Executive Licensing Panel Minutes

Centre 0086 (Kent Fertility Centre)

Renewal Inspection Report

Date:	24 August 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Joanne Anton Kathleen Sarsfield-Watson	Director of Strategy and Corporate Affairs Head of Policy (Job-share) Communications Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood	Licensing Manager

Declarations of interest

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

The panel had before it:

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

1. Consideration of Application

1.1. The panel considered the papers, which included a completed application form, inspection report and licensing minutes for the last five years.

1.2. The panel noted that Kent Fertility Centre, previously known as BMI Chelsfield Park ACU, is located in Orpington and has held a treatment and storage licence with the HFEA since 1992. The centre provides a full range of fertility services, which do not include embryo testing.

1.3. The panel noted that, in the 12 months to 31 May 2021, the centre provided 151 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a small sized centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom is likely to have impacted on treatment numbers during 2020.

1.4. The panel noted that, HFEA register data, for the period 1 March 2020 to 28 February 2021, show the centre's success rates for IVF and ICSI are in line with the national averages, with the following exception:

- Pregnancy rate per fresh cycles (ICSI-only) in patients under 38 years old using their own eggs in treatment are lower than national average at a statistically significant level at the time of the inspection.

1.5. The panel noted that, in 2020, the centre reported that no treatments with partner insemination had been conducted.

1.6. The panel noted that HFEA data, between 1 March 2020 and 28 February 2021, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 7%. This represents performance that is not likely to be statistically lower than the 10% multiple live birth rate target for this period.

1.7. The panel noted that, in November 2019, The Hospital Fertility Group (THFG) took ownership of the Sussex Downs Fertility Centre (HFEA licensed centre 0015). On 30 September 2020, the Person Responsible (PR) of centre 0086, at that time, informed the HFEA that there was to be an imminent change in centre ownership from BMI Healthcare to THFG; there was a plan to relocate the centre to new premises in 'a few months' time'. In order to continue treatment activity at the centre, THFG leased the centre's premises from BMI Healthcare until the relocation. The transfer of ownership was initially planned on 1 November 2020 and was completed on 21 December 2020.

1.8. The panel noted that, in October 2020, the HFEA was notified that the PR, at that time, was no longer able to conduct his duties; a short notice application, for a change of PR, was considered and approved by the Executive Licensing Panel (ELP) on 2 November 2020.

1.9. The panel noted that, on 13 April 2021, the new PR informed the HFEA of her resignation, stating she was leaving the centre within a week. Several meetings were held between the HFEA and PR, the Licence Holder (LH) and THFG management, with no change of PR application form submitted. On 21 April 2021, the HFEA received a request from the centre's legal representative that a change of PR application should be considered with urgency; no such application was received.

1.10. The panel noted that on 22 April 2021, the executive held a management review meeting in accordance with the HFEA Compliance and Enforcement Policy (effective at that time), which

discussed concerns about the possible lack of a PR and effective leadership at centres 0086 and 0015; the executive had significant concerns regarding staffing at centre 0015 and its potential impact on staffing levels at centre 0086. The executive and HFEA's Director of Compliance concluded that, events since 29 December 2020, when centre 0086 had submitted its application to extend the duration of the treatment and storage licence, meant that the assessment of that application by the inspection team was incomplete because it had not considered the latest critical information and risks. Papers submitted to the ELP of 4 May 2021, related to the licence extension application, were therefore withdrawn.

1.11. The panel noted that it was also agreed, on 28 April 2021, that it was proportionate to undertake an on-site un-announced inspection to assess and evaluate whether the PR was in a position to discharge her duties, whether there were sufficient numbers of qualified staff and to ascertain that practices remained safe at the centre.

1.12. The panel noted that, on 29 April 2021, the centre's PR informed the HFEA that she had been reinstated to her post, confirming she was able to continue to fulfil her duties until 11 June 2021. An application to change the PR was approved by ELP on 1 June 2021. The new PR is also the newly appointed PR at centre 0015.

1.13. The panel noted that as centres 0015 and 0086 are both owned by THFG, this overarching body aims to coordinate processes between these centres and ensure staff are able to support both centres in 'emergency' situations. However, in considering the on-site inspection of the centre, the HFEA's 'Group approach' for inspections was not recommended as there is currently no demonstrative evidence that an integrated quality management system (QMS) is yet in place within this group.

1.14. The panel noted that an unannounced inspection occurred on 11 May 2021 and initial findings indicated that further review of the centre was necessary to assess the licence renewal application. Due to concerns identified at this inspection, and in accordance the HFEA's Compliance and Enforcement Policy (effective at that time), a management review meeting was held on 17 May 2021 to evaluate the findings of the additional un-announced inspection and to consider a proportionate course of action.

1.15. The panel noted that, following the management review held on 17 May 2021, the executive concluded they had not been provided with suitable assurances with regards to the leadership at the centre nor that the centre had robust systems in place to manage consents to storage for all cryo-preserved materials. The robustness of governance systems to ensure the compliance of staffing resources for the treatment activity undertaken was also a concern. It was therefore agreed to undertake an announced on-site licence renewal inspection as a priority; the findings of the un-announced inspection would be considered and reported alongside the findings of the renewal inspection.

1.16. The panel noted that, an announced on-site renewal inspection was undertaken on 10 June 2021. The outcomes of the initial un-announced inspection are considered alongside the renewal inspection findings in the report presented for consideration.

1.17. The panel noted that, at time of the inspections, there were five major areas of non-compliance concerning the safety and suitability of premises and facilities, medicines management, the QMS, staffing and consent to storage. There were also three 'other' non-compliances regarding infection control, transport and distribution of gametes and embryos and third-party agreements.

1.18. The panel noted that, since the renewal inspection, the PR has provided evidence that actions have been taken to implement the recommendations concerning medicines management, the QMS, staffing, consent to storage, infection control, transport and distribution of gametes and embryos and third-party agreements, and has committed, where required, to audit the effectiveness of those actions within the required timescales. The PR challenged the recommendation in relation to the suitability of premises and facilities.

1.19. The panel noted that, in accordance with the HFEA's Compliance and Enforcement Policy (effective from 1 June 2021), the non-compliances identified at the inspections on 11 May 2021 and 10 June 2021 which were considered to pose a particular risk to patients (i.e., staffing and storage of gametes and embryos) were reviewed by the inspection team on 15 June 2021. Subsequently (and in accordance with the HFEA's Compliance and Enforcement Policy, the PR's responses to the report were reviewed by the inspection team on 4 August 2021 to reach a decision regarding the recommendation for the renewal of the centre's licence.

1.20. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a QMS, and the PR is encouraged to use it to best effect to monitor and improve their success rates and continue to manage their multiple pregnancy rate, so to improve the quality of the service offered to patients.

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

1.22. The panel noted that the inspection team recommends the renewal of the centre's treatment and storage licence, for a period of three years, as opposed to the usual four years, without additional conditions, reflecting concerns about the centre's level of non-compliance. This will allow a targeted interim inspection to be performed within 12 months of the renewed licence coming into force, to assess the centre's compliance generally and with regards to the implementation of this report's recommendations.

1.23. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to section 24(4AD). Such certificates are generally synchronised to the centre's HFEA licence. The executive therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

2.2. The panel noted that the premises to be licensed are suitable for the conduct of licensed activity.

2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel encouraged the PR to work collaboratively with the inspection team, ensuring all the non-compliances, identified in the reports, are addressed within the prescribed timescales.

2.5. The panel voiced particular concerns regarding the stability in staffing levels and impact this might have on the centre's activity levels; the PR had been asked to submit monthly staffing

rotas and organisational charts to the inspectorate. This area of non-compliance will be a focus at the change of premises inspection, when the centre relocates, in due course.

2.6. The panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of three years, without additional conditions, reflecting concerns about the centre's level of non-compliance. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

2.7. The panel agreed that a targeted interim inspection should be performed within 12 months of the renewed licence coming into force, to assess the centre's compliance generally and with regards to the implementation of the renewal report's recommendations.

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

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

31 August 2021

Inspection Report

Purpose of the Inspection Report

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

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

The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspections: 11 May 2021 and 10 June 2021

Purpose of the inspections: Renewal of a licence to carry out treatment and storage.

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

Inspectors: Rachel Cutting (Director of Compliance) and Sandrine Oakes (lead) (un-announced inspection on 11 May 2021); Sandrine Oakes (lead), Karen Conyers and Polly Todd (announced inspection on 10 June 2021)

Date of Executive Licensing Panel: 24 August 2021

Centre name	Kent Fertility Centre
Centre number	0086
Licence number	L/0086/18/g
Centre address	Bucks Cross Road, Chelsfield, Orpington, Kent, BR6 7RG, United Kingdom
Person Responsible	Mr David Chui
Licence Holder	Mrs Kuljit Moore-Juneja
Date licence issued	1 October 2017
Licence expiry date	30 September 2021
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Kent Fertility Centre, previously known as BMI Chelsfield Park ACU, is located in Orpington and has held a Treatment and Storage licence with the HFEA since 1992. The centre provides a full range of fertility services, which do not include embryo testing.

The centre provided 151 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2021. In relation to activity levels this is a small centre**.** The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom is likely to have had an impact on treatment numbers.

There have been several significant changes at the centre since September 2020 and the current licence has been varied to reflect the following changes:

- 10 June 2021 – change of centre name
- 1 June 2021 – change of Person Responsible (PR)
- 13 May 2021 – change of Licence Holder (LH)
- 4 March 2021 – all centres: variation of licences without application (European Union (EU) Exit requirements)
- 13 January 2021 - change of LH
- 2 November 2020 - change of PR

In November 2019, The Hospital Fertility Group (THFG) took ownership of the Sussex Downs Fertility Centre (HFEA licensed centre 0015). On 30 September 2020, the PR of centre 0086 at that time informed the HFEA that there was to be an imminent change in centre ownership from BMI Healthcare to THFG; and that there was a plan to relocate the centre to new premises in ‘a few months’ time’. In order to continue treatment activity at the centre, THFG leased the centre’s premises from BMI Healthcare until the relocation. The transfer of ownership was initially planned on 1 November 2020 and was completed on 21 December 2020.

On 26 October 2020, the PR of centre 0086 at that time notified the HFEA that he had resigned from his position and would not be able to discharge his duties from 1 November 2020. In view of this, an application to change the PR of centre 0086 was considered and approved by an ELP at short notice on 2 November 2020.

On 29 December 2020, an application to extend the duration of the treatment and storage licence was received. In view of the ongoing Covid-19 pandemic, the executive considered that the application could be assessed by the inspection team in accordance with the ‘Procedure for risk-based inspection during the COVID- 19 pandemic: Licence Extension, Desk Based Assessment and postponement of inspections’. Papers were submitted to ELP to be considered on 4 May 2021.

On 13 April 2021, the PR of the centre at that time (who was also the PR at centre 0015) informed the executive that she had resigned. The next day, she informed the HFEA that she had been asked to leave her post within a week, before the end of her notice period, and had been asked to relinquish her company equipment such as her computer.

Between 13 April 2021 and 29 April 2021 there were several meetings and communications between the HFEA, the PR at the time, the LH and THFG management. In view of this, and since no application to change the PR was made by the LH, significant concerns were raised as to whether there was a PR at the centre to oversee activities.

On 21 April 2021, the HFEA received a request from the centre's legal representative that a change of PR application made by the centre should be considered as a matter of urgency to ensure continuity of care for patients. However, no such application was received.

Therefore, on 22 April 2021, the executive held a management review meeting in accordance with the HFEA Compliance and Enforcement Policy (effective at that time), which discussed concerns about the possible lack of a PR and effective leadership at both centres 0086 and 0015. Furthermore, the executive had significant concerns regarding staffing at centre 0015 and its potential impact on staffing levels at centre 0086. The executive and HFEA's Director of Compliance concluded that events since 29 December 2020, when centre 0086 had submitted its application to extend the duration of the treatment and storage licence, meant that the assessment of that application by the inspection team was incomplete because it had not considered the latest critical information and risks. The papers submitted to the ELP of 4 May 2021 related to the licence extension application were therefore withdrawn. It was also further agreed on 28 April 2021 that it was proportionate to undertake an on-site un-announced inspection to assess and evaluate whether the PR was in a position to discharge her duties, whether there were sufficient numbers of qualified staff and to ascertain that practices remained safe at the centre.

On 29 April 2021, the PR at that time informed the centre's inspector that she had been reinstated in her post at centre 0086; and she confirmed that she was in a position to continue to fulfil her duties as PR until the end of her notice period which was 11 June 2021.

An application to change the PR of centre 0086 was approved by ELP on 1 June 2021. The new PR is also the newly appointed PR at centre 0015.

The inspection team recognises that centres 0015 and 0086 are both owned by THFG, that THFG aims to coordinate processes between centres 0015 and 0086; and that staff are able to support both centres in 'emergency' situations. However, in considering the on-site inspection of the centre, the HFEA's 'Group approach' for inspections was not recommended because there is currently no demonstrative evidence that an integrated quality management system (QMS) is yet in place within this group.

An un-announced inspection took place on 11 May 2021. Initial findings indicated that further review of the centre was necessary to assess the licence renewal application. Therefore, an announced on-site renewal inspection was undertaken on 10 June 2021. The findings of the initial un-announced inspection are considered alongside the renewal inspection findings in this report.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period between 1 March 2020 and 28 February 2021 show the centre's success rates are in line with national averages with the following exception:

- Pregnancy rate per fresh cycles (ICSI-only) in patients under 38 years old using their own eggs in treatment are lower than national average at a statistically significant level at the time of the inspection. This is discussed further in the 'On-going monitoring of centre success rates' section below.

The centre reported that no treatments with partner insemination had been carried out in 2020.

Multiple births[2]

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

Between 1 March 2020 and 28 February 2021, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 7%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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

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

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the current PR was approved by ELP on 1 June 2021 and is considered to have discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable with the exception noted in the main body of the report;
- the centre's practices are suitable with the exceptions noted in the main body of the report;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including five major and three 'other' areas of non-compliance.

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 medicines management practice is compliant with regulatory requirements and best practice guidance.
- The PR should ensure that the QMS is effective and fit for purpose.
- The PR should ensure that personnel are available in sufficient number and are qualified and competent for the tasks they perform; staff competence must be evaluated at appropriate intervals.
- The PR should ensure there is effective consent in place for all cryopreserved gametes and embryos in storage at the centre.

'Other' areas that require improvement:

- The PR should ensure that information directing the actions to be taken in the event of a needlestick injury are readily available in all areas where these injuries may occur.
- The PR should ensure that the centre's standard operative procedures (SOP) for transporting gamete and embryos discuss practices which allow the centre to meet the relevant licence condition requirements.
- The PR should evaluate and select third-parties on the basis of their ability to meet the requirements of these licence conditions and the guidance set out in the HFEA (CoP).

The PR has challenged the following recommendation to:

Major areas of non-compliance:

- The PR should ensure that all medical gases are stored safely at all times.

Recommendation to the Executive Licensing Panel

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

The inspection team notes that the success rates for fresh cycles (ICSI-only) in patients under 38 years old using their own eggs in treatment have recently been below the national average but that the centre's multiple clinical pregnancy/live birth rates are likely to meet the target.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a QMS, and the PR is encouraged to use it to best effect to monitor and improve their success rates and continue to manage their multiple pregnancy rate, so as to improve the quality of the service offered to patients.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

The centre provides a good level of patient support.

Following concerns at the un-announced inspection on 11 May 2021, and in accordance the HFEA's Compliance and Enforcement Policy (effective at that time), a management review meeting was held on 17 May 2021 to evaluate the findings of the additional un-announced inspection and to consider a proportionate course of action. Following the management review, it was concluded that the executive had not been provided with suitable assurances with regards to the leadership at the centre nor that the centre had robust systems in place to manage consents to storage for all cryo-preserved materials. The robustness of governance systems to ensure the compliance of staffing resources for the treatment activity undertaken was also a concern. It was therefore agreed to undertake an announced on-site licence renewal inspection as a priority; and that the findings of the un-announced inspection would be considered and reported alongside the findings of the renewal inspection. The announced renewal inspection was carried out on 10 June 2021.

In accordance with the HFEA's Compliance and Enforcement Policy (effective from 1 June 2021), the non-compliances identified at the inspections on 11 May 2021 and 10 June 2021 which were considered to pose a particular risk to patients (i.e., staffing and storage of gametes and embryos) were reviewed by the inspection team on 15 June 2021. Subsequently (and in accordance with the HFEA's Compliance and Enforcement Policy (effective from 1 June 2021)), the PR's responses to the report were reviewed by the inspection team on 4 August 2021 to reach a decision regarding the recommendation for the renewal of the centre's licence.

The inspection team recommends the renewal of the centre's 'Treatment and Storage' licence for a period of three years, rather than the usual four, reflecting concerns about the centre's level of non-compliance. This will allow a targeted interim inspection to be performed within 12 months of the renewed licence coming into force, to assess the centre's compliance generally and with regards to the implementation of this report's recommendations.

Centre 0086 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

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

What the centre does well

Screening of donors (Guidance note 11)
This centre does not undertake donor recruitment and therefore requirements related to these procedures were not relevant at this inspection.

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)
It is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose. The centre's premises are partially suitable.

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

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

The centre is compliant with HFEA requirements to process gametes and/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 broadly compliant with guidance.

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

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

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

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

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

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

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are broadly compliant with HFEA requirements. It 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, except for the concern noted in the 'Transport and distribution of gametes and embryos' section of this report.

The Human Fertilisation and Embryology Act 1990 (as amended) has since 1 April 2018 incorporated 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 in third countries, 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 have been made since the introduction of the ITE import certification scheme on 1 April 2018. These imports have been made in a manner compliant with General Direction 0006(GB).

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 establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services. The centre has a QMS that is partially compliant with HFEA requirements.

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)

The centre currently does not have any transport and satellite arrangements therefore requirements related to these procedures were not relevant at this inspection.

Equipment and materials (Guidance note 26)

The centre uses equipment and materials that are compliant with HFEA requirements. All 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

Safety and suitability of premises and facilities (Guidance note 25)

At the inspection on 11 May 2021, two small gas cylinders supplying the benchtop incubators were noted to be freestanding under the laboratory bench. This was highlighted as an issue to the PR at that time, the LH and the Senior Embryologist. However, at the inspection on 10 June 2021, the two cylinders remained unsecured; and no actions appeared to have been taken to secure them (SLC T17; Department of Health (DH) Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006) sections 8.77 to 8.79).

Recommendation 1.

Infection control (Guidance Note 25)

At the renewal inspection on 10 June 2021, it was noted that information directing the actions to be taken in the event of a needlestick injury is held on the electronic document system but is not readily available in all areas where these injuries may occur. Such injuries are associated with potential exposure to infectious agents and syringe contents; and it is therefore important that information detailing actions to be taken in the event of injury is readily available in all areas where those injuries may occur (SLC T2).

Recommendation 6.

Medicines management (Guidance Note 25)

Whilst it was noted that the centre had acted on findings discussed at the inspection on 11 May 2021, the following issues were noted at the renewal inspection on 10 June 2021:

- The controlled drug (CD) register is not bound, a number of pages were already coming loose (pages 9 -14 and 53 -56) and pages 6 & 7 were secured using surgical tape; CD registers should be so designed as to preserve the records they contain for a period of two years from the date of the last entry;
- In one patient record, the amount of drug recorded as having been given to the patient did not match the amount recorded in the CD register for the same administration;
- In several patients' records, the concentration of drug given to the patient was not recorded (SLC T2; Dangerous Drugs 'The Misuse of Drugs Regulations 2001', Interpretation, regulations 19 and 23; DH 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007)(section 4.7.1.1).

Recommendation 2.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
At the renewal inspection on 10 June 2021, the centre's standard operative procedure (SOP) for transport of gametes and embryos, including import and export, was reviewed and it did not define specifications for all transport conditions as per SLC T107; ensure that all required information is provided when distributing material (SLC T110); or ensure that shipping containers are appropriately secured (SLC T108) and packaged (SLC T105).

The inspection team was also concerned that the centre could not provide reassurance that the SOP was to be updated to account for the changes to General Direction 0006(GB) being made on 30 June 2021, altering the definition of 'third country'. This did not reflect as a non-compliance at the time of the inspection, but the inspection team suggests that the PR ensures the necessary revisions to the SOP are made.

The inspection team notes that the centre has not undertaken any import or export of material since December 2019; and none are planned in the foreseeable future, minimising the risk of potential future non-compliance.

Recommendation 7.

Quality management system (QMS) (Guidance note 23)
On the day of the renewal inspection on 10 June 2021, the following issues were identified:
- Several audits did not have documented corrective and preventative actions (CAPA) and/or dates for implementation and completion (data submission; traceability; medicines management; record keeping) (SLC T36);
- The data submission SOP did not document quality indicators or the timescale for records to be submitted to the Authority in relation to the patient/partner registration forms and donor information (General Direction 0005; SLC T35);
- Several SOPs did not indicate the last and/or next review date and/or have not been reviewed within the required time frames as per local policy (consent, screening for staff, ACU lab 024, calibration EMB 031, Business continuity plan (SLC T33b)).

Recommendation 3.

Third-party agreements (Guidance note 24)

At the renewal inspection on 10 June 2021, the third-party agreement (TPA) with a supplier that provides a courier service for cryopreserved gametes and embryos was reviewed and found to have been established by the previous PR and owners of the centre; and did not identify the centre's new person responsible for managing the arrangement between the centre and the third party (SLC T114b). Furthermore, the TPA had not been reviewed by its set review date; therefore, the inspection team could not be assured of the ability of that supplier to meet the requirements of the relevant licence conditions (SLC T112).

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 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
There was no PR discharging the specified legal duties under section 17 of the HF&E Act 1990 (as amended) at centre 0086 from 14 to 29 April 2021. A new PR, who is experienced and has been the PR at centre 0015 for some years, notwithstanding a short hiatus between January and April 2021, was subsequently approved by the HFEA on 1 June 2021. The inspection team has not got sufficient information to report on the new PR's leadership at centre 0086 at this time. It is however expected that the PR will discharge his duties at the centre.

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

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

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

What the centre could do better

Staff (Guidance note 2)
The robustness of governance systems to ensure the compliance of staffing resources for the treatment activity undertaken was a concern at the inspection on 11 May 2021. At the renewal inspection on 10 June 2021, the following issues were noted:

- Significant turnover of clinical staff leaving just one permanent qualified nurse at the centre;
- There are no competence assessments for the nurse in post for the provision of information or the pre-operative and surgical pathways and her induction plan had not been completed since her appointment in January 2021;
- There is no evidence of safeguarding or life support training having been completed for the nurse in post;
- The centre has no system in place to ensure that professional registrations remain current and without restrictions, as they only check the professional registration at the time of appointment;
- The administrative and marketing assistant in post since January 2021 was unaware of who the PR was, had not been provided with a copy of her induction plan and had not received any HFEA induction training relevant to her area of practice. This staff has subsequently resigned from her position (SLC T12).

At the time of the inspection on 11 May 2021, the inspection team noted that one of the embryologists allocated to be 'on-call' had not had their competence to undertake this role assessed. This was discussed with the PR at that time and during the on-site inspection on 10 June 2021, the Laboratory Manager confirmed that the embryologist has since been removed from the 'on-call' rota and will not be undertaking this activity until they have been formally assessed as competent; therefore, no further recommendation is being made in relation to this issue.

At the inspection on 11 May 2021, the centre reported to the inspection team that they had decreased their level of licensed treatment activity in preparation for their change of premises. It was also reported at the renewal inspection on 10 June 2021, that the centre was actively recruiting new staff to mitigate the concerns noted by the inspection team on 11 May 2021. Therefore, staffing levels were deemed adequate for the level of licensed activity at the time of the inspections. The PR will need to ensure that governance arrangements are in place to match the qualified and competent staffing resources available in future to safe levels of licensed treatment activity, notably around the time of the move to new premises when additional administrative and regulatory work will be necessary. This area of practice will be a focus at the change of premises inspection, which will inform the licensing committee considering any change of premises application.

Recommendation 4.

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 with the exception noted in the staffing section of this report. 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)
This centre does not undertake embryo testing and therefore requirements related to these procedures were not relevant at this inspection.

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. Thirteen patients have provided feedback in the last 12 months, giving an average 4.5-star rating to the clinic. The majority of patients confirmed that they had paid what they expected to. Several patients provided positive individual comments to the HFEA complimenting the services at the clinic; but there were also several negative comments regarding mis-communication and these were discussed with the PR. He advised that actions have already been taken to address this matter and the effectiveness of the actions taken will be audited at the next patients' feedback review. The inspection team encourages the centre to continue to monitor patient feedback to ensure patients are able to provide feedback on their experience at the clinic.

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 one couple 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;
- 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 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 and sperm sharing arrangements (Guidance note 12; General Direction 0001)
This centre does not undertake egg or sperm sharing agreements and therefore requirements related to these procedures were not relevant at this inspection.

Surrogacy (Guidance note 14)
This centre does not undertake surrogacy treatments and therefore requirements related to these procedures were not relevant at this inspection.

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.

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 are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients

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 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 its effectiveness 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 centre's previous renewal inspection in April 2017, the inspection team considered the processes used to obtain consent to legal parenthood at this centre to be compliant with HFEA requirements.

Following this, at the interim inspection in April 2019, the inspection team reviewed the centre's audit of consent to legal parenthood which showed that it had not been performed according to the methodology specified by the HFEA. The PR at the time responded and provided evidence that this issue had been addressed within the required timeframe.

At the renewal inspection on 10 June 2021, and 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 the most recent legal parenthood consenting audit. It was found that it had been performed according to the methodology specified by the HFEA and actions had been taken in response to the audit findings. 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.

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 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. It is important that the gametes and embryos are stored appropriately to maintain their quality and safety, and that the centre only stores gametes and embryos in accordance with the consent of the gamete providers.

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

What the centre could do better

Storage of gametes and embryos (Guidance note 17)

On the day of the renewal inspection on 10 June 2021, the centre reported that they had four sets of sperm and two sets of embryos in storage without effective consent. These were identified as a result of the centre's audit of all gametes and embryos in storage for over 10 years that had been undertaken in June 2020. In the audit, they noted a further two sets of embryos in storage without effective consent and following discussions with the

patients these had since been allowed to perish. Whilst the centre confirmed that they are in the process of preparing documentation for a legal opinion on the remaining cases, the inspection team was concerned by the delay in acting on the findings of the audit while samples remain in storage without effective consent (Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991; Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009; Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020).

Recommendation 5.

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.

At the renewal inspection on 10 June 2021, the HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register. However, the inspection team considered these to be a small number of outstanding historical donor issues; therefore, no further recommendation is being made in relation to this issue. The PR is encouraged to continue to liaise with the HFEA's register team to ensure resolution.

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

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2019, recommendations for improvement were made in relation to two major and one 'other' area of non-compliance or poor practice.

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

On-going monitoring of centre success rates

Since 2019, the centre has been asked to review procedures for the provision of fresh cycles (ICSI-only) in patients under 38 years old using their own eggs in treatment. The PR at the time provided a commitment to keep success rates in this group of patients under review and evidenced that actions had taken place to remedy to them. Whilst these actions appeared to have been effective after each performance alert, the executive remained concerned that the centre has continued to receive alerts for this group of patients intermittently since 2019.

At the renewal inspection on 10 June 2021, this was discussed with the new Laboratory Manager and the new PR who both provided a commitment to keep success rates in this group of patients under review. The PR reported that he had already started to implement a new plan of actions to improve these success rates, utilising protocols used at their sister centre 0015. Therefore, no further recommendation is being made in relation to this issue; however, the centre's inspector will continue to monitor the effectiveness of the actions taken by the PR in addressing these 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 areas of non-compliance

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

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

Area of practice and reference	Action required and timescale for action	PR response	Executive review
None identified.			

Major areas of non-compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. **Safety and suitability of premises and facilities** At the inspection on 11 May 2021, two small gas cylinders supplying the benchtop incubators were noted to be freestanding under the laboratory bench. This was highlighted as an issue to the PR at that time, the LH and the Senior Embryologist. However, at the inspection on 10 June 2021, the two cylinders remained unsecured; and no actions appeared to have been taken to secure them.	The PR should ensure that all medical gases are stored safely at all times. The PR should inform the centre's inspector of the actions taken to address this non-compliance when responding to this report.	All medical gases are stored safely at all times. The two small gas cylinders supplying the benchtop incubators are freestanbding as there is no where for the cylinders to be attached. It was explained at inspection that we have taken action including: the lab team are aware of the unsecured cylinder; they work with support from another team member ensuring that practice remains safe.	The executive notes the PR's response. The inspection team's concerns were highlighted at the inspection on 11 May 2021, but no further actions had been taken prior to the inspection on 10 June 2021. The executive expected that the PR and centre staff would have undertaken a formal assessment of the potential risks and danger to staff of having unsecured gas cylinders supplying the

SLC T17 DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006); sections 8.77 to 8.79.		Also explained at inspection was that as we are in process of moving to new premises and renting the current space from BMI, it is proving difficult to implement some requirements. The move to new premises is imminent where these recommendations have been noted and implemented.	benchtop incubators in the laboratory. The executive is not clear on the PR's rationale for not taking any action when this was highlighted by the inspection team on 11 May 2021. The executive's concerns for the safety of staff remain paramount and will liaise directly with the PR to address this issue. Further action required.
2. Medicines Management The following issues were noted at the renewal inspection on 10 June 2021: • The controlled drug (CD) register is not bound and a number of pages were already coming loose; and pages 6 & 7 were secured using surgical tape; • In one patient record, the amount of drug recorded as having been given to the patient did not match the amount recorded in	The PR should ensure that medicines management practice is compliant with regulatory requirements and best practice guidance. The PR should ensure that a suitable CD register is used, which should either be an electronic register or a bound book. It is expected that a suitable CD register is in use at the centre by the time of change	The PR will ensure that medicines management practice is compliant with regulatory requirements and best practice guidance. The PR will ensure that a suitable CD register is used, which will be a bound book. A suitable CD register will be is use at the centre by the time of change of premises	The executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required.

the CD register for the same administration; • In several patients' records, the concentration of drug given to the patient was not recorded. SLC T2 Dangerous Drugs The Misuse of Drugs Regulations 2001, Interpretation, regulations 19 and 23 DH 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007); section 4.7.1.1	of premises and/or by 10 September 2021; and confirmation of this should be provided to the centre's inspector. The PR should review medicines management practices at the centre, including, but not exclusively, the issues identified in this report, and provide a summary report of actions taken, including staff training, or any corrective actions implemented to the centre's inspector by 10 September 2021. Three months after the review the PR should audit medicines practices to ensure that any corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of this review should be provided to the centre's inspector by 10 December 2021.	and this statement should be taken as confirmation of this. The PR will review medicines management practices at the centre, including issues identified in this report. We will provide a summary report of actions taken, including staff training and any other corrective actions by 10th September 2021. Three months after the review, the PR will audit medicines practices to ensure that any corrective actions implemented are effective in achieving and maintaining compliance. A summary report of this will be sent to the centre's inspector by 10th December 2021.	

3. QMS On the day of the renewal inspection, the following issues were identified: • Several audits did not have documented CAPA and/or dates for implementation and closure; • The data submission SOP did not document quality indicators or the timescale for records to be submitted to the Authority in relation to the patient/partner registration forms and donor information; • Several SOPs did not indicate the last and/or next review date and/or have not been reviewed within the required time frames as per local policy General Direction 0005 SLCs T33b, T35 and T36	The PR should ensure that the QMS is effective and fit for purpose. The PR should ensure that audits have documented CAPA including dates for implementation and completion. The PR should ensure that quality indicators are indicated for all licensed activities. The PR should ensure that all SOPs are reviewed within the required time frames. The PR should review the QMS, including, but not exclusively the issues identified in this report, and provide a summary report of actions taken or any corrective actions implemented to the centre's inspector by 10 September 2021. In addition, the PR should provide the centre's inspector with a copy of the following by 10 September 2021:	The PR will ensure that the QMS is effective and fit for purpose. The PR will ensure that audits document CAPAs and dates for implementation and completion. The PR will ensure that quality indicators are indicated for all licensed activities. The PR will ensure that all SOPs are reviewed within the required timeframes. The PR will review the QMS and provide a summary report of actions taken to the centre's inspector by 10th Spetember 2021. The PR will provide the centre's inspector by 10th September 2021:	The executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required.

	• Documented CAPA and/or dates for implementation and closure for the audits mentioned in this report; • Quality indicators for all the data submission activities; • Updated SOPs mentioned in this report.	- Documented CAPAs and/or dates for implementation and clisure for the audits mentioned in this report; - Quality indicators for all data submission activities; - updated SOPs mentioned in this report.	
4. Staffing Several non-compliances related to staffing were identified, as described in the main body of the report. SLC T12	The PR should ensure that staff in the centre are available in sufficient number and are qualified and competent to undertake the tasks they perform. The competence of staff must be evaluated at appropriate intervals. When responding to this report the PR should provide the centre's inspector with a plan of action with timelines to address this non-compliance. The PR should provide the centre's inspector with the monthly staffing rota, an updated organisational chart and all the required competence assessments by 10 September 2021.	The PR will ensure that staff in the centre are available in sufficient number and are qualified and competent to undertake the tasks they perform. The competency of staff will be evaluated at appropriate intervals. Plan of action and timeline attached. Monthly staff rota for August attached. Updated organisation chart is attached. The PR will provide required competency assessments by 10th September 2021.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The executive notes that the plan of action with timelines, monthly staff rota for August and an updated THFG organisational chart were not attached with the PR's response; but were provided after several communications with the executive. The inspection team's concerns over staff turnover, recruitment and stability in staffing levels were highlighted at the inspections on 11 May 2021 and 10 June 2021. The executive therefore requested that the PR provide monthly staffing rota and

	Thereafter, the PR should provide monthly evidence to the centre's inspector that staff are available in sufficient number, are qualified and competent for the tasks they perform and that all new staff have completed an induction plan relevant to their area of practice.	Thereafter, the centre will be at the new site and if all goes to plan, the inspectors will be able to verify the attached organisation chart, staff numbers, their qualifications and competency at the time of the change of premises inspection. To that end, we fail to understand what additional value is gained by monthy evidence of this and the clinic's staff rota. We do believe that these additional monthly updates will provide any more regulatory evidence and in fact, will be a burden on our business. Please can the centre's inspector clarify the reasons for this additional regulatory burden, giving a precise reference for this request in the HFEA Code of Practice or the HFE Act, as amended.	organisational charts, so that staff turnover, recruitment and stability in staffing levels at the centre can be appraised (as per SLC T9f). This area of practice will be a focus at the change of premises inspection, which will inform the licensing committee considering any change of premises application. Further action required.
5. Consent to storage On the day of the renewal inspection, the centre reported that they had four sets of	The PR should ensure there is effective consent in place for all cryopreserved gametes	The PR will ensure that there is effective consent inplace for all cryopreserved gametes	The executive notes the PR's response.

sperm and two sets of embryos in storage without effective consent. SLCs T12, T79, T80 and T82 Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020 It is noted that the HFEA's assessment framework recommends the classification of this issue as a 'critical' non-compliance; but, in consideration that the centre had identified these cases and taken actions to address the findings, this has been graded as a major non-compliance.	and embryos in storage at the centre. The PR should seek the opinion of a legal representative conversant with the HF&E Act 1990 (as amended) and the HFEA (Statutory Storage Period for Embryos and Gametes) Regulations 1991, 2009 and 2020, for the four sets of sperm and two sets of embryos in storage, to ascertain if there is lawful consent in place for continued storage of these samples. The PR should provide a detailed summary report of the findings of the legal opinion demonstrating why (where applicable) the samples may continue to be lawfully stored. The PR should provide the timescale for obtaining this legal opinion when responding to this report. Where following legal review there are any patient samples which cannot lawfully remain	and embryos in storage at the centre. It was discussed at inspection, as acknowledged by the inspectors in this report, that this is a historical issue with the previous owners of this centre and the centre's internal audit identified this non-compliance. With the move to the new premises by the current owners, in August or September 2021, a 100% audit is planned, to identify and ensure ensure that only cryopreserved gametes and embryos with a current consent are moved to and stored at the new site. The PR will consider whether, post the further internal audit, and the further review of the HFE Act, as amended and the Code of Practice requirements, the need for a costly legal opinion.	The PR remains responsible for ensuring that there is effective consent in place for all cryopreserved gametes and embryos currently in storage at the centre regardless of when those samples were placed in storage. The executive acknowledged that the centre had identified these cases in its own audit of samples in storage. Given the LH's assurances at the time of the inspection on 10 June 2021 that the centre was in the process of preparing documentation for a legal opinion on the remaining cases, the executive considered this non-compliance could be classified as a major non-compliance rather than a critical non-compliance. The executive is concerned by any further delay in acting on the findings of the audit of over one year ago during which time the samples

	in storage at the clinic, the PR should notify the HFEA of this to discuss further options that may be available for these patients. The PR should ensure that relevant staff are provided with training in the regulations and requirements governing gamete and embryo statutory storage periods and their extension, by a legal representative conversant with the HF&E Act 1990 (as amended) and the relevant HF&E storage regulations. When responding to this report the PR should provide the centre's inspector with a plan of actions, with timelines, by which staff training will be completed.	The PR will ensure that relevant staff are provided with training in the regulations and requirements governing gamete and embryo statutory storage periods and their extension. It would be helpful if the HFEA can recommend a legal representative conversant with the HF&E Act, as amended and the relevant storage regulations. With this response, the PR attaches a plan of action, with timelines by which staff training will be completed.	continue to remain in storage without effective consent. The executive is not clear on the PR's rationale for further delaying seeking a legal opinion until an audit of all stored samples is completed prior to the relocation to new premises, as they have already established that these samples are in storage without effective consent. The executive also notes that the plan of action with timelines was not attached with the PR's response (as per SLC T9f). The executive will therefore liaise directly with the PR to address this issue, especially with regards to actions taken for the four sets of sperm and two sets of embryos in storage without effective consent. The PR is asked to note that whilst is not within the remit of the HFEA to recommend a legal representative conversant with the HF&E Act 1990 (as amended) and the

			relevant HF&E storage regulations, the executive will liaise directly with the PR and provide some assistance. Further action required.

Other areas of practice that require improvement

'Other' areas of practice that require improvement are any areas of practice which cannot be classified as either a critical or major area of non-compliance, but which indicate a departure from statutory requirements or good practice.

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

Area of practice and reference	Action required and timescale for action	PR response	Executive review
6. Infection control Information directing the actions to be taken in the event of a needlestick injury is held on the electronic document system but is not readily available in all areas where these injuries may occur. SLC T2	The PR should ensure that information directing the actions to be taken in the event of a needlestick injury should be made readily available in all areas where these injuries may occur. The PR should inform the centre's inspector of the actions taken to address this non-compliance when responding to this report.	The PR will ensure that information dirtecting the actions to be taken in the event of a needlestick injury are readily available in all areas where these injuries may occur. The actions taken by the PR are: reminder and training to all relevant staff of the requirements and SOP; as we move to the new site from next month, updated training is planned in August; posters will be displayed as appropriate and an external infection control audit will be performed to ensure implemntation of any CAPAs.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The executive will follow-up compliance at the change of premises inspection. No further action required.

7. Transport and distribution of gametes and embryos The centre's SOP for transport of gametes and embryos, including import and export did not define specifications for all transport conditions; ensure that all required information is provided when distributing material; or ensure that shipping containers are appropriately secured and packaged. The inspection team notes that the centre has not undertaken any import or export of material since December 2019; and none are planned in the foreseeable future, minimising the risk of potential future non-compliance. SLCs T105, T107, T108, T109 and T110. CoP guidance note 15 ('Reception at the centre' and 'Packaging, distribution and recall of gametes and embryos').	The PR should review the centre's SOP to ensure that it describes practices which will ensure compliance with all relevant licence condition requirements. The SOP should also be revised to account for recent release of General Direction 0006(GB), version 9, on 30 June 2021. The PR should provide to the centre's inspector a copy of the revised SOP by 10 September 2021 or before any transportation of gametes or embryos, if earlier.	At the time of inspection, the centre's SOP was on the QMS inprovement plan for review and update in line with current requirements. This plan was discussed by the Quality Manager with the lead inspector. The updated SOP will be provided by 10th September 2021.	The executive acknowledges the PR's response and commitment to implementing this recommendation. No further action beyond the submission of a copy of the revised SOP by 10 September 2021 or before any transportation of gametes or embryos, if earlier.

8. Third-party agreements The TPA with a supplier that provides a courier service for cryopreserved gametes and embryos, was established by the previous PR and owners of the centre and did not identify the centre's new person responsible for managing the arrangement between the centre and the third party. Furthermore, the TPA had not been reviewed by its set review date; therefore, the inspection team could not be assured of the ability of that supplier to meet the requirements of the relevant licence conditions. SLCs T112 and T114B	The PR should evaluate and select third-parties on the basis of their ability to meet the requirements of the licence conditions and the guidance set out in the HFEA Code of Practice. The PR should review all TPAs including the one referred to in this report to ensure they are accurate and meet the requirements of standard licence conditions. A summary report of this review including corrective actions taken and a copy of an updated TPA with the courier service mentioned in this report, should be provided to the centre's inspector by 10 September 2021.	The PR will evalaute and select third-parties on the basis of their ability to meet the requirements of the licence conditions and the guidance set out in the HFEA Code of Practice. The PR will review all TPAs as we prepare for the move to new premises as some will be new TPAs. We will ensure that all TPAs are accurate and meet regulatory requirements. A summary report of this review, including corrective actions and a copy of the updated TPA with the courier service, mentioned in this report, will be provided to the centre's inspector by 10th September 2021.	The executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required.

Reponses from the Person Responsible to this inspection report

Factual inaccuracies sited in this renewal report:

1. The centre was not without a PR between 13th & 29th April 2021, as stated in this report. There was a misunderstanding by the previous PR of the 2 month notice period that she was obliged to give under her contract of employment. This has been explained many times to the inspectors. If you still need clarification, please contact us
2. This report is of two inspections: the unannounced visit in May 2021 and the renewal visit in June 2021. For clarity, we would be grateful if the inspection teams for the unannounced can also be listed. It would also be helpful to identify the the non-compliances separately for the two visits. Otherwise, it appears that the non-compliances are common to both visits and this is inacciurate.
3. Staff: It was explained at both inspection visits that staff levels were reduced in line with the closure of clinics at the start of the pandemic. When THFG took over the clinic, staff were emoloyed or Bank staff used to cover the activity levels. At all times, only experienced staff with IVF experience were vetted and recruited. As the clinic started to function at the pre-pandemic level, a number of staff chose to retire or leave the clinic. This, therefore require employing new staff, which is still an on-going process, and we hope to complete this exercise by the time of the move to the new premises. This too, was explained at inspection.
4. In the 'Brief description of the centre and its licensing history', it is stated that: …' the HFEA does not consider THFG to be a 'corporate group' for inspection purposes because there is little inspection history of clinics own by the group'.. We would appreciate clarification of this as both centre 0015 and 0086 have held HFEA licences since 1992 and should be treated as a group for inspection purposes. As discussed at both centre inspections recently, this is what we are working towards.
5. QMS review plan. This was shared with the lead inspector at the renewal inspection; the plan details review and rationalisation of the QMS, including SOPs, forms, policies. This plan also includes revised recruitment, induction and competencies.

Executive review of the 'Responses from the Person Responsible to this inspection report':

1. The HFEA received written communication from the PR at that time, indicating that she was not in a position to discharge her duty under section 17 of the HF&E Act 1990 (as amended) from 14 April 2021 until her reinstatement on 29 April 2021.

2. The executive acknowledges the PR's response and the inspection team of the un-announced inspection on 11 May 2021 is now detailed in this report. The executive would also like to clarify that the findings of the un-announced inspection have been considered and referenced alongside the renewal inspection findings in this report. Further wording has been added to this report to offer clarity.

3. The executive notes the PR's response. However, as described in the body of the report, the executive would like to clarify that, on 11 May 2021, due to the high turnover of staff at the centre, the robustness of governance systems to ensure the compliance of staffing resources for the treatment activity undertaken was a concern; but the centre had reported to have

decreased their level of licensed treatment activity in preparation for their change of premises. It was also reported at the renewal inspection on 10 June 2021, that the centre was actively recruiting new staff to mitigate the concerns noted by the inspection team on 11 May 2021. Therefore, staffing levels were deemed adequate for the level of licensed activity at the time of the inspections. The PR will need to ensure that governance arrangements are in place to match the qualified and competent staffing resources available in future to safe levels of licensed treatment activity, notably around the time of the move to new premises when additional administrative and regulatory work will be necessary.

4. The executive notes the PR's response. As described in the body of the report, the inspection team recognises that THFG aims to coordinate processes between centre 0086 and centre 0015 and staff are able to support both centres in 'emergency' situations. Whilst centres 0015 and 0086 are both owned by THFG, the HFEA's 'Group approach' for inspections was not recommended because there is currently no demonstrative evidence that an integrated QMS is in place within the group. Further wording has been added to this report to offer clarity.

5. The executive notes the PR's response and would like to clarify that the establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services. The centre has a QMS that is partially compliant with HFEA requirements; and further details are described in the body of the report.