Executive Licensing Panel - minutes

Centre 0358 (CARE Fertility, Birmingham)

Renewal Inspection Report

Monday, 18 March 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Kathleen Sarsfield-Watson Dina Halai	Director of Strategy and Corporate Affairs Communications Manager Scientific Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Senior Governance 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 since June 2017 when the initial licence was granted.

1.2. The panel noted that CARE Fertility Birmingham is a private centre, located in Edgbaston, Birmingham and has held a treatment (including embryo testing) and storage licence with the HFEA since June 2017. It is part of the CARE Fertility group and provides a full range of fertility services.

1.3. The panel noted that the centre's licence was varied in February 2018, to reflect a change of Person Responsible (PR), from Ellen Armstrong to Rachel Smith. The licence was varied again in November 2018, to reflect a change of PR, to revert from Rachel Smith, back to Ellen Armstrong, after a period of maternity leave.

1.4. The panel noted that, between 1 November 2017 and 31 October 2018, the centre provided 301 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is a small sized centre.

1.5. The panel noted that, between 1 October 2017 and 30 September 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.6. The panel noted that, for IVF and ICSI, HFEA held register data for the period 1 October 2017 to 30 September 2018, show the centre's success rates are in line with national averages.

1.7. The panel noted that, in 2017, the centre reported 2 cycles of partner insemination with 1 pregnancy, which is in line with the national average.

1.8. An inspection was carried out at the centre on the 8 and 9 January 2019.

1.9. The panel noted that at the time of the inspection, there was one critical area of non-compliance concerning legal parenthood alongside three 'other' non-compliances regarding surrogacy, record keeping, and obligations and reporting requirements. Since the inspection visit, the PR has provided evidence that actions have been taken to implement the recommendations pertaining to the 'other' non-compliances and has committed, where required, to audit the effectiveness of those actions within the required timescales.

1.10. The panel noted that the PR has also provided evidence that action has been taken to implement the recommendation concerning legal parenthood. Due to the nature of this critical non-compliance, further actions have been recommended, based on the outcome of the centre's incident investigation and root cause analysis. The PR has given a commitment to fully implement these further actions within the required timescales.

1.11. 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 the quality of the service offered to patients. Significant improvement is required in order for the centre to reflect suitable practices.

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

1.13. The panel noted that, due to the serious nature of the critical non-compliance identified in the report and the compliance history of the CARE group of centres for legal parenthood consenting, and in accordance with section 3.1 of the HFEA's compliance and enforcement policy, a management review meeting was held on 21 January 2019, to evaluate the findings of this renewal inspection report and consider a proportionate course of action. It was considered appropriate to await the PR's response to this report, including the outcome of the relevant

incident investigation and root cause analysis, before considering whether any formal action is necessary.

1.14. A second management review meeting was held on 14 February 2019. The inspection team reviewed the PR's response to the report, the root cause analysis of the legal parenthood failure and supporting documents. These provided assurance that the PR is fully engaged with implementing required recommendations in relation to non-compliances. Further actions in response to the evidence provided by the PR were agreed and recommended.

1.15. The panel noted that the HFEA guide to licensing was used to guide a decision on an appropriate length of licence to recommend. A recommendation of a reduced three year licence was considered; however, as the centre had no non-compliances at their previous inspection, there are no serious concerns based on multiple births, success rates or patient feedback, and the PR has taken suitable remedial action and is fully engaged with the HFEA to address the non-compliances highlighted in this report, the inspection team assessed that a recommendation of a four year licence is suitable on this occasion, without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

1.16. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. These 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.

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 the licensed activities.

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 noted the serious nature of the critical non-compliance, regarding legal parenthood, identified at the renewal inspection, and encouraged the PR to continue working with the inspectorate to ensure all aspects of this are fully addressed.

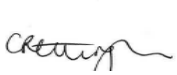
2.5. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years, without additional conditions, subject to the recommendations in the report being implemented within the prescribed timescales.

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

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

22 March 2019

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's 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: 8 and 9 January 2019

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

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

Inspectors: Lesley Brown (Lead), Vicki Lamb, Polly Todd, Neil McComb, Rosie O'Grady, Niamh Marren (Observer).

Date of Executive Licensing Panel: 12 March 2019

Centre name	CARE Fertility, Birmingham.
Centre number	0358
Licence number	L/0358/1/c
Centre address	27, Highfield Road, Edgbaston, Birmingham, B15 3DP, United Kingdom
Person Responsible	Ellen Armstrong
Licence Holder	CARE Fertility Group Limited
Date licence issued	27/06/2017
Licence expiry date	26/06/2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

CARE Fertility Birmingham is a private centre, located in Edgbaston, Birmingham and has held a Treatment (including embryo testing) and Storage licence with HFEA since June 2017. It is part of the CARE Fertility group.

The centre provides a full range of fertility services including embryo testing.

The centre provided 301 cycles of treatment (excluding partner intrauterine insemination) between 1 November 2017 and 31 October 2018. In relation to activity levels this is a small centre.

The licence was varied in February 2018, to reflect a change of Person Responsible (PR), from Ellen Armstrong to Rachel Smith. The licence was varied again in November 2018, to reflect a change of PR, to revert from Rachel Smith, back to Ellen Armstrong, after a period of maternity leave.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 October 2017 – 30 September 2018 show the centre's success rates are in line with national averages.

In 2017, the centre reported two cycles of partner insemination with one pregnancy, which is in line the national average.

Multiple births[2]

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

Between 1 October 2017 – 30 September 2018 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[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), 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 one critical, 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:

'Other' areas of non compliance:

- The PR should ensure that welfare of the child assessments are completed for the husband/partner of any surrogate being treated.
- The PR should maintain a record for each patient/donor, of how, and by whom, the patient/donor has been reliably identified.
- The PR should ensure that all licensed treatment activity is accurately reported to the HFEA within the timeframe required by General Direction 0005.

The PR has provided evidence that action has been taken to implement the following recommendation:

Critical areas of non compliance:

- **The PR should ensure that appropriate legal parenthood consent forms are completed prior to treatment using donor sperm.**

Due to the nature of this critical non-compliance, further actions have been recommended, based on the outcome of the centre's incident investigation and root cause analysis. The PR has given a commitment to fully implement these further actions within the required timescales.

Recommendation to the Executive Licensing Panel

The centre has one critical area of concern and three 'other' areas of concern.

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/live birth rates meet the target. The PR is encouraged

to continue to use the quality management system (QMS) to best effect to monitor and improve their success rates and the quality of the service offered to patients.

Significant improvement is required in order for the centre to reflect suitable practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided.

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

Due to the serious nature of the critical non-compliance identified in this report and the compliance history of the CARE group of centres for legal parenthood consenting, and in accordance with section 3.1 of the HFEA's compliance and enforcement policy, a management review meeting was held on 21 January 2019, to evaluate the findings of this renewal inspection report and consider a proportionate course of action. It was considered appropriate to await the PR's response to this report, including the outcome of the relevant incident investigation and root cause analysis, before considering whether any formal action is necessary.

The inspection team held a second management review meeting on 14 February 2019. The inspection team reviewed the PR's response to the report, the root cause analysis of the legal parenthood failure and supporting documents. These provided assurance that the PR is fully engaged with implementing required recommendations in relation to non compliances. Further actions in response to the evidence provided by the PR were agreed and recommended.

The HFEA guide to licensing was used to guide a decision on an appropriate length of licence to recommend. A recommendation of a reduced three year licence was considered, however as the centre had no non-compliances at their previous inspection, there are no serious concerns based on multiple births, success rates or patient feedback, and the PR has taken suitable remedial action and is fully engaged with the HFEA to address the non compliances highlighted in this report, the inspection team assessed that a recommendation of a four year licence is suitable on this occasion, without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Centre 0358 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

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

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

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

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor

and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

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

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

Suitable premises and suitable practices

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

What the centre does well

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

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

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

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

Prescription of intralipid 'off label'
Intralipid is 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)
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

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

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

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

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

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

Receipt of gametes and embryos (Guidance note15)

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. Imports of gametes and embryos from third country suppliers (TCS) outside the EU/EEA have not been initiated since the introduction of the ITE import certification scheme on 1 April 2018. The centre is therefore compliant with General Direction 0006.

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

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

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

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

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

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

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

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

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

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

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

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

The PR has academic qualifications in the field of 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.

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

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

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

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account, before licensed treatment is provided, the welfare of any child who may be born as a result of that

treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements (with the exception of surrogacy treatments, discussed in the relevant section of this report).

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. Thirteen patients have provided feedback in the last 12 months, giving an average five star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting staff on their caring and attentive manner and the cleanliness of the clinic.

During the inspection the inspectors spoke to one patient and one patient 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

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.

Counselling (Guidance note 3)

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent [and prior to consenting to legal parenthood].

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

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

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are partially 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

Surrogacy (Guidance note 14)
The centre has provided one treatment involving surrogacy. A review of the treatment records revealed that 'welfare of the child' assessments have been performed for both the intended parents and the surrogate. However, the surrogate's partner has not been assessed (SLC T56, CoP guidance 8.9; recommendation 2).

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and 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 was established after 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Other CARE Group centres were affected by historic legal parenthood failings and, as part of the group's shared learning, processes and procedures have been revised to avoid further failings. The centre has a local legal parenthood pathway; all staff involved in consent taking must be observed successfully completing 10 complicated consents before being approved as competent. A multidisciplinary review of the patient records, including their consent forms, takes place prior to patients progressing to treatment. These activities enabled the inspection team to conclude that the documented processes used to collect legal parenthood consent at this centre appeared compliant with HFEA requirements.

Seven 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. A significant anomaly discovered in this audit, discussed below, led the inspection team to conclude that the practice of collecting legal parenthood consent at the centre is not 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

Legal parenthood (Guidance note 6)
Seven sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were audited by the inspection team. A legal parenthood consent anomaly was found for one, unmarried, pregnant, patient couple, as a WP consent form had not been completed. A full review of the records showed that this missing consent forms had not been identified at the beginning of the treatment pathway. This error was not identified during subsequent, documented record checks. The treatment took place in July 2018, shortly after the end of the time period covered by the centre's last audit of legal parenthood practices (1 January 2018 and 30 June 2018). Thus this finding raises concerns about the effectiveness of the centre's legal parenthood consenting practices and the checks of legal parenthood consents performed before treatment is provided, but not necessarily about the centre's audit process (Section 44(1) of Part 2 of the HF&E Act 2008; recommendation 1).

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 17)

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

Storage of gametes and embryos (Guidance note 17)

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

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

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

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

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

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are broadly compliant with HFEA requirements. It 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

Record keeping and document control (Guidance note 31)
In four out of five records reviewed during the inspection, the staff member who reliably identified the patient/donor was not documented (SLC T46b; See recommendation 3).

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

9% (12/137) of the IVF and 5% (1/19) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005. A small number of minor data quality issues were also found and a list provided to the centre for editing (General Direction 0005, SLC T41; recommendation 4).

The centre did not have an EDI system fitted for some time, due to HFEA failings. When it was installed they experienced EDI system failures, that they have reported to the HFEA. These failings are highly likely to have impacted the register data concerns. The centre has committed to continue to work with the HFEA register team to ensure the accuracy of their register data.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2018, there were no areas of practice that required improvement.

On-going monitoring of centre success rates

The centre has not received any risk tool alerts related to success rates since the time of the last inspection.

Areas of practice requiring action

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

Critical area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. **Legal Parenthood** An audit of treatment with donor sperm, in circumstances where consent to legal parenthood is required, revealed one anomaly. A WP consent form had not been completed when the couple seeking treatment were unmarried. This finding raises concerns about the	The PR should ensure that appropriate legal parenthood consent forms are completed prior to treatment using donated sperm. The PR should complete a full incident investigation and root cause analysis (RCA) to understand the reasons why the consent documentation and checking processes have failed on this occasion. A copy of the investigation report and	An audit of all treatment cycles with donor sperm carried out by CARE Birmingham has been conducted by two members of the CARE team independent of CARE Birmingham. No other anomalies were found. A copy of the audit has been provided. A full RCA has been completed and has been provided. A further audit prompted by the RCA was also	The executive acknowledges the PR's response describing the actions taken since the inspection. The executive acknowledges receipt of the two audits, providing assurance that this is an isolated incident. The PR has provided a RCA identifying several areas where practice did not meet expectations, with documented

effectiveness of the centre's legal parenthood consenting practices and the checks of legal parenthood consents performed before treatment is provided, but not necessarily about the centre's audit process. Section 44(1) of Part 2 of the HF&E Act 2008.	RCA should be submitted to the centre's inspector when responding to this report. The PR should perform a full audit of all treatments involving donor sperm, to assure themselves there are no further anomalies. A copy of this audit should be submitted to the centre's inspector when responding to this report. As agreed during the inspection, the PR should review all records of treatment involving donor sperm, prior to progressing to treatment, until such a time the centre's inspector is assured that documented processes are being followed appropriately and are effective. The PR should produce a monthly report, detailing the findings of their treatment record review (including any corrective actions), to be submitted to the centre's inspector. As agreed during the inspection, the PR should inform the affected patient	completed of all cases across the CARE group with a similar profile to the one identified in CARE Birmingham. No other anomalies were identified. A copy of this audit has also been provided. The PR is reviewing all records of treatment using donor sperm and will continue to do so until this report is considered and further guidance provided. The couple have been contacted and offered a full apology. CARE will provide emotional and legal support to the couple to resolve any potential challenge to the partner's status as legal parent. A copy of the correspondence has been provided.	corrective actions. Based on the findings of the RCA, the PR should; • Confirm all identified actions are taken within the documented timescales. • Perform an audit to ensure nurses have reviewed patient records 48 hours in advance of consent signing appointment (as per CARE policy), to be submitted to the centre's inspector by 14 April 2019. • Perform an audit to ensure correct patient consent forms and associated information have been posted to the Patient Portal at least 48 hours prior to consent signing appointment (as per CARE policy), to be submitted to the centre's inspector by 14 April 2019. • Perform an audit to ensure the follicularam check best practice policy has embedded into practice, to be submitted to the centre's inspector by 28 May 2019.

	couple and provide full emotional and legal support. The centre's inspector should be kept informed of all steps taken in this respect. Further recommendations will be made based on the findings of the incident investigation and RCA.		• The PR should continue to review all records of treatment involving donor sperm, prior to progressing to treatment, until such a time that the centre's inspector is assured that documented processes are being followed appropriately and are effective. The PR should produce a monthly report, detailing the findings of their treatment record review (including any corrective actions), to be submitted to the centre's inspector. These additional actions have been agreed by the PR. Further action required.

Major area of non compliance

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

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

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

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

Other areas of practice that requires improvement

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. **Surrogacy** The centre is currently undertaking their first surrogacy treatment and has not completed a welfare of the child assessment on the husband of the surrogate. SLC T56, CoP 8.9.	The PR should ensure that welfare of the child assessments are completed for the husband/partner of any surrogate being treated. The PR should not provide any further treatment to the surrogate woman referred to in this report until a welfare of the child assessment has been completed on her husband, in line with the centre's own standard operating procedure. The PR should ensure that all relevant practitioners are aware of the requirements to complete welfare of the child assessments on all parties in a surrogacy arrangementincluding partners/husbands of	At the time of the inspection, the surrogacy case had not proceeded to treatment. Embryo transfer to the surrogate was performed on 29.01.19. Prior to the treatment cycle, folliculargram checks are performed to ensure all appropriate consents are in place as shown in document sent separately to this report. WOC assessment of the surrogates husband was completed prior to the treatment and in line with our SOP. The patient self referred as a single patient and was registered on 06.09.18. She was invited to attend a consultation 11.09.18 as a	The executive acknowledges the PR's explanation for the deviation from documented protocol and as a result has downgraded this non compliance from a major to an 'other'. However the executive is concerned that the donation team was unable to provide this explanation at the time of inspection. The PR is therefore encouraged to ensure any practice deviations are clearly documented in patient records and communicated to relevant team members. No further action required.

	surrogates and intended parents. The PR should confirm to the centre's inspector the actions taken to address this recommendation by 8 April 2019.	single patient and attended 04.10.18. On 03.10.18 the patients registration was ammended to 'married'. As the patient's husband didn't attend the appointment, the WOC could not be completed at this time. A consultant had a video call consultation with the surrogates husband during which she confirmed his identification which matched the photographic ID in the patients notes. She also confirmed he was happy to proceed with treatment and understood his state as legal parent until the parental order is granted. The WOC assessment was completed by the surrogates husband on 21.01.2019 and she brought it into clinic on 29.01.2019 when it was signed by the same consulatnt prior to the embryo transfer. The surrogates husband currently has health issues and lives over 140miles away. As per protocol, WOC assessments are signed prior	

		to offering treatment, however concidering the above, the team made provision to be reassured the WOC assessment had been completed in a timely manner but didn't sign to verify this until the day of embryo transfer. The HFEA inspection team reviewed the notes prior to the final checks being performed treatment and the team feel confident that treatment would not have been completed without the WOC assessment being in place. Please see attached image of the folliculargram checks showing that a WOC for the surrogates husband was required prior to treatment proceeding.	
3. **Record keeping** In four of five patient records audited, the person by whom the patient had been reliably identified had not been recorded. SLC T46b.	The PR should maintain a record for each patient/donor record, of how and by whom, the patient/donor has been reliably identified. The PR should review the centre's record keeping practices against compliance with the regulatory	Copies of photographic identification are present in each set of notes. A stamp is in use stating the identification has been verified, the person who has verified it and the date of verification. This is checked during the folliculorgram process.	The Executive acknowledges the PR's response and receipt of practice audit with corrective actions. The PR should provide a copy of the follow up audit by 28 May 2019. Further action required.

	requirements. A summary report of the review including corrective actions implemented, should be provided to the centre's inspector by 8 April 2019. Three months after this review the PR should audit record keeping practice to ensure that any corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 8 July 2019.	An audit following the inspection has been carried out by the PR and has been sent to the inspector. A further audit 3 months after this review will be completed as requested and a copy provided.	
4. **Obligations and reporting requirements.** On inspection the following issues were found: • 9% (12/137) of the IVF and 5% (1/19) of the DI treatments reviewed, had been reported to the HFEA outside the period required by General Direction 0005. • A small number of	The PR should ensure that all licensed treatment activity is reported to the Authority accurately and within the timeframe required by General Direction 0005. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for delayed and/or inaccurate submissions.	The review is underway. The PR has liaised with CARE's IT team and is awaiting their response. She will liase with the HFEA to resolve reporting anomalies. A report of the review findings will be provided as requested.	The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation. Further action required.

minor data quality issues were found, and a list provided to the centre for editing. General Direction 0005, SLC T41.	This recommendation should be implemented by 8 April 2019, 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. The EDI system is due to be replaced very soon. The PR should emphasise to their IT team, the absolute necessity to engage with the HFEA in redeveloping their patient data storage system, to make use of the new Application Programming Interface (APIs) which is in final development and will soon provide the system by which treatment data is submitted to the register.		

Reponses from the Person Responsible to this inspection report

The CARE Birmingham team fully recognise the serious impact of the LP consent failure on the patient couple. All staff are working together to ensure that this doesn't happen again. We have had the full support of the CARE team in identifying possible system changes.

I acknowledge the further recommendations from the executive review and confirm I will provide the evidence required within the timeframes stated.