Executive Licensing Panel Minutes

Centre 0139 (CARE Bath)

Renewal Inspection Report

Date:	18 May 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Richard Sydee (Chair) Dina Halai Dan Howard	Director of Finance and Resources Senior Scientific Policy Manager Chief Information Officer
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood Dee Knoyle	Licensing Manager Committee Officer

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 CARE Bath has held a treatment and storage licence with the HFEA since 1994 and provides a full range of fertility services. Other licensed activities at the centre include storage of gametes and embryos. The centre was acquired by the CARE Fertility group in February 2019.

1.3. The panel noted that, in the 12 months to 31 December 2020, the centre provided 749 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre.

1.4. The panel noted that, HFEA register data, for the period 1 October 2019 to 30 September 2020, show the centre's success rates for IVF and ICSI are in line with the national averages.

1.5. The panel noted that, in 2019, the centre reported 26 cycle of partner insemination, with one pregnancy. This represents a clinical pregnancy rate which is comparable to the national average.

1.6. The panel noted that, HFEA register data, between 1 October 2019 and 30 September 2020, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 4%. This represents performance that is likely to be significantly lower than the 10% multiple live birth rate target for this period.

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

1.8. The panel noted that, the centre's interim inspection occurred in March 2019 and a renewal inspection was scheduled to be undertaken by March 2021. However, due to the Covid-19 pandemic, a Desk Based Assessment and Risk Based Approach (DBA/RBA) was conducted. Following this, it was established that any items of concern identified were of relatively low risk and could be reviewed effectively using virtual technology, rather than an on-site inspection. This process removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

1.9. The panel noted that a DBA, followed by a virtual inspection, was conducted on 9 February 2021, which included videoconferencing with key members of staff.

1.10. The panel noted that, at time of the inspection, there were three major areas of non-compliance concerning premises and facilities, medicines management and surgical pathways. There were also four 'other' non-compliances regarding transport and satellite agreements, storage of gametes and embryos, embryos for training and obligations and reporting requirements. Since the virtual inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations surrounding transport and satellite agreements, storage of gametes and embryos, embryos for training and obligations and reporting requirements, and where required, will audit the effectiveness of these actions within the required timescales. The panel noted that the PR has given a commitment to fully implementing the recommendations concerning medicines management.

1.11. The panel noted that the PR has challenged the major areas of non-compliance regarding premises and facilities, alongside surgical pathways. Acknowledging the major non-compliance

concerning premises and facilities, the panel sought clarification, from the inspectorate, as to the submission deadline set for the receipt of the Health and Safety risk assessment for the 12 cylinder trolley location. Given the nature of the non-compliance, the panel was concerned that an earlier date, than 21 July 2021, had not been agreed with the centre.

1.12. The panel noted that, with regards to the major area of non-compliance relating to medicines management practices, a similar issue was identified at the centre's interim inspection, conducted in 2019. The inspectors were concerned that previous corrective actions did not appear to have been effective in ensuring compliance in this area of practice.

1.13. The panel noted that, due to the inspection teams concerns, the executive held a management review meeting, on 16 March 2021, in accordance with the HFEA Compliance and Enforcement Policy to evaluate the inspection findings. This meeting found that the non-compliances identified in relation to medicines management and sedation practices did not pose a direct risk to patients, as described in the report, but did reflect the centre's failure to comply with medicines management regulations, specific HFEA guidance in these areas of practice, and a failure to embed learning from previous non-compliances.

1.14. The executive also noted, at the management review meeting, that the current PR was not in this role at the time of the interim inspection, the recent changes in ownership and overall governance of the centre under the CARE Fertility group. The executive considered the engagement of the current PR and noted that she had taken corrective actions to address some of the findings immediately after the inspection and is fully engaged and committed to fulfilling her duties. The executive concluded that on balance it was sufficiently assured that the centre will now ensure that the issues identified are fully addressed such that they will not recur.

1.15. The panel noted that the executive will closely monitor the centre's implementation of the report's recommendations, including where the PR has challenged the inspection findings, and will be able to evaluate the effectiveness of corrective actions taken at the time of the centre's next inspection. In addition, and where relevant, the executive will be able to evaluate learning at other centres in the group during their next inspections.

1.16. The panel noted that the PR is encouraged to continue using the quality management system (QMS) to best effect to monitor and improve their success rates and quality of service offered to patients. The centre is well led and provides a good level of patient support.

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

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

1.19. The panel noted that the inspection team recommends the renewal of the centre's treatment (including embryo testing) and storage licence, for a period of four years, without additional conditions, subject to the recommendations in the report being implemented in the prescribed timescales.

1.20. 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, noting that a major non-compliance, regarding the location of the 12 cylinder storage trolley, currently remains outstanding.

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

2.4. The panel expressed particularly concern that the non-compliance regarding medicines management had also been identified at the centre's interim inspection in 2019, noting that the PR has committed to reviewing practices in this area and a summary report would be submitted to the inspectorate by 9 June 2021. The panel hoped that all actions relating to this non-compliance would be fully implemented and no further issues, relating to medicines management, would be identified at future inspections.

2.5. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

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

3. Chair's signature

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

Signature

Name

Richard Sydee

Date

24 May 2021

Inspection Report

Purpose of the Inspection Report

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

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

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

Date of inspection: 9 February 2021.

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

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

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

This centre was last inspected in March 2019, therefore an on-site inspection should usually be conducted by March 2021. However, following the DBA/RBA for this clinic, it was concluded that any items of concern identified during the DBA were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site inspection. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

This inspection was therefore carried out by DBA followed by a virtual inspection on 9 February 2021, which included videoconferencing with key members of centre staff.

Inspectors: Lesley Brown (lead), Sara Parlett, Sandrine Oakes and Sarah Stedman (HFEA observer)

Date of Executive Licensing Panel: 18 May 2021

Centre name	CARE Bath
Centre number	0139
Licence number	L/0139/14/f
Centre address	Bath Business Park, Roman Way, Peasedown St John, Bath, Somerset, BA2 8SG, United Kingdom
Person Responsible	Dr Stephanie Gadd
Licence Holder	CARE Fertility Group Ltd
Date licence issued	1 September 2017
Licence expiry date	31 August 2021
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

CARE Bath has held a treatment and storage licence with the HFEA since 1994 and provides a full range of fertility services. Other licensed activities at the centre include storage of gametes and embryos. The centre was acquired by the CARE Fertility group in February 2019.

The centre provided 749 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2020. In relation to activity levels this is a medium centre.

This current licence has been varied to reflect the following changes:

- October 2018 - Person Responsible (PR) and Licence Holder (LH);
- October 2019 - centre name;
- January 2020 - variation of activities to include embryo testing;
- April 2020 - LH;
- July 2020 - PR.

The renewal application form requests a variation of centre name however the PR has since confirmed by email that the centre name is to remain as 'CARE Bath'.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 October 2019 to 30 September 2020 show the centre's success rates are in line with national averages.

In 2019, the centre reported 26 cycles of partner insemination with one pregnancy, which is in line with the national average.

Multiple births[2]

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

From 1 October 2019 to 30 September 2020 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 4%. This represents performance that is likely to be significantly lower than the 10% multiple live birth rate target for this period.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

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

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

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including three major and four '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:

'Other' areas that requires improvement:

- The PR should ensure that the centre's satellite agreements are compliant with General Direction 0010.
- The PR should ensure that the centre's processes used to monitor consent to storage expiry dates are robust.
- The PR should ensure that processes are in place so that there is no perceived conflict of interest when allocating embryos for training, and that all patients receive appropriate patient information prior to donating their embryos for use in training.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

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

Major areas of non compliance:

- The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice requirements, that learning from guidance provided by the HFEA and/or other sources is implemented, and that staff are trained in how to respond if critical parameters of equipment are not maintained within acceptable limits.

The PR has challenged the following recommendations to:

Major areas of non compliance:

- The PR should ensure that systems are in place for the safe storage of gases at all times, with appropriate safety signage present.

- The PR should ensure that sedation practices at the centre are compliant with professional guidance and best practice requirements and ensure that learning from guidance provided by the HFEA and/or other sources is implemented.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have three major areas of concern. One of the major areas of concern relates to medicines management practices at the centre. A similar issue was identified at the time of the interim inspection of the centre in 2019, and it was of concern to the inspection team that previous corrective actions did not appear to have been effective in ensuring compliance in this area of practice.

In view of these concerns the executive held a management review meeting in accordance with the HFEA Compliance and Enforcement Policy to evaluate the inspection findings. This meeting on 16 March 2021 found that the non-compliances seen in relation to medicines management and sedation practices did not pose a direct risk to patients, as described in the body of the report, but did reflect the centre's failure to comply with medicines management regulations, specific HFEA guidance in these areas of practice, and a failure to embed learning from previous non-compliances. The executive noted that the current PR was not PR at the time of the interim inspection and the recent changes in ownership and overall governance of the centre under the CARE Fertility group. The executive considered the engagement of the PR and noted that she had taken corrective actions to address some of the findings immediately after the inspection and is fully engaged and committed to fulfilling her duties as PR. The executive concluded that on balance it was sufficiently assured that the centre will now ensure that the issues identified are fully addressed such that they will not recur. The executive will closely monitor the centre's implementation of the recommendations made in this report, including where the PR has challenged the inspection findings, and will be able to evaluate the effectiveness of corrective actions taken at the time of the centre's next inspection. In addition, and where relevant, the executive will be able to evaluate learning at other centres in the group during their next inspections.

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy rates are below the target. Some improvement is required in order for the centre to demonstrate the suitability of their practices. The PR is encouraged to continue to use the 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 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.

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

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

Centre 0139 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 partially 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 partially 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 third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

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

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

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

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

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

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

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

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- 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. No imports have been made from TCS which are not specified on the centre's ITE import certificate. The centre is therefore compliant with General Direction 0006.

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

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

Quality management system (QMS) (Guidance note 23)
The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services. With the exception of audits described elsewhere in this report, the centre has a QMS that is compliant with HFEA requirements.

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

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

Equipment and materials (Guidance note 26)

The centre uses equipment and materials that are 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

Safety and suitability of premises and facilities (Guidance note 25)
Photographs of the premises were provided by the centre as part of the DBA and videoconference inspection. The inspection team noted that, both empty and full, portable small (CD size) oxygen cylinders are stored in a trolley located in the corridor outside the procedure room. The inspection team was concerned that this poses a health and safety hazard to staff and patients. Gas cylinders should be securely stored in a designated storeroom either in the building, or outside; and it should be clearly labelled with the types of gases contained, appropriate safety signage and access should be key-controlled (SLC T17; DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006)(8.20; 8.27; 8.59)). See recommendation 1.

Medicines management (Guidance Note 25)
The inspection team noted the following issues in several entries in the controlled drugs (CD) register seen in photographs provided by the centre and during the videoconference inspection.

- The carry-over of CDs from one page to another is not recorded or witnessed (Department of Health (DH) (2007) Safer management of Controlled Drugs: a guide to good practice in secondary care (England) section 4.7.1.3).
- The supply of CDs is not consistently signed and/or witnessed (DH (2007) Safer management of Controlled Drugs: a guide to good practice in secondary care (England) section 4.7.1.2).
- The discard of CDs not is not consistently signed and/or witnessed (The Misuse of Drugs Regulations 2001 27 (3)), regulation 27.3 DH (2007); Safer management of Controlled Drugs: a guide to good practice in secondary care (England) section 4.7.1.2.); (NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management', section 1.7.8.); (Association of Anaesthetists 'Controlled drugs in peri-operative care' 2019, section titled 'Good practice for controlled drugs administered directly by registered healthcare professionals in the theatre environment/ record of administration').

- In two entries (pages 66 and 68), the prescribed unit of measurement (i.e. mcg or mg) of the CD administered and/or discarded was not recorded (Misuse of Drugs (safe Custody) Regulations (2001) (19.a)).

The inspection team considered that the centre's methodology for auditing the CD register is not sufficiently robust as it does not include review of the carry-over/witnessing; if all prescribed unit of measurement (i.e. mcg or mg) has been entered, and/or the legibility of the records. In addition, whilst the audit states 'Each entry for each patient was signed by the responsible person and a witness', it is not clear which line (supply, administer or discarded) is being audited (SLC T36).

The centre has also not implemented learning issued by the HFEA in February 2020 on 'Focussing on medicines management non-compliances' (Clinic Focus (February 2020), SLC T2).

The inspection team noted that the errors in the CD register were a recurrence of three non-compliances identified at the time of the last inspection in 2019. The inspection team was concerned that the centre's corrective actions have not been effective in ensuring compliance, especially taken into consideration that 'the quantity destroyed and shall be signed by the authorised person in whose presence the drug is destroyed' is a regulatory requirement. In addition, this was discussed with staff during the inspection and no rationale was provided for the recurrence. Whilst these findings raise concerns that the centre's medicines management processes are not in line with best practice, the inspection team is assured that the issues identified does not appear to pose a direct risk to patients as this relates to the discard of CDs. The inspection team noted that the administration of CDs was correctly recorded and accordance with regulations in all entries reviewed, and no incidents have been reported in relation to this area of practice.

Staff were unable to describe the process to follow if the temperature of the refrigerator containing medicines is found to be outside the required parameters (SLC T12).

See recommendation 2.

Pre-operative assessment and the surgical pathway (Guidance Note 25)

The centre is using an operator-sedationist care model, in which a clinician administers the sedation and patient's care is handed-over to a dedicated practitioner who may administer further sedative drugs if required, whilst the clinician performs the required procedure. It is therefore essential that all second dedicated practitioners, monitoring the patient's status and administering further sedative drugs, other than the one performing the procedure, are trained as per 'Safe sedation practice for healthcare procedures' professional guidance; it expected that any deviation to the professional guidance should be risk-assessed and the rationale clearly documented.

During the virtual inspection, the following issue was identified.

- The centre was unable to demonstrate that formal accredited competency-based training and advanced life support training had been provided for all dedicated practitioners involved in sedation practices; or whether sedation practices had been formally risk-assessed against the 'safe sedation practice for healthcare procedures' professional guidance. Since the inspection, the centre has provided a risk-assessment of 'Operative procedures carried out under sedation using midazolam and alfentanil' but the rationale for deviating from the training

requirement of the ‘safe sedation practice for healthcare procedures’ professional guidance was not clear.

In addition, essential anaesthetic information is either not documented, or inaccurately documented in the patient’s anaesthetic records. The following issues were noted.

- During the virtual inspection, it was identified that the opioid ‘alfentanil’ was administered to patients during sedation, as per clinician requirement; and accurately recorded in the CD register; however, it was recorded as ‘fentanyl’ in the electronic anaesthetic patient’s records. Whilst it is noted that alfentanil is an analogue of fentanyl, it has a different potency and duration of action; and therefore, these are considered as two different controlled drugs. On discussion with staff, they explained that the centre recently started using the patients’ electronic system provided by the CARE group (known as ‘CIS’); and since fentanyl is used by other clinics in the group there was no option for alfentanil in the programme. The inspection team was concerned that this anomaly was not identified and addressed by the centre staff when they transferred to CIS. The centre immediately acted upon the inspection finding, photographic evidence was provided the day after the inspection and alfentanil has been added to the CIS system. However, in the evidence provided, another anomaly was noted, in that the alfentanil prescribed unit of measurement was incorrectly recorded as ‘ucg’ instead of ‘mcg’ or ‘ug’. Therefore, there is a risk that the amount of drug provided is inaccurately recorded (The Royal College of Anaesthetists (RCA) and the Association of Anaesthetists of Great-Britain and Ireland (AAGBI) ‘Good practice, a guide for departments of anaesthesia, critical care and pain management’ (2006)(7; 7.1)); (The Association of Anaesthetists of Great-Britain and Ireland (AAGBI) ‘Controlled Drugs in Perioperative Care’ (2019)(recommendation 3); SLC T2).
- The name of the dedicated practitioner assigned to care for the patient during the sedation whilst the clinician undertakes the procedure is not recorded (The Royal College of Anaesthetists (RCA) and the Association of Anaesthetists of Great-Britain and Ireland (AAGBI) ‘Good practice, a guide for departments of anaesthesia, critical care and pain management’ (2006)(7; 7.1)).
- The clinician documents the total amount of CD administered for the procedure (including any top-up sedative drugs) without any time of administration, rather than contemporaneously documenting intraoperative drugs given, doses and time of administration. On discussion during the inspection, staff explained procedures usually last about 15 minutes and additional doses ‘top-up’ of drugs are rarely given. However, the inspection team would expect anaesthetic records to be accurate and reflect specific details in relation to each patient, especially drugs as and when these have been administered (The Royal College of Anaesthetists (RCA) and the Association of Anaesthetists of Great-Britain and Ireland (AAGBI) ‘Good practice, a guide for departments of anaesthesia, critical care and pain management’ (2006)(7; 7.1)).
- In one electronic record, it was recorded that the patient had been given ‘5l of Oxygen (inhal)’. On discussion during the inspection, staff were able to clarify that the ‘5l’ was in fact the oxygen flow rate rather than the dose of oxygen given to the patient. The inspection team was concerned that the records were not clear (The Royal College of Anaesthetists (RCA) and the Association of Anaesthetists of Great-Britain and Ireland (AAGBI) ‘Good practice, a guide for departments of anaesthesia, critical care and pain management’ (2006)(7; 7.1)).

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

Whilst these findings demonstrate that sedation practices are not in line with best practice, the inspection team considered that several staff are competent in sedation techniques, regular audits are conducted and no incidents have been reported therefore, there does not appear to be a direct risk to patients.

SLCs T2; SLC T12; Academy of Royal Colleges, Safe sedation practice for healthcare procedures - standards and Guidance (October 2013) (pages 2, 9, 12, 20, 24, 27, 35, 36); The Royal College of Anaesthetists (RCA) and the Association of Anaesthetists of Great-Britain and Ireland (AAGBI) 'Good practice; a guide for departments of anaesthesia, critical care and pain management' (2006)(7.1); Clinic Focus (September 2019).

See recommendation 3.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
All satellite agreements were audited as part of the DBA process. Two of the centre's satellite agreements were not compliant with General Direction 10 (b, iii) as the written agreement did not make clear the responsibility of the offer of counselling. Instead the agreements both stated that counselling was an additional service available on request. The PR provided an audit of satellite services which demonstrated that the offer of counselling was made. The PR has since submitted updated agreements which are compliant.

See recommendation 4.

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

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

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

governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services with the exception noted in the 'Medicines management' and the 'Pre-operative assessment and the surgical pathway' sections of this report. The centre has an organisational chart which clearly defines accountability and reporting relationships.

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

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

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

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

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

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.
What the centre could do better Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only one patient has provided feedback in the last 12 months, giving an average 3.5 star rating to the clinic. For the system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.

The centre's own most recent patient survey responses were therefore reviewed. The centre received 120 responses between January and November 2020 and the inspection team noted that 99% of respondents provided positive feedback.

On the basis of this feedback and observations made in the course of the desk based assessment and virtual 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)

HFEA guidance emphasises the need for staff to provide support to patients throughout their treatment, 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)
The centre are no longer offering egg and sperm sharing arrangements. During the virtual inspection the centre's historic procedures for egg and sperm sharing arrangements were reviewed and were found to be compliant with HFEA requirements. This is important to ensure that:

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

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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

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

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

Information

What the centre does well

Information (Guidance note 4
The centre's procedures for providing information to patients and / 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 centre's previous inspection in March 2017 the inspection team found that the centre had not performed an audit of consent to legal parenthood since 2014, despite reassurances from the PR to the HFEA in October 2015. This resulted in a critical non compliance in the renewal inspection report. At that time, it was considered that, in his response, the PR in post at that time (not the current PR), engaged fully with the HFEA in addressing all the areas of concern identified in the report, and that the centre had provided the requested assurances regarding the centre's processes for checking consents prior to treatments.

Following this, at the interim inspection in March 2019 the inspection team noted that the centre's processes for documenting marital status were not robust. The PR in post at the time of that inspection (not the current PR) again engaged fully with the HFEA in addressing the issues identified and provided assurances the centre's processes for obtaining consent to legal parenthood would be made more robust.

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

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)

The centre’s procedures for taking consent to disclosure to researchers are compliant with HFEA requirements. This is important to ensure that the HFEA holds an accurate record of patients’ consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.
What the centre could do better Nothing identified at this inspection.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)

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

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

What the centre could do better

Storage of gametes and embryos (Guidance note 17)

The storage consent period documented within the electronic database used to manage the centre's bring forward system for embryos is not checked against the patient's consent form to ensure that this information is accurate. Instead, the audit reviews the storage periods which have been previously transcribed from the consent forms to the cryostorage record. This creates a risk of the bring forward system using an incorrect date if there has been a transcription error (SLC T36).

See 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 broadly compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

What the centre could do better

Use of embryos for training staff (Guidance note 22)
The centre's own audit tool used to audit embryos for staff training asks: 'at the point embryo assigned to training, was it by a different embryologist to the one who used it in training?'. This was recorded on the audit tool as 'not applicable' for all embryos audited. It was unclear to the inspection team why this would be 'not applicable' and also suggests that it was possible for the embryologist who allocated embryos for training, to then go on to use the same embryos in their own training, thus risking a perceived conflict of interest.

The centre's own audit also documented that patients who had provided fresh embryos for training had not received the relevant patient information document (SLC T95; SLC T97).

See recommendation 6.

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
With the exception noted under the sections 'Medicines management' and 'Pre-operative assessment and the surgical pathway' above, 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 broadly compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
Twenty-two percent (26/120) of the IVF and 22% (14/63) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005 .

See recommendation 7.

Section 3: Monitoring of the centre's performance

Following the interim inspection in March 2019, recommendations for improvement were made in relation to five areas of major non compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales. However, the inspection team noted that issues previously identified in relation to medicines management practices had recurred.

On-going monitoring of centre success rates

In October 2019, the centre was asked to review procedures for the provision of frozen embryo transfers in patients aged over 40 years. The PR responded to the request and has provided a commitment to keep success rates in this group of patients under review. The centre's success rates are in line with national averages.

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. **Premises and facilities** Photographs of the premises were provided by the centre as part of the DBA and videoconference inspection. The inspection team noted that both empty and full portable small (CD size) oxygen cylinders are stored in a trolley located in the corridor outside the procedure room. The inspection team was concerned that this poses a health and safety hazard to staff and patients. Gas cylinders should be	The PR should ensure that systems are in place for the safe storage of gases at all times, with appropriate safety signage present. The PR should take immediate action to ensure that the premises are safe for staff and patients and medical gases are stored appropriately. The PR should undertake a review to identify the circumstances that have led to this non- compliance. A summary of the findings of the review including corrective	We do not believe our storage of oxygen cylinders is non-compliant with the guidance cited. It meets the requirements in Sections 8.34 - 8.36: Local storage. Cylinders of medical oxygen are mounted on a trolley for use as emergency gas supplies in an access-controlled corridor next to the ward area. There is a designated "parking" area for the trolley, with signs to indicate its purpose. All staff are aware of the location and function of these cylinders.	The executive acknowledges the PR's response. Having reviewed the Health & Safety Assessment provided by the PR post-inspection, the executive notes that it does not mention an assessment of the 12 cylinder storage trolley. The PR is therefore required to seek a Health & Safety risk-assessment for the 12 cylinder storage trolley location to assess compliance. A copy of this assessment should be provided to the centre's inspector by 21 July 2021.

securely stored in a designated storeroom either in the building, or outside; and it should be clearly labelled with the types of gases contained, appropriate safety signage and access should be key-controlled. SLC T17 DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006)(8.20; 8.27; 8.59)).	actions and the timescales for implementation should be provided to the centre's inspector when responding to this report. It is expected that the storage of all medical gases are compliant with requirements by 9 August 2021. The LH should consider if this finding is relevant to other CARE centres within the group.	The storage of oxygen cylinders was not identified as a hazard in our most recent Health & Safety inspection which was undertaken by independent external contractors.	Further action required.
2. **Medicines Management** There were several issues related to Medicines management practice and procedures and auditing. These are described in the body of the report. SLC T2, SLC T24, and SLC T36. Clinic Focus (February 2020).	The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice requirements, that learning from guidance provided by the HFEA and/or other sources is implemented, and that staff are trained in how to respond if critical parameters of equipment are not maintained within acceptable limits. The PR should review medicines management practices in	We will undertake a review of medicines management practices and undertake a root cause analysis into the recurrence of non-compliances. A summary report will be provided to our inspector by 9 June 2021. We will undertake a further audit of medicines management practices by 9 September 2021. We have taken immediate action and affixed a notice to	The executive acknowledges the PR's response and commitment to review medicines management practice, and further related actions. The executive acknowledges that action has been taken to ensure staff are aware of the process to follow if the refrigerator is outside of the required range.

DH (2007) Safer management of Controlled Drugs: a guide to good practice in secondary care (England) sections, 4.7.1.2, 4.7.1.3). The Misuse of Drugs Regulations 2001); (Misuse of Drugs (safe Custody) Regulations (2001) (19.a)); (NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management', section 1.7.8.). Association of Anaesthetists 'Controlled drugs in peri-operative care' 2019, section titled 'Good practice for controlled drugs administered directly by registered healthcare professionals in the theatre environment/ record of administration'. The Association of Anaesthetists of Great-Britain and Ireland (AAGBI 'Controlled Drugs in Perioperative Care' (2019).	relation to the non-compliances identified during the inspection and undertake a root cause analysis into the circumstances which led to the recurrence of three of the non-compliances identified at the last inspection, to include consideration of the lack of effectiveness of the corrective actions previously implemented. A summary report of the root cause analysis, findings of this review, including timescales for implementation of corrective actions identified, staff training requirements should be provided to the centre's inspector by 9 June 2021. Three months after this review the PR should audit medicines management practices to ensure that corrective actions implemented have been effective in achieving and maintaining compliance. A detailed audit report, including audit scope, criteria and methodology, and redacted images of the sections of the CD book audited, should be	the outside of the medicines refrigerator which details actions to take if the temperature is outside the required range. These actions will be discussed at the next Nurses' meeting in April 2021. With respect to implementation of learning from HFEA guidance, CARE Bath is now using CARE's DATIX system to log all actions derived from HFEA and other professional guidance. This ensures actions are completed. The PR does not believe there are current barriers to sharing and implementing good practice since the adoption of the DATIX reporting system. The LH considers that there are effective systems for sharing learning from all HFEA inspections. It is expected that the non-conformance highlighted would have been identified if audits and alerts had been logged using CARE systems,	The executive acknowledges the PR's assurance that there are no longer barriers to sharing and implementing good practice, as CARE Bath now has access to the CARE group wide incident reporting system. Further actions required by 9 June 2021.

The Royal College of Anaesthetists (RCA)and the Association of Anaesthetists of Great-Britain and Ireland (AAGBI) 'Good practice, a guide for departments of anaesthesia, critical care and pain management' (2006)(7; 7.1). Although a number of issues were identified, this non-compliance has been graded as a 'major' rather than a 'critical' because the failings s do not pose a direct risk to patients.	provided to the centre's inspector by 9 September 2021. The PR should ensure that learning from guidance provided by the HFEA and/or other sources is implemented. The PR should review whether there are barriers to the implementation of learning from guidance provided by the HFEA and/or other sources. The PR should provide feedback on this review to the centre's inspector by 9 June 2021. The PR should ensure that all staff are trained and aware of the process to follow in the event that a refrigerator containing medicines is found to be outside the required parameters. The PR should provide evidence to the centre's inspector that training has been provided by 9 September 2021. The LH should consider if these findings are relevant to other CARE centres within the group.	which are now in use at CARE Bath.	

3. **Surgical Pathway** There were several issues related to sedation practice and procedures. These are described in the body of the report. SLCT2, SLC T12. Clinic Focus September 2019. Academy of Royal colleges, Safe sedation practice for healthcare procedures, Standard and Guidance (2013), pages 2, 9, 12, 20, 24, 27, 35, 36)). The Royal College of Anaesthetists (RCA) and the Association of Anaesthetists of Great-Britain and Ireland (AAGBI) 'Good practice, a guide for departments of anaesthesia, critical care and pain management' (2006)(7.1). Although a number of issues were identified, this non-compliance has been graded as a 'major' rather than a 'critical' because it is noted	The PR should ensure that sedation practices at the centre are compliant with professional guidance and best practice requirements and ensure that learning from guidance provided by the HFEA and/or other sources is implemented. The PR should ensure that adequate clinical supervision by fully trained staff is in place at all times. The PR should provide evidence that either, all relevant staff are able to demonstrate formal competency training in sedation practice, or provide the rationale for any deviations from the relevant HFEA and professional guidance, by 9 September 2021. The PR should review sedation practices and anaesthetic information record requirements in relation to the non-compliances identified during the inspection, including a root cause analysis into the circumstances which led to the failure to identify the limitations of the CIS system for recording the CD used by the centre. A	We have undertaken procedures under non-anaesthetist led sedation safely since the clinic opened in 1994 without incident or event. All of our clinicians and nurses have been trained in Immediate Life Support by the Resuscitation Council UK. This is in line with professional guidance from AOMRC regarding levels of expertise required for conscious sedation. Staff have previously been trained in sedation practices in-house before having their competency assessed. We acknowledge that the documentation for these competency assessments is lacking in detail and are in the process of undertaking more thorough competency assessments for all clinicians and nurses who assist in sedation. We will inform our inspector when these have been completed.	The executive acknowledges the PR's response. Even though no incidents have been reported, the executive would expect the PR to adjust practices to new professional guidance when they are published. The executive also acknowledges that training in Immediate Life Support is in line with professional AOMRC guidance recently published on 25 February 2021 (post inspection). The executive would like to clarify that this AOMRC update does not replace the 2013 publication, which indicates 'Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended'. Therefore, the PR should reassure themselves that all

that several staff at the centre are competent in sedation techniques and that adequate clinical supervision of patients could be maintained and no incidents have occurred.	summary report of the root cause analysis, findings of this review, including timescales for implementation of corrective actions identified, staff training requirements, clinical amendments to all patients' records affected by the inaccurate recording of the CD used in their sedation, should be provided to the centre's inspector by 9 June 2021. Three months after this review the PR should audit sedation practices to ensure that corrective actions implemented have been effective in achieving and maintaining compliance. An audit report should be provided to the centre's inspector by 9 September 2021. The LH should consider if this finding is relevant to other CARE centres within the group.	All staff involved in sedation were scheduled to attend Safe Sedation Courses run by Sedate UK in 2020. Unfortunately there were cancellations due to the Covid-19 pandemic. The courses are now available again and staff will be booked to attend as soon as practically possible. We will review sedation practices and provide a report to our inspector by 9 June 2021. Sedation practices will be re-audited by 9 September 2021.	practitioners involved in sedation practices are able to rescue patients whose level of sedation becomes deeper than initially intended and trained accordingly. The PR should ensure this recommendation is implemented in full. 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
4. **Transport and satellite agreements** Two of the centre's satellite agreements were not compliant with General Direction 10 (b, iii) as the written agreement did not make clear the responsibility of the offer of counselling. Instead the agreements both stated that counselling was an additional service available on request. General Direction 0010.	The PR should ensure that satellite agreements are fully compliant with General Direction 0010. During the desk based assessment process the PR submitted updated agreements which are compliant. No further action required, beyond that the LH should consider if this finding is relevant to other CARE centres within the group.		The executive acknowledges that the PR and LH confirmed, in response to recommendation two, that inspection findings will be entered into the CARE group incident reporting system which facilitates shared learning across the CARE group. No further action required.
5. **Storage of gametes and embryos** The storage consent period documented within the electronic database used to manage the	The PR should ensure that the centre's processes used to monitor consent to storage expiry dates are robust.		The executive acknowledges that the PR and LH confirmed, in response to recommendation two, that inspection findings will be entered into the CARE group

centre's bring forward system for embryos is not checked against the patient's consent form to ensure that this information is accurate. SLC T36.	The PR submitted a sample audit on 11 February 2021, to demonstrate consent periods had been documented accurately. The audit report provided assurance that the PR has reviewed the process for populating the electronic records used for managing the bring forward system. No further action required, beyond that the LH should consider if this finding is relevant to other CARE centres within the group.		incident reporting system which facilitates shared learning across the CARE group. No further action required.
6. **Embryos for training** The centre's own audit tool used to audit the use of embryos for training, asks 'at the point embryo assigned to training, was it by a different embryologist to the one who used it in training?'. This was recorded on the audit tool as 'not applicable'. This suggests that it was possible for the embryologist who allocated embryos for training, to then go on to use the same embryos in their own training,	The PR should ensure that there are process in so that there is no perceived conflict of interest when allocating embryos for training, and ensure that all patients receive appropriate patient information prior to donating their embryos for use in training. The PR provided evidence on 11 February 2021 to show that the embryologists who have assigned embryos for training, did not go on to use those same embryos in their own	The notation of not applicable on the audit was used only where frozen embryos had been assigned for training. In these cases, the embryos are not being "allocated" but are effectively being donated by the patients and as such there is no perceived conflict of interest. We do have robust procedures for ensuring there is no conflict where fresh embryos may be allocated to training rather than being used	The executive acknowledges the PR's response and explanation of why, when this audit noted what appeared to be significant non-compliance, that this was not then investigated further. The executive acknowledges the PR's confirmation that the SOP for the use of embryos in training also makes sure that the person allocating embryos to training is not the person using them in training.

thus risking a perceived conflict of interest. The centre's own audit of embryos for training also documented that patients who had provided fresh embryos for training had not received the relevant patient information document. SLC T95; SLC T97.	training. The PR is asked is asked to ensure that the SOP for the use of embryos in training also makes sure that the person allocating embryos to training is not the person using them in training, and provide confirmation when responding to this report. Immediately after the inspection the PR investigated the incidents recorded in the audit in relation to patients not receiving the appropriate information. The PR confirmed that this was due to a change in patient information documents and method of providing those to patients following the change of ownership. The PR was able to confirm that there was evidence in these patients records that they had indeed received the relevant information prior to giving consent to donation of their embryos for use in training. The PR confirmed that the centre has classified this as a 'near-miss' and it is being followed up in their own	clinically. From the relevant SOP: "The grading of embryos for transfer, freezing or assigning to research or training is checked by a second embryologist in order to ensure no bias in selection. Roles involving clinical and training use of embryos are clearly separated, ensuring that the embryologist who will use the samples for training purposes is not involved in clinical decisions regarding the allocation of embryos." The non-compliance noted by the audit was documented on our Datix system at the time in order to ensure further investigation was undertaken. A summary of the Datix report has been provided with this response.	The executive confirms receipt of Datix investigation report. No further action required.

	incident management processes. The PR has confirmed that systems are in place to ensure that information is provided to patients prior to giving consent to donation of their embryos for use in training. The PR is asked to review why this audit noted what appeared to be significant non-compliance that was not then investigated further. A summary of this review and any learning for future audit practice to be provided by 9 June 2021. The LH should consider if this finding is relevant to other CARE centres within the group.		
7. Obligations and reporting requirements Twenty-two percent (26/120) of the IVF and 22% (14/63) of the DI treatments reviewed at inspection had been reported to the HFEA outside the	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The procedures used to submit licensed treatment data	The delay in reporting these treatments was due to our transition to CARE systems. Our clinic switched from using the IDEAS database to the CARE CIS database in mid-September 2019. We understood that CIS would	The executive acknowledges the PR's response and reasons for the delayed submissions. The PR should provide the follow up audit, to ensure that

period required by General Direction 0005. General Direction 0005.	should be reviewed to identify and address the reasons for delayed submissions. This recommendation should be implemented by 9 June 2021, and the inspector informed of the results of the review and actions taken. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the centre's inspector by 9 December 2021. The LH should consider if this finding is relevant to other CARE centres within the group.	automatically submit treatment reports to the HFEA, however it transpired in January 2020 that the EDI facility had not been enabled on CARE Bath's CIS. In 2019, 22% of treatment cycles were carried out from mid-September onwards.	the issue has been fully resolved, by 14 October 2021.

Reponses from the Person Responsible to this inspection report