noted that, at time of the inspection, there were three major areas of non-compliance regarding the Quality Management System (QMS), adverse incidents and staff. There were also four 'other' areas of non-compliance concerning imports and exports, third party agreements, information and record keeping and document control. Since the inspection, the PR has provided evidence that the recommendations concerning staff and third party agreements have been fully implemented. The PR had provided evidence that actions have been taken to implement the recommendations regarding the QMS, adverse incidents, imports and exports, information and record keeping and document control, committing, where required, to audit the effectiveness of those actions within the required timescales.

1.14. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices and the PR is encouraged to ensure that the QMS is used to best effect to monitor and improve their success rates and the quality of the service offered to patients.

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

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 urged the new PR to work closely with the HFEA inspectorate to ensure that the QMS is used to best effect to monitor and improve the centre's success rates and the quality of the service offered to patients.

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

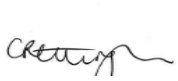
conditions, subject to the recommendations made in the report being implemented within the prescribed timescales. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

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

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

25 October 2021

Renewal Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors.

The 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 Licence Committee 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: 23 June 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 September 2018; therefore, an on-site inspection should usually be conducted by July 2021. A significant DBA was undertaken for this clinic, followed by video-conferences with centre staff to clarify areas of concern. RBA of outstanding areas to review and remaining concerns after the DBA indicated that an inspector should visit the centre for one day to address these matters. This reduced on-site inspection activity thus minimising the risk of onsite inspection to patients and staff but allowed the inspection team to finalise evidence collection to ensure the compliance of the centre.

Inspectors: Grace Lyndon (lead), Andy Leonard and Nicola Lawrence

Date of Executive Licensing Panel: 19 October 2021

Centre name	City Fertility
Centre number	0324
Licence number	L/0324/3/d
Centre address	16, St John Street, London, EC1M 4NT, United Kingdom
Person Responsible	Dr Malini Uppal
Licence Holder	Mr Matej Stejskal
Date licence issued	29 November 2016
Licence expiry date	28 November 2021
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

City Fertility is located in London and has held a 'Treatment (including embryo testing) and Storage' licence with the HFEA since 2012. The centre provides a full range of fertility treatment service. Other licensed activities at the centre include the storage of gametes and embryos.

The centre provided 293 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2021 In relation to activity levels this is a small centre, though the Covid-19 pandemic has reduced treatment activity at the centre.

The centre's last on-site inspection was undertaken on 20 September 2018 as an interim inspection. The licensing panel which considered the inspection report agreed to the continuance of the centre's licence.

The centre was due a renewal of licence inspection during the Covid-19 pandemic related suspension of fertility treatments in 2020. 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. 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.

This current licence was issued from 29 November 2016 and has been varied since the last on-site inspection to reflect the following changes:

- April 2021 – variation of licence to change the centre's PR.
- 4 March 2021 – All centres: Variation of all licences without application (European Union (EU) Exit requirements).
- 27 August 2020 – Extension of the four-year licence to a five-year term due to the Covid-19 pandemic preventing inspection of the centre

Pregnancy outcomes[1]

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

In 2020, the centre reported 17 cycles of partner insemination with one pregnancy, which is in line with the national average.

Multiple births[2]

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

Between March 2020 to February 2020 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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

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

Summary for licensing decision

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;
- 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 three major and four 'other' areas of non compliance.

Since the inspection visit the PR has provided evidence that the following recommendations have been fully implemented:

Major area of non compliance:

- The PR should ensure that staff are available in sufficient number and are suitably trained and competent to undertake their roles.

Other area of non compliance:

- The PR should ensure that all agreements with third parties meet the relevant HFEA requirements and guidance.

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

Major areas of non compliance:

- The PR should ensure that the centre's quality management system (QMS) is effective and robust to improve the quality and effectiveness of the service provided.
- The PR should ensure that all adverse incidents, including serious adverse events, reactions and near misses, are reported to the HFEA.

'Other' areas that requires improvement:

- The PR should ensure that donor compensation reports are provided to the centre for all gametes imported and that evidence is present for compliant compensation arrangements before imports are undertaken under General Direction 0006(GB).
- The PR should ensure that the centre's website is compliant with guidance.
- The PR should ensure that the staff member who verifies a patient's identity is documented in the patient's records.

Recommendation to the Executive Licensing Panel

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

The inspection team notes the centre's success rates are comparable to the national averages and their multiple clinical pregnancy/ live birth rates meet the target. Some improvement is required in order for the centre to demonstrate the suitability of their practices. The PR should ensure that the QMS is used to best effect to monitor and improve the centre's compliance and their success rates so as to improve the quality of the service offered 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 0324 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 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.

The issues reported in 'Quality Management System (QMS)' below related to donor standard operating procedures (SOP) have not impacted on the compliance of donor recruitment, in significant part because such activity at the centre is very limited.

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

Donor assisted conception (Guidance note 20)

It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

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

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

Suitable premises and suitable practices

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

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are 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 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 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 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 compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is a sterile liquid soybean and egg yolk-based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable. Written information provided to patients offered intralipid therapy is compliant with guidance.

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 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 and embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the contamination risk 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 broadly compliant with HFEA requirements.

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. The centre has been allocated an ITE import certificate and imports of gametes and embryos from TCSs outside the EU/EEA have been made, all from TCSs listed on the ITE import certificate. The centre is therefore compliant with the relevant requirements for ITE import certification in General Direction 0006.

Traceability (Guidance note 19)

The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;

- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is partially compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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

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

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

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are partially compliant with HFEA requirements. The centre reports some 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

Imports and exports (Guidance note 16; General Direction 0006)
For two imported donor sperm samples, reports were not available of the total compensation provided to each donor during their course of donation for loss of earnings and, separately, for reasonable expenses connected with their donation visits. To evidence compliant compensation, the centre could only provide an import agreement which discussed payments 'up to £35 per visit'. This provided no reassurance of

compliance with the £250 limit on compensation for loss of earnings per course of donation.

General Direction (GD) 0001, paragraphs 12 and 13; recommendation 4.

Imports can only be undertaken under GD 0006(GB) if all requirements within it are met, one of which (paragraph 3h) requires that 'no money or other benefit has been given or received in respect of the supply of the gametes or embryos unless the money or benefit paid or received is in accordance with GD 0001 (Gamete and embryo donation)'. For the two donor sperm samples imported, the centre's evidence to support the imports' compliance with the requirements of GD 0006(GB), paragraph 3h, is lacking and it is questionable whether the imports should have been made using the authorisation of GD 0006(GB).

GD 0006, paragraph 3(h); recommendation 4.

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

- The centre's standard operating procedures (SOP) are in some cases not subject to rigorous document review to ensure they remain compliant with requirements and best practice guidance. For example, the SOP for medicines management (version 9) references the UKCC as the professional regulator for nurses and midwives in the UK. The UKCC was replaced by its successor body, the Nursing and Midwifery Council (NMC) in April 2002. In addition, the SOP states that the centre's doctors have access to the controlled drug keys, which is not compliant with regulatory requirements. When staff were questioned about this, they stated that only nurses have access to the CD keys. The SOP was last reviewed in April 2021, but these errors were not addressed. A second example involves the egg, sperm and embryo donor selection SOPs, which are out of date, referencing: a need for the laboratories used for screening tests to be CPA (UK) accredited, whereas the current requirement is for accreditation by UKAS; a recommended age limit for sperm donors of 40 years whereas the limit is now 45 years; and allowing frozen oocytes to be used within three months of procurement without retesting, whereas the requirements are now for frozen oocytes, the donors of which have been tested serologically and using nucleic acid testing (NAT), to be quarantined for 3 months and the donors then retested before release for use in treatment.
- Non conformances in audits are not always clearly documented.
- Corrective and preventative actions are not always documented. For example, it was noted in a centre audit that in one patient's records, a COVID-19 triage form and emergency contact numbers were not present; no corrective and preventative actions were documented.
- The implementation of corrective and preventative actions is not routinely documented (e.g. record keeping audits) so it is unclear if the actions have been completed and non conformances have been addressed.
- Quality indictors (QIs) are not always clearly documented, nor are they reviewed when audits are undertaken to verify if the QIs are being met or not, and whether corrective and preventative actions are necessary to improve processes. For example the centre monitors success rates as QIs, and has set quality objectives for success rates, but has taken no actions to address success rate QIs being below the set objectives.

SLCs T32, T33b, T35, T36; See recommendation 1

Third party agreements (Guidance note 24)
It was noted during the DBA of documents provided by the centre that, in two out of five third party agreements, the date that the third-party agreements should be reviewed by was not documented.

SLC T114; See recommendation 5.

Adverse incidents (Guidance note 27)
The centre has not reported two adverse incidents to the HFEA, contrary to GD 0011. The centre has investigated the incidents, but the inspection team did not consider that the investigations were sufficiently detailed.

The SOP to guide staff on reporting incidents to the HFEA does not including the type of adverse incidents which are required to be reported to the HFEA, the time frame in which the incidents need to be reported, or which staff member is responsible for reporting incidents to the HFEA.

GD0011, SLCs T118, T120 and T121; See recommendation 2.

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 medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

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

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

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

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

What the centre could do better

Staff (Guidance note 2)
The centre has also not carried out a work force assessment in the last two years to ensure that appropriate staffing resources are available for the activity undertaken.

The centre is operating with only one GMC registered clinician, which carries risks for the continuity of patient care. A contingency arrangement with another GMC registered clinician has been developed, but the efficacy of this arrangement is open to question as the clinician is employed in an NHS hospital and therefore may not be available to provide care at the centre if requested.

The competence assessment framework for laboratory staff is generally robust but does not cover certain processes which are less frequently used, for example oocyte vitrification and thaw, assisted hatching, surgical sperm recovery and import and export of gametes and embryos.

SLCs T12 and T15a; See recommendation 3.

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 nine patients have provided feedback in the last 12 months, giving an average four-star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.

The 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. Several patients provided individual comments to the HFEA complimenting the nice friendly staff at the clinic.

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

The inspection was undertaken via video conferencing and an onsite inspection. No patients were available to speak to inspectors during this visit.

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

- provides a clean and well organised environment for patient treatment.
- has staff who are supportive and professional.

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 consents to treatment and legal parenthood.

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The centre's does not undertake egg sharing arrangements; therefore this area of practice was not reviewed during the DBA or physical inspection.

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
A review of the centre's website indicated that it contained:

- The data relating to activity, pregnancy rates and live birth rates are more than three years old;
- The live birth rate per embryo transferred is not given;
- The national success rates are not provided, nor is data analysed by maternal age or treatment type;
- The information does not state clearly that information on success rates is of limited value in comparing centres and choosing where to seek treatment, nor is there a link to the HFEA's advice on choosing a clinic: www.hfea.gov.uk/choose-a-clinic/learn-about-choosing-a-clinic/

CoP 4.8; See recommendation 6.

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

What the centre does well

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

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

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At that inspection in September 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. Five 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.

The HFEA Register is a rich source of information about treatment using assisted reproductive technologies (ART). It can be used by researchers and linked to other health registers, to improve knowledge about the health of patients who have undergone ART and those born following ART treatment. The HFEA is permitted to disclose non-identifying information to researchers but can only provide patient identifying information with the consent of the patient. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA. The centre's procedures for doing this ensure that the HFEA holds an accurate record of such consent, so that it only releases patient identifying information to researchers, when consent has been provided.

It is noted that the centre has experienced significant difficulties for some time in submitting data to the HFEA register via the electronic data interface. These difficulties have led to some issues regarding data submission and accuracy, which the centre is working with the HFEA to address. The PR is urged to continue to monitor the patient consents to ensure their consent to disclosure is accurately recorded.

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)

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

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)

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

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

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are broadly compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are broadly 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 some evidence of problems with the timeliness of the centre's submission of data to the Register: 7% (7/104) of the IVF and 22% (2/9) of the DI treatments reviewed at inspection had not been reported to the HFEA in line with General Direction 0005. Three treatments using unregistered donors are also present in the centre's register data.

The centre has been working with the HFEA Information Technology (IT) team for some time to address issues they are experiencing with the submission of data to the HFEA register via the Electronic Data Interface (EDI). These issues have prevented the clinic from submitted data for some time and the missing treatments and unregistered donors all occurred in this period of disrupted data submission.

This data submission issue will not be noted as a non compliance because it is resulting from the failure of the Electronic Data Interface, which is in greater part a HFEA responsibility. However, the HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

Because of these facts, the centre must continue to work with the HFEA to reinstate data submission and should address the missing treatments and unregistered donors, as a matter of urgency, as soon as it is able to submit data to the HFEA in an accurate and timely manner. It is hoped the implementation of the PRISM project in September 2021 will allow this.

What the centre could do better

Record keeping and document control (Guidance note 31)
The centre does not routinely document in patient records by whom a patient/donor has been reliably identified.

SLC T46; See recommendation 7.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2018, recommendations for improvement were made in relation to four areas of major non compliance and two 'other' areas of non compliance.

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

On-going monitoring of centre success rates

The centre received a risk tool alert in March 2021 relating to the centre's clinical pregnancy rates following IVF in patients aged over 38 years but the centre did not respond to the HFEA regarding this alert.

As reported in 'QMS', the centre has not responded to QI monitoring which showed that success rates are below the centre's quality objectives, i.e. the success rate limit below which the centre should be taking corrective and preventative actions.

Success rates appear low in some age-treatment groups in the centre's data but are not significantly varying from the national averages. The executive encourages the PR to continue to review and monitor success rates and to take action, if necessary, in accordance with SLC T35 (see recommendation 1).

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. QMS A number of non compliances were identified within the QMS, as discussed in detail in the body of the report. SLC T32, T33b, T35, T36.	The PR should ensure that the centre's QMS is effective and robust to improve the quality and effectiveness of the service provided in accordance with standard licence conditions and HFEA practice guidance. The PR should review the functioning of the QMS generally, and specifically to address the non compliances in SOP management, QI monitoring, audit and records of corrective and preventative actions, identified in this report. A summary report of	The PR believes that the centre's QMS is effective, robust and does improve the quality and effectiveness of our service in accordance with licence conditions and HFEA practice guidance. We would like to understand why QMS findings are a "Major" non-compliance, especially as there are factual inaccuracies in the report, as highlighted below. The QMS and the system we use was discussed, at length, during the DBA and the	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. This non compliance has been graded as a major in view of the inspection team's concerns of the number of issues noted in relation to the centre's QMS, as set out above this table. The PR indicated there are factual inaccuracies in the report, however it is not clear what the PR is referring to as

	this review should be provided to the centre's inspector by 30 September 2021. Evidence of the correction of the specific concerns identified within the QMS and discussed in detail with the centre staff and in this report, should also be provided to the centre's inspector by 30 September 2021.	remote inspection. We demonstrated to the inspector how the electronic QMS database works: document review and updates, audits,the CAPA plan, actions and implementation of those actions to ensure that the QMS functions to function effectively. Following the inspection, we confirmed the discussion with a follow up email to the centre's inspector, as follows: 1.QMS email box receives notification of documents to update, audits due and CAPA actions, further audits as the fall due by date. 2.These are actioned by QM by sending them to Heads of Depts, including QM 3.Actioned in time allocated and captured on CAPA 4.Any update required as a result of changes in law, guidance, Alerts, incident, complaints or audit learning, is added to CAPA and actioned in line with the QMS system.	no specific details have been provided. The PR has provided a summary report of her review of the QMS, and actions taken to address the inspection findings. The executive notes that the proposed actions include improving the recording of audit findings, making corrective and preventative actions (CAPA) identified clearer, ensuring completion of CAPA, and that a new audit template has been developed. The PR also confirmed that other documents, SOPs and QIs are to be reviewed. The timescales for completion of all actions are 31 December 2021. The PR provided a copy of the centre's SOP 'LABSOP28 Import and Export of Gametes and Embryos' issued on 27 September 2021. However, the executive notes that this SOP describes processes for compliance with version 8 of General Direction 0006(GB)

		5.The updated documents, audit finding and learning are shared and discussed at meetings (there was a gap in meetings last year due to Covid and staff being furloughed); meetings re-commenced in July 2021, and the QMS is working as we expect. Updates to documents and processes are discussed and agreed at team meeting and updates circulated to staff. This includes all HFEA updates. 6.All CAPA log actions are closed off when completed; re-audited, to ensure effectiveness of changes. 7.This is our system that our staff perfectly understand and work with it, providing reassurances for the management team. We do however, acknowledge that a more thorough review of documents are required; we identified this as an action and have an action plan to review all the QMS documents.	which in no longer in force. The centre's inspector will liaise with the PR to ensure this SOP is reviewed to reflect General Direction 0006(GB) version 9 which has been in force since 30 June 2021, and to ensure that centre's egg, sperm and embryo donor selection SOPs are also updated to address concerns noted during the inspection. **Further action is required.**

		With regard to the non-compliances stated for Medicines Management, this has been revised to reflect practice, in line with requirements, and submitted to the centre's inspector. Therefore, we do not accept the non-compliance reported here is a 'major'. Our current system already does what we are required to address to be a non-compliance. We are however, currently undertaking a complete review of our QMS, following the Covid-19 pandemic. We would welcome a discussion to explain our QMS system again, if required. We do not believe the action required is any more than what we are currently doing.	
2. Adverse incidents The centre has not reported two adverse incidents to the HFEA, contrary to GD 0011. The centre has investigated the incidents, but the	The PR should ensure that all adverse incidents, including serious adverse events, reactions and near misses, are reported to the HFEA in a timely manner.	The centre's newly appointed PR will ensure that all adverse incidents, including serious adverse events, reactions and near misses,	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation.

inspection team considered that the investigations were not sufficiently detailed. The SOP to guide staff on reporting incidents to the HFEA does not include the type of adverse incidents which are required to be reported to the HFEA, the time frame in which the incidents need to be reported, or which staff member is responsible for reporting incidents to the HFEA. GD0011, SLCs T118, T120 and T121.	The PR should review all adverse incidents in the centre's incident register since the time of the renewal inspection in June 2016 and retrospectively report to the HFEA any which fulfil the criteria of adverse incidents or near misses, as defined in GD0011. This recommendation should be implemented by 23 December 2021 and a report of the review provided to the centre's inspector on that date. Whilst it is recognised that the under-reporting of incidents is not intentional, the PR should review the centre's processes for submitting reports of and investigating adverse incidents. A summary of the findings of this review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 23 December 2021.	are reported to the HFEA in a timely manner. The PR will, by 23rd December 2021: 1.review all adverse incidents since June 2016 2. retrospectively report any that were missed and 3. submit a summary report of review. The Incidents SOP does include the types of adverse incidents which are required to be reported and the reporting timeframes to the HFEA. This inaccuracy in the report needs updating. The SOP, with incident types was sent to the centre's inspector on 9th June 2021 and again on 22nd June, at her request; can the inspector confirm receipt of the updated	The centre's Incident SOP was provided prior to the inspection team for the DBA, however, as noted in the report the SOP provided does not include or clearly identify, the type of adverse incidents which are required to be reported to the HFEA, the time frame in which the incidents need to be reported, or which staff member is responsible for reporting incidents to the HFEA. The PR should review the SOP and provide a copy of the updated document together with the other submissions due by 23 December 2021. **Further action is required.**

	The PR should audit the effectiveness of changes introduced in this area of practice six months of their introduction. A summary report of the findings of the audit should be provided to the centre's inspector by 23 June 2022.	SOP and what, if any, further action is required. The PR will audit the effectiveness of changes introduced six months afetr implementation. A summary report of the audit will be provided to the centre's inspector by 23rd June 2022.	
3. Staff The centre has not carried out a work force assessment in the last two years to ensure that appropriate staffing resources are available for the activity undertaken. The centre is operating with only one GMC registered clinician, which carries risks for the continuity of patient care. A contingency arrangement with another GMC registered clinician has been developed, but its efficacy is open to question as the clinician is employed in an NHS hospital and therefore	The PR should ensure that staff are available in sufficient number and are suitably trained and assessed as competent to undertake their roles. The PR should review the centre's staffing levels. The review should include, but not be limited to, consideration of the issues identified by the inspection team. A summary report of the findings of the review including corrective actions and timescales for implementation should be provided to the centre's inspector when responding to this report.	The PR will ensure that staff are available in sufficient number and are suitable trained and assessed as competent to undertake their roles. The PR has reviewed the centre's staffing levels and a summary report of the findings have been provided to the centre's inspector with this response.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided a summary report of her review of the centre's staffing levels and confirmed that an additional consultant doctor commenced employment at the centre on 9 September 2021, and that senior management are looking to employ another fertility specialist. The executive notes that the PR has confirmed that the

may not be available to provide care if requested. The competence assessment framework for laboratory staff is generally robust but does not cover certain processes which are less frequently used, for example oocyte vitrification and thaw, assisted hatching, surgical sperm recovery and import and export of gametes and embryos. SLCs T12 and T15a	The competence of laboratory staff to undertake processes which are less frequently used (see the body of the report for details) should be assessed at a suitable frequency. A summary report of the actions taken to implement this recommendation should be provided to the centre's inspector by 30 September 2021.	The competency of laboratory staff to undertake processes which are less frequently used will be assessed at a suitable frequency. A summary report of the actions taken to implement this recommendation will be provided to the centre's inspector by 30th September 2021.	competency assessment framework for laboratory staff has been reviewed and updated to ensure that processes which are less frequently used are included, and that competencies will be assessed at a suitable frequency. **No further action is required.**

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
4. Import and exports For two imported donor sperm samples, reports were not available of the total compensation provided to each donor during their course of donation for loss of earnings and, separately, for reasonable expenses connected with their donation visits. The relevant import agreement discusses payments 'up to £35 per visit'. This provides no reassurance of compliance with the £250 limit on compensation for loss of earnings per course of donation. Imports can only be undertaken under GD 0006(GB) if all requirements are met. Paragraph 3h	The PR should ensure that the donor compensation reports required by General Direction 0001 paragraph 13, are provided to the centre for all donors whose gametes have been imported since 1 January 2020, as well as for all future imports. The PR should audit the compensation provided to all donors whose gametes have been imported since 1 January 2020 and should report to the HFEA where it does not comply with the requirements of General Direction 0001, paragraph 12. The PR should ensure that all requirements of GD0006(GB) are considered, and that	The PR will ensure that the donor compensation reports required by General Directions(GD) 0001, para 13, are provided to the centre for all donors whose gametes have been imported since 1st January 2021 and for all future imports. The PR will audit the compensation provided to all donors whose gametes have been imported since 1st January 2020 and will report to the HFEA where there is non-compliance with GD 0001, para 12. The PR will ensure that all requirements of GD0006 (GB)	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has confirmed that donor compensation reports required by General Direction 0001 paragraph 13 are to be obtained for all donors whose gametes have been imported since 1 January 2020, as well as for all future imports. The findings of the PR's audit of compensation provided to all donors whose gametes have been imported since 1 January 2020 should be provided by 23 December 2021.

requires that 'no money or other benefit has been given or received in respect of the supply of the gametes or embryos unless the money or benefit paid or received is in accordance with GD 0001. For the two donor sperm samples imported, the centre's evidence to support the imports' compliance with the requirements of GD 0006(GB), paragraph 3h, is lacking and it is questionable whether the imports should have been made using the authorisation of GD 0006(GB). General Direction (GD) 0001, paragraphs 12 and 13 GD 0006, paragraph 3(h)	evidence is available to show they are met for each import or export, before an import or export is undertaken under GD0006(GB). This recommendation should be implemented and the HFEA informed of the actions taken by 23 December 2021.	are met before an import or export is undertaken. This recommendation will be implemented and the HFEA informed of the actions taken by 23rd December 2021.	The PR should report to the HFEA any cases where compensation provided to donors does not comply with the requirements of General Direction 0001, paragraph 12. **Further action is required.**
5. Third party agreements It was noted during the DBA of documents provided by the centre that, in two out of five third party agreements, the date that the third party agreements should be reviewed by was not documented.	The PR should ensure that the content of all agreements with third parties complies with HFEA requirements and guidance. A summary of findings and corrective actions, with time scales for implementation, should be provided to the	The PR will ensure that the contents of all agreements with third parties comply with HFEA requirements and guidance. A summary of findings and corrective actions, with time scales for impementation, will be provided to the centre's	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided a summary report of her review of the centre's agreements with third parties and minor

SLC T114	centre's inspector by 30 September 2021.	inspector by 30th September 2021.	amendments have been made to ensure the template is compliant with HFEA requirements. The PR confirmed that the centre's agreements are currently under review and due for completion by 31 December 2021. **No further action is required.**
6. Information A number of non compliances were identified in the information provided on the centre's website. These are described in the body of the report. CoP 4.8.	The PR should ensure that the centre's website is compliant with guidance. When responding to this report, the PR should provide an action plan, with time scales for implementation, to ensure the compliance of information on the centre's website. It is expected that the centre's website will be compliant by 30 September 2021.	The PR will ensure that the centre's website is compliant with guidance by 30th September 2021. With this response, the PR has provided to the centre's inspector, an action plan for implementation to ensure compliance of information on the centre's website. The inaccuracy noted was in relation to the link, www.hfea.gov.uk/choose-a-clinic-about-choosing-a-clinic/ which is clearly provided on our website.	The executive acknowledges the PR's response and her confirmation through the action plan provided, that the website will be reviewed. The link on the centre's website was directing patients to the home page of the HFEA website, and not the 'Choose a clinic' page (as set out in CoP), however the executive notes that these links have now been corrected. The PR provided additional responses to the inspection team's finding which are included in the papers with

			this report and further responses on 30 September 2021 reiterating that 'the requirement in 4.8 is not a mandatory requirement, and City Fertility has chosen NOT to provide the information on our website'. The executive is dismayed at the PR's response and the decision not to comply with the CoP guidance in relation to success rates displayed on the centre's website. It is an expectation of the PR, to comply with the requirements of the CoP. On 30 September 2021 the PR informed the centre's inspector that a further review of the website is underway and expected to be completed by 30 November 2021. This review is to consider further whether to include live birth rate per embryo transferred and data split by maternal age and treatment type. The review is expected to be completed by 30 November 2021.

			The PR indicated that until the review is completed statistics in relation to the centre's success rates will not be displayed on the website and only data for the 'FutureLife' clinics (which is a group of clinics that centre 0324 is part of) will be displayed. On reviewing the centre's success rate website page on 4 October 2021, the executive notes that the first set of data displayed is for the 'FutureLife clinics' which could be confusing to patients. There is also some data for City Fertility for egg donation cycles (March 2021-December 2020), IVF/ICSI by maternal age (March 2021-December 2020) and clinical pregnancy rates (January - December 2020). The executive will liaise further with the PR to determine what further changes will be made to the website as a result of the review due to be completed by 30 November 2021.

			Further action is required.
7. Record keeping and document control The centre does not routinely document in patient records by whom a patient/donor has been reliably identified. SLC T46	The PR should ensure that the staff member who verifies a patient's identity is documented in the patient's records. The PR should inform the centre's inspector of the actions taken to implement this recommendation when responding to this report. Three months after corrective actions have been implemented, the PR should perform a records audit to ensure these actions have been effective. A summary report of this audit should be provided to the centre's inspector by 23 December 2021.	The PR will ensure that the staff member who verifies a patient's identity is doicumented in the patient's records. With this response, the PR has provided to the centre's inspector, a summary report of the actions taken to implement this action. Three months after corrective actions have been implemented, the PR will perfom a records audit to ensure these actions have been effective. A summary report of this audit will be provided to the centre's inspector by 23rd December 2021.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided information on the actions taken to address this inspection finding and confirmed that a final report will be provided by 23 December 2021. A summary report of the findings of the audit of records is due by 23 December 2021. **Further action is required.**

Reponses from the Person Responsible to this inspection report
We have noted a few factual inaccuracies in the draft inspection report as highlighted in the PR response: 1. QMS 2. Adverse incidents 3. Information We are hopeful that the inaccuracies will be corrected in this report before consideration by ELP. The PR would welcome a further discussion if any of what has been highlighted above and in the summary report, is still not clear. We have also noted track changes in this draft; please can these also be addressed? The inspection team thanks the PR for the comments provided in the body of the report and above. The PR has indicated that there are factual inaccuracies in the inspection report, however, it is not clear what these are. The PR has provided additional responses to those in this report that have been submitted to ELP for consideration.