Licence Committee - minutes

Centre 0333 (Harley Street Fertility Clinic) Renewal Licence

Thursday, 7 May 2020

Teleconference

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle Karen Conyers (Observing)	Committee Secretary Inspector
Legal Adviser	Darryn Hale	DAC Beachcroft LLP
Specialist Adviser		
Observers	Ermal Kirby	HFEA Authority Member (Induction)

Declarations of interest:

- Members of the committee declared that they had no conflicts of interest in relation to this item.

The committee had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

Papers enclosed:

- Renewal inspection report with PR response
- Renewal application form
- Licensing minutes:
    - 5 September 2019 - Licence Committee Minutes - Targeted Unannounced Interim Inspection
    - 10 January 2019 - Licence Committee Minutes - Executive Update - Interim inspection
    - 16 August 2018 - Executive Licensing Panel Minutes - Interim Inspection
    - 6 October 2017 - Executive Licensing Panel Minutes - Whistle Blower Concerns
    - 20 May 2016 - Executive Licensing Panel Minutes - Renewal Inspection

1. Background

1.1. Harley Street Fertility Clinic, centre 0333 is located in central London. The centre has held a treatment (including embryo testing) and storage licence with the HFEA since July 2014 and provides a full range of fertility services.

Current Licence

1.2. The centre's current licence was granted for a period of four years from 23 July 2016 and is due to expire on 22 July 2020.

History of non-compliance:

Interim Inspection – April 2018

1.3. An interim inspection undertaken in April 2018 found significant non-compliance. The report of this inspection was considered by the Executive Licensing Panel (ELP) at its meeting held on 16 August 2018. The panel was not confident in the PR's ability to ensure regulatory compliance in a timely manner and decided to adjourn its decision and refer the matter to the Licence Committee for consideration with the relevant updates.

1.4. The Licence Committee considered the centre's interim inspection report at its meeting held on 10 January 2019 and agreed with the concerns of the panel. The committee also agreed to an additional unannounced targeted interim inspection of the centre.

Additional Unannounced Targeted Interim Inspection – April 2019

1.5. An additional unannounced targeted interim inspection was undertaken in April 2019 to ensure compliance with the recommendations made at the interim inspection. At its meeting in September 2019, the Licence Committee reviewed the findings of this inspection and endorsed the Executive's recommendation for the continuation of the centre's licence. The committee noted that this is a relatively new centre and that the PR had received significant support from the Executive. The committee agreed that the PR should be more proactive and take ownership of her responsibility to ensure that the centre is compliant and maintains compliance. The committee was disappointed to see reoccurring non-compliances and suggested that the PR considers seeking support from her peers at other established compliant centres.

1.6. The committee requested that the Licence Committee also considers the licence renewal inspection report, expecting to hear that the PR had been proactive in leading the centre and embedding learning, demonstrating a notable shift in culture to learning and improving and maintaining good practice.

Renewal Inspection – December 2019

1.7. A licence renewal inspection was carried out on 10 and 11 December 2019 and a report of this inspection has been submitted for consideration by the Licence Committee.

2. Consideration of application

Renewal Inspection

Application

2.1. The committee noted that the centre had submitted an application for the renewal of a treatment (including embryo testing) and storage licence.

2.2. The committee noted that the application contains the supporting information required by General Direction 0008 and that the appropriate fee has been paid.

Inspection Process

2.3. The committee noted that the renewal inspection report covers the performance of the centre since the last inspection, the findings from the renewal inspection visit and communications received from the centre.

2.4. The committee noted that in the 12 months to 31 October 2019, the centre provided 213 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

2.5. The committee noted that HFEA-held register data for the period 1 August 2018 to 31 July 2019, showed the centre's success rates for IVF and ICSI were in line with national averages.

2.6. The committee noted that in 2018, the centre reported 68 cycles of partner insemination with nine pregnancies. This represented a clinical pregnancy rate of 13%, which was consistent with the national average.

2.7. The committee noted that between 1 August 2018 and 31 July 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 9%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

2.8. The committee noted that at the time of the renewal inspection on 10 and 11 December 2019 there were two major and eight other areas of non-compliance identified:

Major areas of non-compliance:

- The PR should ensure that the quality management system (QMS) is effective and fit for purpose.
- The PR should ensure that patients are provided with accurate and balanced information about intralipid treatment and Pre-implantation Genetic Screening (PGS), and that staff providing intralipid treatments are fully trained and assessed as competent.

Other areas of non-compliance or poor practice:

- The PR should ensure that the compensation provided to each donor of imported gametes is actively reviewed.
- The PR should risk assess the current practices for securing patients' legs during procedures and ensure that appropriate, suitable and purpose specific equipment is used for this purpose.
- The PR should ensure that gamete and embryo recall procedures comply with Code of Practice requirements.
- The PR should ensure that satellite agreements are provided to the HFEA and that evidence is collected to support the compliance of the satellite service.
- The PR should ensure that medical devices used in the centre are CE marked at an appropriate level.
- The PR should ensure that patients consenting to embryo use in training, are informed that they can vary or withdraw their consent until the point the embryos are used in training and also whether any information will be fed back to them.
- The PR should ensure that the offer of counselling is always documented in the records and that the document management system is compliant and provides staff access to active document versions while controlling access to out of date versions.
- The PR should ensure that all third-party agreements (TPAs) are regularly reviewed and updated. The content of TPAs should comply with HFEA requirements and guidance.

2.9. The committee noted that since the inspection visit, the PR has committed to fully implementing the outstanding recommendations relating to treatment add-ons and third-party agreements. The PR has also committed to audit the effectiveness of corrective actions within the required timescales.

2.10. The committee noted that the centre has accumulated a history of non-compliances within a relatively short period, since it was licensed in 2014. The committee also noted that the Executive would expect to see maintained improvements going forward, which will be reviewed during the next inspection.

2.11. The committee noted that some improvement is required in order for the centre to demonstrate the suitability of its practices. The PR is encouraged to continue to use the Quality Management System (QMS) to best effect to monitor and improve the success rates and the quality of service offered to patients.

Recommendations

Licence

2.12. The committee noted that the Executive 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.

2.13. The Executive will continue to monitor the centre's performance and the implementation of the recommendations within the required timescales.

Importing Tissue Establishment (ITE) import certificate

2.14. The committee noted that centre 0333 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The Executive recommends the renewal of the centre's ITE import certificate.

3. Decision

3.1. The committee had regard to its decision tree and HFEA Guidance on Licensing.

Administrative Requirements

Supporting Information under General Direction 0008

Application

3.2. The committee was satisfied that the application was submitted on an application form and contained all the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid.

Proposed Person Responsible (PR) – Dr Geetha Venkataraman

3.3. The committee was satisfied that the proposed PR possesses the required qualifications and experience and that the character of the proposed PR is such as is required for supervision of the licensed activities. It was further satisfied that the proposed PR will discharge her duties under section 17 of the HF&E Act 1990 (as amended).

Proposed Licence Holder (LH) – Mr Lawrence Ashford

3.4. The committee was satisfied that the proposed LH is suitable.

Activities

3.5. The committee was satisfied with the suitability of the activities applied for.

Premises – 134 Harley Street, London, W1G 7JY

3.6. The committee was satisfied that the premises and facilities are suitable for the conduct of the licensed activity applied for.

3.7. The committee was satisfied that the third-party premises are also suitable.

Treatment add-ons - Pre-implantation Genetic Screening (PGS) and Prescription of intralipid 'off label'

3.8. The committee noted that the recommendation to ensure that patients are provided with accurate and balanced information about PGS and intralipid treatment, and staff providing intralipid treatments are fully trained and assessed as competent, is still outstanding.

3.9. The committee noted that the patient information leaflet on intralipid use was considered by the Executive to be potentially inaccurate and misleading. The information does not make clear the lack of strong evidence to support the efficacy of intralipid use and the HFEA website assigns a red light to this treatment add-on. The patient information also states that the treatment is non-invasive and is increasingly being prescribed to women undergoing IVF and those with a history of recurrent miscarriage, whereas the treatment involves intravenous infusion and no clear evidence is presented to support the assertion regarding increased use.

3.10. The committee noted that staff administering intralipid infusion therapy to patients do not have a specific documented competence for this practice, albeit the PR is assured of their competence and skills and provided her rationale for this.

3.11. The committee noted that the Executive awaits the updated information sheets and an update on centre staff competencies, developed documents such as the equipment check lists, competency check list/sign off sheet, Standard Operating Procedure (SOP) and accompanying documentation. The committee expects this to be addressed by the PR as a matter of urgency.

Third Party Agreements

3.12. The committee noted that the PR planned to submit a copy of the satellite agreement to the HFEA by 10 March 2020, and as a part of the revised QMS, the PR planned regular audits with the first in April 2020, submitting a report by 30 April 2020. The Executive acknowledged the PR's response and action taken and agreed to extend the deadlines.

Quality Management System (QMS)

3.13. The committee noted that the centre has a QMS that is partially compliant with HFEA requirements and the recommendation to ensure that the QMS is effective and fit for purpose is still outstanding. Concerns regarding the QMS were previously identified at inspections completed in April 2018 and April 2019. This is a major area of non-compliance. The issues identified led the Executive to question the robustness and effectiveness of the QMS.

3.14. The committee noted that there were a number of issues identified relating to the centre's Standard Operating Procedures (SOPs) and audits. The mechanisms to assure compliance with new requirements and guidance issued by the HFEA are not always effective since a number of staff members were not aware of the content of the patient support SOP and pathway, and use of the PBR consent form was not embedded in the SOPs and audit programme.

3.15. The PR has struggled to appoint an experienced Quality Manager to develop the QMS and ensure its compliance, however the post has now been filled. The PR and the new Quality Manager outlined plans to ensure the future compliance of the QMS and the Executive considers that these plans should lead to significant improvements.

3.16. The committee noted that the Executive acknowledges the PR's commitment to implementing the recommendation and action already taken to address the issues, noting that there is no further action required beyond the submission of the audit.

Licence

3.17. The committee had regard to its decision tree and the HFEA Guidance on Licensing.

3.18. The committee deliberated on the seriousness of the non-compliances and the centre's history of failure to meet the requirements. Due to the continued number and nature of non-compliances, the committee considered granting a three year licence instead of the standard four. However, the committee felt reassured by the Executive, that the PR was now fully engaged and had committed to addressing all the non-compliances by the deadlines set.

3.19. Carefully weighing all factors in the balance, the committee agreed that a four year treatment (including embryo testing) and storage licence was appropriate, subject to the recommendations made in this report being fully implemented within the prescribed timescales. This licence offer will become final and come into effect on 23 July 2020 unless the PR chooses to make representations regarding the proposed decision, or submit any other information within 28 days.

Importing Tissue Establishment (ITE) import certificate

3.20. The committee endorsed the Executive's recommendation to renew the centre's Importing Tissue Establishment (ITE) import certificate.

Monitoring

3.21. The committee agreed that given the centre's history, there should be further monitoring to ensure the outstanding recommendations are fully implemented, and to ensure that the PR provides effective leadership and non-compliances do not continue to recur.

3.22. The committee noted that the Executive expects to see improvements made and maintained, which will be reviewed during the next inspection. If further areas of concerns arise regarding the centre's ability to maintain compliance, then further regulatory action may be considered at that time.

3.23. The committee requested that a progress report is submitted to the Licence Committee in due course. The committee expects to see a change in culture towards continuous learning, improving and maintaining good practice, acting at all times in the best interest of patients.

Timescales

3.24. In accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic, fertility centres suspended treatments in March 2020. Therefore, the Executive will liaise with the PR to consider appropriate timescales to fully implement the recommendations.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

1 June 2020

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Licence Committee (LC) 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: 10 and 11 December 2019

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 visit and communications received from the centre.

Inspectors: Grace Lyndon (lead), Julie Katsaros and Andy Leonard

Date of Licence Committee: 7 May 2020

Centre name	Harley Street Fertility Clinic
Centre number	0333
Licence number	L/0333/2/a
Centre address	134 Harley Street, London, W1G 7JY, United Kingdom
Person Responsible	Dr Geetha Venkataraman
Licence Holder	Mr Lawrence Ashford
Date licence issued	23/07/2016
Licence expiry date	22/07/2020
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Harley Street Fertility Clinic is located in central London and has held a Treatment (including embryo testing) and Storage licence with the HFEA since July 2014.

The centre provides a full range of fertility services and is registered with the Care Quality Commission (CQC).

The centre provided 213 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2019. In relation to activity levels this is a small centre**.**

The centre's current licence was issued on 23 July 2016. An interim inspection was undertaken in April 2018, which found significant non compliances. The report was considered initially by the ELP and then LC, who agreed with the concerns ELP had. An additional interim inspection was suggested and was undertaken in April 2019 to ensure compliance with the recommendations made after the previous inspection. The LC, which reviewed the findings of the April 2019 inspection, expressed concerns and asked that the report of the upcoming renewal inspection of the centre, i.e. this report, should be returned to the LC.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 August 2018 to 31 July 2019 show the centre's success rates are in line with national averages.

In 2018, the centre reported 68 cycles of partner insemination with nine pregnancies. This represents a clinical pregnancy rate of 13%, which is consistent with the national average.

Multiple births[2]

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

Between 1 August 2018 and 31 July 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate.

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

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

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP) and standard licence conditions (SLCs), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The LC is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including two major and eight 'other' areas of non compliance or poor practice,

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 quality management system (QMS) is effective and fit for purpose.

'Other' areas of non compliance:

- The PR should ensure that the compensation provided to each donor of imported gametes is actively reviewed.
- The PR should risk assess the current practices for securing patients' legs during procedures and ensure that appropriate, suitable and purpose specific equipment is used for this purpose.
- The PR should ensure that gamete and embryo recall procedures comply with Code of Practice requirements.
- The PR should ensure that satellite agreements are provided to the HFEA and that evidence is collected to support the compliance of the satellite service.
- The PR should ensure that medical devices used in the centre are CE marked at an appropriate level.
- The PR should ensure that patients consenting to embryo use in training, are informed that they can vary or withdraw their consent until the point the embryos are used in training and also whether any information will be fed back to them.
- The PR should ensure that the offer of counselling is always documented in the records and that the document management system is compliant and provides staff access to active document versions while controlling access to out of date versions.

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

Major areas of non compliance:

- The PR should ensure that patients are provided with accurate and balanced information about intralipid treatment and Pre-implantation Genetic Screening (PGS), and that staff providing intralipid treatments are fully trained and assessed as competent.

'Other' area of non compliance

- The PR should ensure that all third party agreements (TPAs) are regularly reviewed and updated. The content of TPAs should comply with HFEA requirements and guidance.

Recommendation to the LC

The inspection team notes that the centre's success rates are consistent with the national average and the multiple clinical pregnancy rate meets the target. Some improvement is required in order for the centre to demonstrate the suitability of their practices. The PR is encouraged to continue to use the QMS to best effect to monitor and improve their success rates and 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 relatively 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.

Given the history of non-compliances found in this report and in previous reports, within a relatively short licencing history for this centre, the Executive would expect to see improvements being made and maintained going forward, which will be reviewed during the next inspection. If further areas of concerns arise regarding the centre's ability to maintain compliance, then further regulatory action may be considered at that time.

Centre 0333 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 broadly 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 does not actively review the compensation provided to each donor of gametes which are imported. Passive measures are in place to ensure compliance, e.g. assertions from donor banks of compliant compensation and third party agreements describing compliant compensation practices. This evidence might be taken to satisfy the requirements of GD0006 but not GD0001 paragraph 13, which requires: 'When receiving donated gametes from overseas, the centre must keep a record (provided by the overseas centre) of: (a) the actual expenses incurred by the donor; (b) the amount reimbursed to the donor'.

General Direction 0001 and 0006; recommendation 3.

Suitable premises and suitable practices

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

What the centre does well

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

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.

The premises of the centre's satellite and transport facilities and laboratories conducting tests that impact on the quality and safety of gametes and embryos (relevant third parties) are suitable.

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and 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 controlled drugs (CDs) and other medicines that are compliant with guidance, albeit the SOP for medicines management does not reflect current practice at the centre, as discussed below in 'Quality Management System'.

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 and written information provided to patients offered intralipid therapy, were reviewed and considered to be partially suitable.

Pre-operative assessment and the surgical pathway (Guidance note 25)
The centre has policies and procedures in place that are broadly compliant with professional body guidelines for pre-operative assessment and management of the

surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

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

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

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

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are broadly 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 risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements, notwithstanding the non compliance noted in 'Payments for Donors' above, regarding the failure to collect and review evidence of payments made to donors whose gametes are imported to the centre. 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.

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 have been made since the introduction of the ITE import certification scheme on 1 April 2018. Three imports have been made from TCS which are specified on the centre's ITE import certificate. The centre is therefore compliant with General Direction 0006.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

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

Third party agreements (Guidance note 24)
The centre's third party agreements, including those associated with ITE/TCS import certificates, are 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 broadly compliant with HFEA requirements. This 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 broadly compliant with HFEA requirements. Some of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and staff.

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

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA

requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Prescription of intralipid 'off label'
The patient information leaflet about intralipid use was considered by the inspection team to be potentially inaccurate and misleading. It does not make clear the lack of strong evidence to support the efficacy of intralipid use or that the HFEA website assigns a red light to this treatment add on. It also states that the treatment is non-invasive and is increasingly being prescribed to women undergoing IVF and those with a history of recurrent miscarriage, whereas the treatment involves intravenous infusion and no clear evidence is presented to support the assertion regarding increased use.

The staff who infuse intralipid into patients do not have a specific documented competence for this practice, albeit the PR is assured of their competence and skills and provided a rationale for this.

SLCs T12 and T58; recommendation 1.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
During vaginal egg collection procedures, tourniquets designed for venepuncture procedures are used to immobilise and keep a patient's legs in the required position. The inspection team felt that this presents a risk to the circulation of the patient's legs and the centre should be using the appropriate straps specified for the purpose.

SLC T2; recommendation 4.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The recall procedure does not discuss how to process returned materials or to report and investigate all material recalls as adverse incidents.

CoP interpretation of mandatory requirements 15C; recommendation 5.

QMS (Guidance note 23)
A number of problems were noted in the centre's audits

- Several audits (e.g. medicines management and legal parenthood) used a sample size too small for the audits to be representative of the centre's practices, so the audits did not give assurance of the compliance of the audited practices.
- In some audits, the audit scope and methodology were not clearly documented or were too restricted, e.g. the patient information audit did not include the provision of information about the use of the PBR consent form.
- An audit of the counselling service has not been performed since the centre commenced activity in 2014. The centre has two counsellors who work independently and have not collaborated to undertake an audit or to review patient feedback; neither counsellor is invited to attend multidisciplinary team meetings.
- An audit of the consenting process has not been performed in the last two years.
- Non-compliances identified in audit reports, were not included in the corrective

actions at the end of the report, therefore no corrective actions were undertaken.
- Corrective actions to address non-compliance, with deadlines for implementation, were not always noted in audit reports (e.g. the donor screening audit), nor was confirmation of the implementation and completion of corrective actions.

The inspection team also noted problems related to SOPs:

i. The medicines management SOP was not being followed as the anaesthetist was found to be holding the controlled drug (CD) keys on the day of the inspection, which is not in line with the centre's own processes and procedures.
ii. The medicine management SOP does not state that CD destruction should be witnessed by an appropriate person, as is required and is not the established practice at the centre.
iii. The SOP directs staff to take action 'as per local policy' in the event of a medicines fridge temperature alarm but a suitable local policy has yet to be documented in a SOP.
iv. There is no SOP defining the practices used to manage third party agreements.
v. The SOPs for patient information and documenting patient consent do not refer to the use of the PBR consent form.

The centre has not established quality indicators for some practices.

Mechanisms to assure compliance with new requirements and guidance issued by the HFEA are not always effective, since:

- A number of staff members were not aware of the content of the patient support SOP and pathway.
- Use of the PBR form is not embedded in SOPs and the audit programme.

The problems identified above lead the inspection team to question the robustness and effectiveness of the QMS. Concerns regarding the QMS have been previously identified by the inspections in April 2018 and April 2019. The PR has struggled to appoint an experienced quality manager (QM) to develop the QMS and ensure its compliance but has recently made an appointment. The PR and new QM outlined plans to ensure the compliance of the QMS in future and the inspection team considers that these plans should lead to significant improvements. Given these facts, though this was a major non compliance at the last inspection, the inspection team consider it proportionate to cite this non compliance as a 'major' in this report.

SLCs T32, T33, T35 and T36; recommendation 2.

Third Party Agreements

- The persons responsible for managing arrangements between the centre and a third party were not identified in all third party agreements reviewed.
- Third party agreements are not regularly reviewed and updated. For example two agreements were last reviewed in 2016 and have not been updated.
- The TPA with the third party courier company does not specifically require that dry shippers in which embryos or gametes are transported, are charged with liquid nitrogen and are validated, nor does it specify the critical storage conditions required to be met during transit.

SLCs T114 and T116; recommendation 6.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
Fertility in Community is operating as a satellite to centre 0333. It recruits patients and undertakes activities required for the patients to undergo licensed treatment. The patients then undergo egg collections at centre 0333. A satellite agreement between Fertility in Community and centre 0333 has however not been provided to the HFEA.

General Direction 0010, paragraph 3; recommendation 7

Equipment and materials (Guidance note 26)
Kitizato Repro plates are used at the centre during vitrification of gametes and embryos but are not appropriately CE marked. According to the centre, this certification is being sought by the manufacturer and should be provided in early 2020. The centre has tried to use an alternative vitrification kit but saw a 20% reduction in success rates. The centre contends that no suitable CE marked medical device is available which provides equivalent success rates to the vitrification kit it is using. The inspection team notes that other CE marked vitrification kits are available but also that re-training and trialling such kits is time consuming.

This was a major non compliance at the last inspection but the inspection team is minded to cite this non compliance as an 'other' non compliance in this report, given the efforts made by the centre to source an alternative, the centre's rationale that there is no suitable alternative which provides equivalent success rates, and because the inspection team has confirmed that the manufacturer is seeking appropriate CE marking for the ''Repro' plate.

SLC T30; recommendation 8.

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of 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 partially compliant with HFEA guidance regarding effective leadership. Consideration was given to the number of non-compliances noted in this report, the repetitive non-compliances identified and staff members being unaware of the 'Patient Support Policy' for example, which may indicate poor leadership within the centre. The Executive notes the progress the centre has made over the past year to meet the requirements of compliance of which a new quality manager has now been employed. The Executive has concluded that the findings in the report will be addressed through the appointment of an experienced QM and urges the PR to take action to provide effective

leadership. No recommendation has been given at this time but the Executive will closely review this area of practice during the next inspection.

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, notwithstanding concerns related to the information provided to patients regarding pre-implantation genetic screening discussed in 'Information'. The centre's

compliance 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, and opportunities 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. Twenty-five patients have provided feedback in the last 12 months, giving an average 4.5 star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. Just over half of the patients (13) confirmed that they had paid what they expected to but eleven others indicated they had paid either more or way more than the expected cost. This was discussed with the PR who confirmed that individual pricelists are provided to patients and full pricelists are given. The PR advised the inspectors that they will continue to give advice to all patients on pricing and individual costs of treatment.

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

During the inspection, the inspectors spoke to four patients who also provided positive feedback on their experiences.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- treats patients with empathy and understanding.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Patient support
Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Patient support (Guidance note 3)

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

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

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

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

- care is taken when selecting egg 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)
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 partially compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Information (Guidance note 4)
Written information provided to patients about pre-implantation genetic screening (PGS) did not indicate that this treatment add on is considered by the HFEA to have very poor evidence for efficacy. At the time of the inspection, PGS was ascribed within the HFEA treatment add on traffic light system, an amber rating, if undertaken at embryo development day 5, and a red rating if undertaken at day 3. The rating for day 5 PGS has since been changed to red. Instead, the information cites only two research papers positive about the methodology. There is no mention that some research shows PGS has little efficacy. The HFEA website is referred to generally but not as a source of further information about treatment add ons. The inspection team considered that the PGS information did not provide an accurate and balanced discussion about efficacy.

HF&E Act 1990 as amended, Schedule 3, 3, 1B; recommendation 1.

Concerns about the patient information leaflet: 'Intralipid Infusions', are discussed above in 'Prescription of intralipid off label' and also in recommendation 1.

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

What the centre does well

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

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

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the inspection in February 2016, 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. Four sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements,

notwithstanding the concerns about the centre's audit of legal parenthood consenting procedures, discussed above in 'QMS'.

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)

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

What the centre could do better

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 broadly 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

Use of embryos for training staff (Guidance note 22)
The combined information sheet - consent form completed by patients for the use of aneuploid embryos in biopsy training, does not include that the persons consenting can vary or withdraw the terms of their consent until the point the embryos are used in training or whether any information will be fed back to them.

SLC T97; recommendation 9.

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

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

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Record keeping and document control (Guidance note 31)
The offer of counselling is not always documented in the patient's notes.

When retrieving documents from the electronic document management system, archived out of date document versions were accessible, and were in some cases retrieved before the most recent, active document version. This caused delays and confusion for staff trying to locate active documents and SOPs.

SLCs T34, T37 and T46; recommendation 10.

Section 3: Monitoring of the centre's performance

Following the additional focussed interim inspection in April 2019, recommendations for improvement were made in relation to two critical, three major and one 'other' areas of non compliance.

The PR provided information and evidence that all but one of the recommendations were fully implemented within required timeframes.

The following recommendation was not implemented:

- The PR should ensure that the quality management system is effective and fit for purpose.

The centre appointed a QM in February 2019 who subsequently left the centre after the inspection in April 2019. The PR sought to appoint a new QM but only managed to do so three weeks before this renewal inspection. Non-compliances were consequently identified in the QMS at this inspection, probably because of the lack of oversight provided by an experienced QM. The PR and new QM outlined plans to ensure the compliance of the QMS in future and the inspection team considers that these plans should lead to significant improvements.

On-going monitoring of centre success rates

Since August 2019, the centre has received no Risk tool alerts concerning treatment success rates.

Areas of practice requiring action

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

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non compliance requires immediate action to be taken by the Person Responsible.

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None identified			

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several 'other' areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

A major area of non compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Patient information; PGS; Prescription of intralipid 'off label' Patient information leaflets about intralipid treatment and PGS, were considered by the inspection team to be potentially inaccurate and misleading, for reasons discussed in the main body of the inspection report. The staff who infuse intralipid into patients do not have a specific documented competence for this practice, albeit the PR is assured of their competence and skills	The PR should ensure patient information about intralipid use, PGS, and other 'add on' treatments is accurate, balanced and compliant with HFEA requirements. The PR should review information provided to patients about treatment 'add ons' such as PGS and intralipid treatment and should revise it to ensure that patients are provided with accurate and balanced information about their treatment options. A plan for the review of patient	The PR accepts the feedback and recommendations and the is currently in the process of reviewing the Clinic's information sheets. HFEA guidance will be considered and included as appropriate to ensure that patients receive complete and unbiased information. The clinic is aiming to get the revised Information Sheets ready for June 2020. The PR accepts and agrees with the feedback around the practice of intralipid infusion. The lead nurse is in the	The Executive acknowledges the PR's commitment to implementing this recommendation. The Executive awaits the updated information sheets and an update on the centre staff competencies; developed documents such as the equipment check lists, competency check list/sign off sheet, SOP and accompanying documentation. In March 2020 the PR suspended fertility treatments in accordance with HFEA requirements and professional body guidance

and provided a rationale for this. HF&E Act 1990 as amended, Schedule 3, 3, 1B; SLCs T12 and T58.	information should be provided to the centre's inspector with the PR's response to this report. Copies of the updated information sheets should be provided to the centre's inspector by 10 June 2020. The PR should ensure that staff providing intralipid treatments are fully trained and assessed as competent. Confirmation of the actions taken to address this concern should be provided with the PR's response to this report.	process of developing the documents (SOPs, Check Lists, Competencies etc) currently. Once ready, the Nursing staff will be competency assessed.	issued in response to the COVID-19 pandemic. In view of this the centre's inspector will liaise with the PR to consider an appropriate timescale for fully implementing the recommendation. Further action required
2. QMS The inspection team question the robustness and effectiveness of the QMS, for reasons detailed, in full, in the main body of the report. SLCs T32, T33b, T35 and T36.	The PR should ensure that the QMS is compliant and fit for purpose. The PR should review practices and procedures relating to the QMS, including those associated with the issues identified in this report, and should implement plans to ensure the full compliance of the QMS. A copy of the review and planned corrective actions should be provided to the centre's inspector with the PR's	In November 2019, the clinic appointed a new Quality Manager, who is developing the Quality Management System (QMS). A copy of the review and recommendations report, produced by the Quality Manager in December 2019 is enclosed, along with the Action Plan, indicating the progress that has been made. Summary: 1. Current file structure has been reorganised to make the	The Executive acknowledges the PR's commitment to implementing this recommendation and the implementations that have already been undertaken. No further action beyond the submission of the audit. In March 2020 the PR suspended fertility treatments in accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic. In view of this the centre's inspector will liaise

	response to this inspection report. The PR should then provide monthly updates to the centre's inspector regarding the development of the QMS. The PR should ensure the implementation of all corrective actions and the full compliance of the QMS by 10 June 2020. Thereafter, a sample of audits, SOPs and quality indicators will be requested for review by the centre's inspector.	system more user friendly. 2. New document templates have been created. 3. New policies have been written. 4. Audit schedule for 2020 created. 5. Process to track and close off Corrective Actions has been established.	with the PR to consider an appropriate timescale for fully implementing the recommendation.

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

An 'other' area of non compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
3. Payments for donors The centre does not actively review the compensation provided to each donor of gametes which are imported. Passive measures are in place to ensure compliance, e.g. assertions from donor banks of compliant compensation and TPAs describing compliant compensation practices. This evidence might be taken to satisfy the requirements of GD0006 but not GD0001 paragraph 13, which requires: 'When receiving donated gametes from overseas, the centre must keep a record (provided by the overseas centre) of: (a) the actual expenses incurred by the donor; (b) the amount reimbursed to the donor'.	The PR should ensure that the compensation provided to each donor of imported gametes is actively reviewed. The PR should review the centre's practices against relevant requirements and guidance and ensure the practices are appropriate to ensure the centre's compliance. The PR should provide a summary report of this review, including appropriate corrective actions, to the centre's inspector by 10 March 2020. Three months after the implementation of corrective actions, the PR should audit	The centre has struggled in obtaining records of actual expenses paid to the donor, by the Donor Bank. Usually, the Donor Bank will provide a signed statement saying that the amount paid to the donor is compliant with the standard. However, recently, some of the Donor Banks has started to provide details of the actual payments to the donors. This will now be actively requested and monitored by the centre. The corresponding SOP (Section D6 on document: LABSOP02 (Transport of Gametes and Embryos Nationally and Internationally) V5 23 11 19)) and checklist (item 9 on document: FRM-014 - Transport of gametes	The Executive acknowledges the PR's commitment to implementing this recommendation. No further action beyond the submission of the audit. In March 2020 the PR suspended fertility treatments in accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic. In view of this the centre's inspector will liaise with the PR to consider an appropriate timescale for fully implementing the recommendation. .

General Direction 0001 and 0006	practice to ensure that the actions taken have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 10 June 2020.	checklist), have been amended. An audit will be caried out at the end of Q2 2020 to ensure compliance with the standard.	
4. Pre-operative assessment and the surgical pathway During vaginal egg collection procedures, tourniquets designed for venepuncture procedures are used to immobilise and keep the patients legs in the required position. The inspection team felt that this presents a risk to the circulation in the patient's legs and the centre should be using the appropriate straps that are designed for this specific purpose. SLC T2	The PR should risk assess the current practices for securing patients' legs during procedures and ensure that appropriate, suitable and purpose specific equipment is used for this purpose. An update regarding the result of the risk assessment and actions taken, should be provided to the centre's inspector by 10 March 2020.	At present, the patient is secured using tourniquet loosely tightened. However, the PR accepts that this is not good practice. Following a Risk Assessment (See document: RA-002 - Patient secure during procedure), the lead nurse is liaising with suppliers to purchase lithotomy stirrups. Due to the Supplier turnaround times, the centre expects to have these in place by the end of April.	The Executive acknowledges the PR's comments and commitment to implementing the changes necessary for compliance with this recommendation. No further action beyond confirmation that lithotomy stirrups are in use at the clinic. In March 2020 the PR suspended fertility treatments in accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic. In view of this the centre's inspector will liaise with the PR to consider an appropriate timescale for fully implementing the recommendation.

5. Transport and distribution of gametes and embryos The recall procedure does not discuss how to process returned materials or to report and investigate all material recalls as adverse incidents. CoP interpretation mandatory requirements 15C	The PR should ensure that the recall procedure meets the CoP requirements, including those highlighted in this report. A summary of the actions taken to implement this recommendation should be provided to the centre's inspector when responding to the report.	The recall process was reviewed and the SOP has now been updated (refer to sub-section G in document: LABSOP02 (Transport of Gametes and Embryos Nationally and Internationally) V5 23 11 19)). A Risk Assessment has also been carried out (See attached document: RA-001 - Cryo Sample Recall Process).	The Executive acknowledges the PR's comments and commitment to implementing this recommendation. The Executive also acknowledges the receipt of the documents disclosed. No further action
6. Third Party agreements • TPAs are not regularly reviewed and updated. For example two agreements were last reviewed in 2016 and have not been updated. • The persons responsible for managing arrangements between the centre and a third party were not both identified in all third party agreements reviewed. • The TPA with the third party courier company does not specifically require that dry shippers in which embryos	The PR should ensure that all TPAs are regularly reviewed and updated, as appropriate. The content of TPAs should also comply with HFEA requirements and guidance. A plan to implement this recommendation should be provided to the centre's inspector with the PR's response to this inspection report. All actions to implement this recommendation should be completed by 10 June 2020	Generally, Third Party Agreements (TPAs) are on a rolling basis and only amended when the centre becomes aware of significant change in the terms and conditions of the agreement. Following the feedback from the inspection, the centre has updated the policy to review TPAs on an annual basis and to notify the third party, in writing, of our intention to continue with the agreement. Please refer to section: Third Party Agreements (TPAs) of the	The Executive acknowledges the PR's comments and commitment to implementing this recommendation. Further action required. In March 2020 the PR suspended fertility treatments in accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic. In view of this the centre's inspector will liaise with the PR to consider an

or gametes are transported, are charged with liquid nitrogen and are validated, nor does it specify the critical storage conditions required to be met during transit. SLC T114 and T116.	and a list of TPAs provided to the centre's inspector. Thereafter, a sample of TPAs will be requested for review by the centre's inspector.	attached policy document: POL-001 – Operations Policy. As part of the new QMS process, all TPAs will be reviewed and update will be provided to the inspectors by 10 June 2020. The TPA with the third-party courier does specify validating the shipper (See section 4), charging it with liquid nitrogen (See section 13) and critical storage conditions (see section 13). This TPA has been in place since 2019. Unfortunately, the inspectors were shown an older version of the TPA, erroneously, during the inspection. Attached is the correct document: TPA: TPA-002 - Kynisi IVF Cryo Courier.	appropriate timescale for fully implementing the recommendation.
7. Transport and satellite arrangements The centre has recently developed a satellite service, without notifying or providing a copy of the satellite agreement to the HFEA. General Direction 0010,	The PR should ensure that satellite agreements are provided to the HFEA and that evidence is collected to support the compliance of the satellite service with the terms of the satellite agreement and CoP requirements.	The PR accepts the non-compliance. We will submit a copy of the satellite agreement to the HFEA by 10 March as requetsed. This satellite agreement is a recent one and as a part of our revised QMS, we plan to audit	The Executive acknowledges the PR's response to this non-compliance and the implementation that has already been undertaken and will extend the submission of the satellite agreement and audit of compliance until 30 April 2020.

paragraph 3.	The PR must submit a copy of the satellite agreement and a report of an audit of the compliance of the agreement, to the HFEA by 10 March 2020.	this service regularly. We have arranged to perform the first audit in April. Hence, we request additional time for providing a report of the audit of compliance to the HFEA. We can submit this report by 30 April 2020.	No further action beyond the submission of the satellite agreement and audit of compliance of treatment. In March 2020 the PR suspended fertility treatments in accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic. In view of this the centre's inspector will liaise with the PR to consider an appropriate timescale for fully implementing the recommendation.
8. Equipment and materials Kitizato Repro plates are not appropriately CE marked. SLC T30. This was a major non-compliance at the last inspection but has been graded as an 'other' non-compliance, for reasons discussed in the main body of the report.	The PR should ensure that medical devices used in the centre are CE marked at an appropriate level. The PR should liaise with the manufacturer to ensure the centre is regularly updated regarding progress of the Repro plate to attain appropriate CE marking. This progress should be forwarded to the centre's inspector.	Since the inspection, Kitizato Repro plates have provided the CE marking certification. See attached document: CE 548538 (Cryotop Plasticware Reproplate) 2024.05.26 certificate.	The Executive acknowledges the PR's commitment in the implementation of this non-compliance. No further action required.

	Should the device not attain an appropriate CE mark by 10 June 2020, the PR should provide the centre's inspector with an action plan, as to how the centre will attain compliance with SLC T30 by 10 September 2020.		
9. Use of embryos in training The combined information sheet - consent form completed by patients for the use of aneuploid embryos in biopsy training, does not include that the persons consenting can vary or withdraw the terms of their consent until the point the embryos are used in training or whether any information will be fed back to them. SLC T97.	The PR should ensure that patients consenting to the use of embryos in training, are informed that they can vary or withdraw their consent until the point the embryos are used in training and also whether any information will be fed back to them. The PR must submit a copy of the review and revised consent forms to the centre's inspector by 10 June 2020.	Following feedback from the inspectors, the consents for embryo biopsy have been amended to include statements about the patient's right to withdraw or vary consent. A statement has also been added about requesting feedback on the research being carried out. See: PGT-M Consent and PGT-A Consent33 As part of the QMS improvement plan, all in-house consents will be amended to include a statement about the patient's right to vary or withdraw consent. The appropriate information sheets will also be reviewed, to include a section on consenting so that patients are	The Executive acknowledges the PR's commitment to implementing this recommendation, by the implementations that have already been undertaken. The Executive acknowledges the receipt of the POL-004 Consenting Policy. No further action required.

		fully informed. A new consenting policy has already been drafted – See attached: POL-004 - Consenting Policy v2.0	
10. Record keeping and document control The offer of counselling is not always documented in the patient's notes. When retrieving documents from the electronic document management system, archived out of date document versions were accessible, and were in some cases retrieved before the most recent, active document version. This caused delays and confusion for the staff locating the latest documents. SLCs T34, T37 and T46.	The PR should ensure that the offer of counselling is always documented in the patient records and that the document management system functions in a compliant manner, providing staff access to active document versions while controlling access to out of date versions. The actions taken to implement these recommendations should be included in the PR's response to the inspection report. Within three months of the implementation of corrective actions, the centre should carry out an audit of the patient records and of document control, to assess if those actions have been effective. Further action should be taken, if necessary, until the recommendation is	The offer of counselling was added to the Nursing Checklist in July 2019 and has been in place since. It is possible the that an older set of notes were reviewed at the inspection. See item 10 in document: Nurse Consult Checklist Version 1. 2019.pdf As part of the Audit Schedule for 2020, an audit of records will be carried out and shared with the inspectors. At the time of the inspection, the QMS document structure included multiple copies of documents. These would be obsolete documents (filed in an archive folder), an editable MS Word version of the current document and PDF version of the same, for use. The QMS has since been restructured and the following improvements were have been made:	The Executive acknowledges the PR's commitment to implementing this recommendation and the implementations that have already been undertaken. No further action beyond the submission of the audit. In March 2020 the PR suspended fertility treatments in accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic. In view of this the centre's inspector will liaise with the PR to consider an appropriate timescale for fully implementing the recommendation.

	implemented. A summary report of the audit should be provided to the centre's inspector by 10 June 2020.	1. The new directory structure is much easier to navigate through instinctively (without the use of the search functionality, though this is still present). 2. The Document Control spreadsheet includes hyperlinks to the documents to further improve locating the correct document. 3. Only the final, active PDF version of the document is stored under the new structure. Archive and Ms Word versions are saved outside the QMS and do not appear in the search results. See slides 3 – 5 of Presentation: QMS Plan 2020.pptx	

Reponses from the Person Responsible to this inspection report
The PR feels that findings of the inspection are very fair and gratefully accepts the guidance and recommendations from the inspectors. Some of the actions listed are already closed, for the reason explained in the relevant section. These include the Transport TPA and the CE certification for the Kitizato Repro plates. Whilst the PR is satisfied that the clinic delivers safe and effective care to all patients and is validated by the success rates and feedback from the patients, she is cognisant of the fact that the centre must have a robust Quality Management System in place. A key priority for 2020 therefore is to develop the QMS. Work on this has already commenced and is progressing well. The PR will provide the inspectors with periodic updates on the progress with the QMS and will share findings of audits and other key information through the course of the year. The Executive acknowledges the challenges the centre has encountered without an adequate quality manager or quality management system in place, which has also been reflected in the report. The Executive also acknowledges the improvements made at the centre over the years and encourages the centre to build on the skills they have, to continue to move the centre forward to ensure repeated non-compliances are no longer identified.