Licence Committee - minutes

Centre 0341 (The Fertility and Gynaecology Academy)

Renewal Inspection

Date:	Thursday, 4 March 2021
Venue:	Teleconference
Attendees:	Jonathan Herring (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore Ermal Kirby
Executive:	Dee Knoyle – Committee Secretary Sarah Stedman - Inspector (Induction)
Legal Adviser:	Darryn Hale – DAC Beachcroft LLP
Observers:	Alison Marsden - Authority Member (Induction)

1. Declaration of interest

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

2. The committee had before it:

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

3. The following papers were considered by the committee:

Papers enclosed:

- Executive Update
- Revised Renewal Inspection Report
- Application form
- Current Importing Tissue Establishment (ITE) Import Certificate
- Licensing minutes up to the last licence renewal
    - 2020-07-09 Licence Committee Minutes - Additional Focused Unannounced Interim Inspection
    - 2019-11-07 Licence Committee Minutes - Executive Update
    - 2019-09-05 Licence Committee Minutes - Interim Inspection
    - 2017-07-14 Executive Licensing Panel Minutes - Executive update
    - 2017-03-24 Executive Licensing Panel Minutes - Renewal inspection report

4. Background

4.1. The Fertility and Gynaecology Academy, centre 0341 is located in central London. The centre has held a treatment (including embryo testing) and storage licence with the HFEA since May 2015 and provides a full range of fertility services.

History of non-compliance:

Renewal Inspection - December 2016

4.2. A licence renewal inspection was carried out at the centre in December 2016. The centre's licence was renewed for a period of four years with no additional conditions, from 22 May 2017 to 21 May 2021.

Interim inspection (Unannounced) - 28 March 2019

4.3. An interim inspection was carried out at the centre on 28 March 2019 and six major non-compliances were identified. Two of the major non-compliances relating to medicines management and patient information on reproductive immunology treatments, were also identified at the renewal inspection and therefore upgraded to critical. The remaining four major non-compliances related to gas storage facilities, staff qualifications and competency, implementation of Code of Practice guidance and clinical waste and infection control regulations.

4.4. The report of this interim inspection was considered by the Licence Committee at its meeting in September 2019. The committee noted that since the inspection visit the PR had provided evidence that action had been taken to address the major non-compliance relating to gas storage facilities. The PR had committed to fully implementing all of the other recommendations to address the critical and major areas of non-compliance. The committee noted that the Executive had a number of concerns regarding intralipid therapy, including patient information, staff competency and processes. The committee recommended that the centre voluntarily suspends intralipid treatment for all patients until the Executive was satisfied that the centre was following HFEA guidance and implements the recommendations. The committee endorsed the Executive's recommendation for the continuation of the centre's licence. The committee agreed that the Executive should complete an unannounced interim inspection within twelve months of the interim inspection which was carried out on 28 March 2019, to focus on the non-compliances identified in the interim inspection report and ensure compliance had been maintained and corrective action was effective. The committee also agreed that the report of the unannounced interim inspection should be considered by the Licence Committee to oversee that patient information was revised and satisfactory and that staff had been trained and are competent to provide the relevant treatments available to patients.

Executive Update to Licence Committee – 7 November 2019

4.5. At its meeting on 7 November 2019, the Licence Committee considered the Executive's update on the centre's progress with implementation of the recommendations detailed in the unannounced interim inspection report. The PR had implemented the recommendations to address the two critical and four major areas of non-compliance and there was one action to be completed relating to staffing. The Executive had provided the PR with further guidance in the area of intralipid infusion to ensure that information about reproductive immunology treatments provided to patients is compliant with HFEA guidance. The committee was satisfied that the Executive had plans to monitor the centre's compliance in a number of areas of practice and complete a further unannounced interim inspection.

Additional Focused Unannounced Interim Inspection – 11 February 2020

4.6. The Executive carried out an additional focused unannounced interim inspection on 11 February 2020 to focus on the non-compliances identified in the interim inspection report and ensure compliance had been maintained and corrective action was effective.

4.7. At the time of inspection, one major area of non-compliance relating to medicine management and two other areas of non-compliance relating to compressed gas storage facilities and the submission of data to the HFEA were identified.

4.8. The PR had provided evidence that action had been taken to implement the recommendations and had committed, where required, to audit the effectiveness of action taken within the required timescales.

4.9. At its meeting on 9 July 2020 the Licence Committee considered the report of the additional focused unannounced interim inspection carried out on 11 February 2020.

4.10. The committee noted that the Executive was satisfied that the centre had addressed the non-compliances relating to medicines management, off label' use of intralipid therapy, storage of gas cylinders, staffing, QMS, infection control and submission of data to the HFEA.

4.11. The centre's performance data between 1 December 2018 and 30 November 2019, in relation to multiple live births, showed that performance was not likely to be statistically different from the 10% maximum multiple live birth rate target for that period. The committee questioned the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups which was reported to be 26% and appeared to be high in relation to the expected outcome for live births. Therefore, the committee requested that the centre's most recent actual multiple live birth rate was included in the report of the centre's forthcoming licence renewal inspection.

4.12. The committee noted the progress the centre had made over the last year to address concerns regarding the level of compliance and endorsed the Executive's recommendation for the continuation of the centre's treatment (including embryo testing) and storage licence.

Timescales

4.13. In accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic, centres were required to suspend fertility treatments for a short period of time. Therefore, the Executive planned to liaise with the PR to consider appropriate timescales to fully implement outstanding recommendations.

5. Consideration of application

Renewal Inspection

Application

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

5.2. 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

5.3. The committee noted that the renewal inspection report covers the performance of the centre since the last inspection and the findings from the renewal desk-based assessment.

5.4. The committee noted that in the 12 months to July 2020, the centre provided 105 cycles of treatment (excluding partner intrauterine insemination). The Covid-19 pandemic and suspension of fertility treatment across the sector had impacted on cycle numbers, however taking this into account, in relation to activity levels this is a small centre.

5.5. The committee noted that HFEA-held register data for the period September 2019 to August 2020 showed the centre's success rates for IVF and ICSI, were in line with national averages.

5.6. The committee noted that in 2019, the centre reported 10 cycles of partner insemination with three pregnancies which was in line with the national average.

5.7. The committee noted that between September 2019 to August 2020 the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 14%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

5.8. The committee noted that the PR had provided information and evidence that all of the recommendations following the interim inspection in February 2020 were fully implemented.

5.9. The committee noted that at the time of the renewal inspection on 24 November 2020 there were two other areas of non-compliance identified:

Other areas of non-compliance:

- The PR should ensure that audit reports clearly define the audit criteria, scope and methods used. The date that audits are performed and the date corrective action is taken must be accurately documented.
- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.

5.10. The committee noted that since the inspection visit, the PR has committed to fully implementing the recommendations.

5.11. The Executive reported sustained improvement in the level of compliance demonstrated by this centre.

5.12. The committee noted that 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

5.13. The committee noted that the Executive recommended 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.

Importing Tissue Establishment (ITE) import certificate

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

6. Decision

6.1. The committee had regard to its decision tree.

Administrative Requirements

Supporting Information under General Direction 0008

Application

6.2. 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 Amin Gorgy

6.3. 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 his duties under section 17 of the HF&E Act 1990 (as amended).

Proposed Licence Holder (LH) – Dr Adel Eskander

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

Activities

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

Premises – 57A, Wimpole Street, London, W1G 8YP

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

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

Licence

6.8. 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 22 May 2021 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

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

Multiple Births

6.10. The committee had concerns about the actual number of multiple live births resulting from the centre's performance between 1 December 2018 to 30 November 2019 as the data provided in the report of the interim inspection on 11 February 2020 showed that there was a high number of pregnancies compared to the expected number of live births.

6.11. The Executive submitted further information on data provided by the centre during the renewal inspection which confirmed that the multiple live birth rate for 2018 was 6%. However, the data for 2019 was not available at the time of the inspection.

Monitoring

6.12. The committee deliberated on the information provided by the Executive. The committee was not satisfied that it had received sufficient information to be assured that the centre's performance for multiple births is compliant and requested that the Executive reviews the actual multiple live birth rate data for the period 1 December 2018 to 30 November 2019, when it becomes available, and provides the Licence Committee with an update.

7. Chair's signature

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

Signature

Name

Jonathan Herring

Date

23 March 2021

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The 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. The inspection was conducted via a Desk Based Assessment using a Risk Based Approach (DBA/RBA) combined with an on-site visit.

Date of inspection: 24 November 2020

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

Inspection details: The report covers the performance of the centre since the last inspection, findings from the desk based assessment and the inspection visit

Inspectors: Sara Parlett (lead), Nicola Lawrence and Lesley Brown

Date of Licence Committee: 4 March 2021

Centre name	The Fertility and Gynaecology Academy
Centre number	0341
Licence number	L/0341/2/a
Centre address	57A, Wimpole Street, London, W1G 8YP
Person Responsible	Dr Amin Gorgy
Licence Holder	Dr Adel Eskander
Date licence issued	22/05/2017
Licence expiry date	21/05/2021
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
The Fertility and Gynaecology Academy is located in central London and has held a Treatment (including embryo testing) and Storage licence with the HFEA since 2015.

The centre provides a full range of fertility services.

The centre provided 105 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to July 2020. The Covid-19 pandemic and suspension of fertility treatment across the sector has impacted on cycle numbers, but taking this into account, in relation to activity levels, this is a small centre**.**

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

The centre's licence was last renewed in March 2017 for a period of four years with no additional conditions. An interim inspection of the centre in March 2019 found six major non-compliances, two of which had recurred after having been noted at the licence renewal inspection in December 2016.

In line with the HFEA Compliance Assessment Framework, the two recurring major non-compliances were upgraded to critical non-compliances. Thus, two critical non-compliances were noted regarding: medicines management and patient information about the 'off label' use of intralipid therapy.

Subsequently the Chief Inspector met with the Person Responsible (PR) to discuss the centre's progress since licensing and the HFEA's concerns regarding the centre's level of non-compliance. The PR committed to address the inspection report's concerns.

A report of the interim inspection was considered by Licence Committee (LC) in September 2019 and LC requested an update, which was considered in November 2019. The LC subsequently required that an additional focused inspection be carried out within a year to review the progress made in addressing non compliance at the centre and that a report of the inspection be provided to the LC. That further inspection was performed in February 2020 and was considered by LC in July 2020. One major and two 'other' areas of non compliance were identified. The PR provided evidence that action had been taken to implement the recommendations following the inspection. The committee noted the progress the centre has made over the last year to address concerns regarding the level of compliance. The committee requested that the report of the renewal inspection is submitted to LC for consideration.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period September 2019 to August 2020 show the centre's success rates are in line with national averages.

In 2019, the centre reported 10 cycles of partner insemination with three pregnancies which is in line with the national average.

Multiple births[2]

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

Between September 2019 to August 2020 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

The licence committee, considering the centre's additional focussed inspection report on 9 July 2020, stated:

'The committee noted that the centre's performance, in relation to multiple births, shows that it is not likely to be statistically different from the 10% maximum multiple live birth rate target for that period. However, the committee also noted that the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 26%, which does appear to be high. Therefore, the committee has requested that the centre's most recent actual multiple live birth rate is included in the report of the centre's forthcoming licence renewal inspection.'

The most current verified multiple birth rate data available on the HFEA website is from 2017 and is 3%.

More current data was provided by the centre during this inspection process. Their multiple birth rate for 2018 is 6%. 2019 data was not yet available at the time of the inspection.

Therefore, the centre's multiple live birth rate for 2018 and 2019 is below 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 his 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 'other' areas of non compliance which have resulted in the following recommendations.

Since the inspection visit, the PR has given a commitment to fully implement both of the following recommendations:

'Other' areas that requires improvement:

- The PR should ensure that audit reports clearly define the audit criteria, scope and methods used. The date that audits are performed and the date corrective action is taken must be accurately documented.
- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.

Recommendation to the Licence Committee

The centre has no critical or major areas of non-compliance.

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/live birth rates meet or are below the target. The PR is encouraged to continue to use the quality management system (QMS) to best effect to monitor and improve their success rates and the quality of the service offered to patients.

The centre is well led and provides a good level of patient support. The inspection team notes the sustained improvement in the level of compliance demonstrated at this clinic.

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 0341 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 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
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 satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited

by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are 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 progress and

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

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

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

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

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

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

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements.

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. The centre has been allocated an ITE import certificate and imports of gametes and embryos from TCSs outside the EU/EEA have been made since the introduction of the ITE import certification scheme on 1 April 2018. An import of frozen patient sperm from a TCS which was not specified on the centre's ITE import certificate was made in October 2019. The clinic reported this as an incident to the HFEA and applied for an ITE retrospectively. Clinic processes were reviewed and are now 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 broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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

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

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

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

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Quality management system (QMS) (Guidance note 23)

Audit reports submitted by the clinic for the DBA/RBA part of the inspection process did not provide sufficient assurance to the inspection team that clinic processes were compliant with regulatory requirements, their own approved protocols and quality indicators.

This was because the reports did not include details of audit scope and methodology, for example:

- an audit report of donor gametes in treatment in 2020 was provided. The report states that five egg donors and three sperm donors were included in the audit. However, the report does not provide any other detail of what the audit looked at.
- An audit of legal parenthood in Jan 2020 gave no information on what was audited apart from stating 'all consents and EDI are completed according to the HFEA CoP'.

There was also a general lack of attention to detail in the audit reports, especially with respect to recorded dates. For example: a welfare of the child assessment audit was recorded as being performed on 27 January 2020, but with the results of that report being discussed at a clinic meeting on 9 January 2020.

However, overall, a good level of compliance with regulatory requirements was noted on inspection, as documented throughout this inspection report. The inspection team is therefore of the opinion that audits of practice are conducted appropriately, but with poor documentation of the audit criteria, scope and methods and with a lack of attention to detail (SLC T36; CoP Guidance 23.20). Recommendation 1.

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 compliant with HFEA guidance regarding effective leadership.

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

Staff (Guidance note 2)

The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services.

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

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

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10)
The centre's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

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

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

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

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Fifteen 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. The majority of patients confirmed that they had paid what they expected to.

The centre's own most recent patient survey responses were also reviewed. Feedback was positive.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Patient support
Counselling
Egg [and sperm] sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

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

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

Patient support (Guidance note 3)

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

to assist them. Patient feedback should be collected to enhance the patient support procedures.

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

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

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The clinic does not provide egg sharing services.

Surrogacy (Guidance note 14)
The centre has not performed treatments involving surrogacy in the last two years. The centre's SOP has not been reviewed and updated to reflect guidance issued by the Department of Health and Social Care: 'Care in Surrogacy' and 'The Surrogacy Pathway', nor does it include accurate information about who can apply for a parental order. It states that only couples can apply for a parental order, however the law changed in January 2019 to allow single people to apply for a parental order. The PR acknowledges this and has confirmed that the SOP will be reviewed and updated prior to any further surrogacy treatment taking place.

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

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

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

Information

What the centre does well

Information (Guidance note 4)
The centre's procedures for providing information to patients and/or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

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

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

What the centre does well

Consent (Guidance note 5;6)
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 last inspection in February 2020, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Three sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements. However, refer to the QMS section of this report and the non compliance regarding audit report documentation.

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 broadly 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

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Five discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register in ten consent forms audited. Therefore the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure. This failing leads to a risk that

the HFEA may release patient identifying information, to researchers, without consent. CH(10)05 and General Direction 0005 (5). Recommendation 2.

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 compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

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

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

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

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

Section 3: Monitoring of the centre's performance

Following the interim inspection in February 2020, recommendations for improvement were made in relation to one area of major non compliance and two 'other' areas of non compliance.

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

On-going monitoring of centre success rates

The centre has not received any risk tool alerts relating to success rates in the last year.

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 noted.			

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
None noted.			

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
1. Quality management system: audit Audit reports submitted by the clinic for the DBA/RBA part of the inspection process did not provide sufficient assurance to the inspection team that clinic processes were compliant with regulatory requirements, their own approved protocols and quality indicators. However, overall, a good level of compliance with regulatory requirements was noted on inspection. The inspection team is therefore of the opinion that audits of practice are conducted appropriately, but with poor documentation of the audit	The PR should ensure that audit reports clearly define the audit criteria, scope and methods used. The date that audits are performed, and the date corrective action is taken, must be accurately documented. The PR should review the centre's processes for documenting audits performed. A summary of the actions taken should be provided to the centre's inspector by 24 February 2021. It is expected that the consent to disclosure audits required under recommendation 2 will demonstrate the	We are reviewing and revising the internal audit SOP and the internal audit template form to ensure that they comply with the section 23.20 and T36 of the Code of Practice. All relevant staff will be re-trained to ensure compliance and this training will be documented. The Quality Manager will continue to review audits following these chnages to ensure that the required changes are being implemented.	The executive acknowledges the PR's response and commitment to implementing this recommendation. **Further action is required.**

criteria, scope and methods and with a lack of attention to detail. SLC T36; CoP Guidance 23.20.	improvement that is required.		
2. **Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)** Five discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register in ten consent forms audited. CH(10)05 and General Direction 0005.	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register. The PR should confirm that the incorrect submissions identified have been corrected when responding to this report. The PR should review the centre's procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's	The consents to disclosure to researchers errors identified will be reviewed and corrected where needed and appropriate staff training will take place in order to remove these errors in the future. This process will be completed and documented to the HFEA by April 30th 2021. A follow up audit will be carried out on July 30th to ensure that there have been no further errors following the revisions and re-training completed on April 30th above. A horizontal retrospective audit covering all consent to disclosure submissions since the clinic began operations will be carried out. Corrections will be made where necessary. This is a major project and we will endeavour to meet the	The executive acknowledges the PR's response and commitment to implementing this recommendation. The details of the errors identified were indeed only provided to the centre on 26 February 2021, for which the executive apologises. Therefore, the executive agrees that the timescales for completion of the requested actions should be extended. The executive will liaise with the PR regarding new timescales once the PR has verified the HFEA's audit findings. **Further action is required.**

	inspector by 24 February 2021. Three months after corrective actions have been implemented, the PR should audit practice to ensure actions taken have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 24 May 2021. Due to the high error rate noted, it is considered proportionate to request that a wider retrospective audit of consent to disclosure submissions is performed. The PR should audit **all** consent to disclosure submissions to the HFEA since the centre was first licensed and correct any inaccuracies found. It is acknowledged that this will take time, therefore a summary report of this audit should be provided to the centre's inspector by 24 August 2021.	August 24th deadline set for this work. The following response from the PR was sent to the lead inspector by email on 26 February 2021, further to his previous response above which was provided on 17 February 2021: 'The list of the patient and partner numbers of the following findings were not given to the PR or any of the staff of the Fertility & Gynaecology Academy until today; 26 Feb 2021. "Five discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register in ten consent forms audited" Therefore we cannot correct any of these findings. We also withhold the proposed action above until we receive and verify this list of patients.'	

Reponses from the Person Responsible to this inspection report