Executive Licensing Panel – minutes

Centre 0061 (CARE Sheffield)

Renewal Inspection Report

Friday, 11 August 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Anna Quinn Ian Peacock	Director of Strategy and Corporate Affairs Policy Manager Systems Manager
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Observers		

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:

- 8th 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 the last licence renewal.

1.2. The panel noted that CARE Sheffield has been licensed by the HFEA since 1992 and provides a full range of fertility services, including embryo testing.

1.3. The panel noted that in the 12 months to 31 May 2017, the centre provided 718 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

1.4. The panel noted that for IVF and ICSI, HFEA-held register data for the period 1 March 2016 to 28 February 2017 showed the centre's success rates were in line with national averages.

1.5. The panel noted that in 2016, the centre reported 20 cycles of partner insemination with two pregnancies, which was in line with the national average

1.6. Between 1 March 2016 and 28 February 2017 the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 5%. This represents performance that is likely to be statistically lower than the 10% maximum multiple live birth rate target for this period.

1.7. The panel noted that at the time of the renewal inspection on 28 and 29 June 2017 there were three major and four other areas of non-compliance identified. The panel noted that since the inspection the PR has started to address the non-compliances and given a commitment to fully implement the outstanding recommendations. The panel noted that the inspectorate will continue to monitor the centre's performance and the implementation of the recommendations within the required timescales.

1.8. The panel noted that the centre has a Quality Management System (QMS) and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients.

1.9. The panel noted that the inspectorate recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of four years with no additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

2. Decision

2.1. The panel had regard to its decision tree.

2.2. The panel was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

2.3. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.4. 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 their duty under section 17 of the HFE Act 1990 (as amended).

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 with no additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales.

2.6. The panel noted that the centre's IVF success rates are consistent with the national average and its multiple birth rate is below the maximum live birth rate target and commended the centre on its performance in this area.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

18 August 2017

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: 28 and 29 June 2017

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), Janet Kirkland, Victoria Lamb.

Executive Licensing Panel: 11 August 2017

Centre name	CARE Sheffield
Centre number	0061
Licence number	L/0061/15/c
Centre address	24-26, Glen Road, Sheffield, South Yorkshire, S7 1RA, United Kingdom
Person Responsible	Mrs Rachel Smith
Licence Holder	CARE Fertility Group Limited
Date licence issued	1 January 2014
Licence expiry date	31 December 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

CARE Sheffield has held a licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 718 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2017. In relation to activity levels this is a medium size centre.

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

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

- Change of Licence Holder (April 2016).
- Change of licensed activities to include embryo testing (February 2016).

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 March 2016 to 28 February 2017 show the centre's success rates are in line with national averages.

In 2016, the centre reported 20 cycles of partner insemination with two pregnancies, which is in line with the national average.

Multiple births[2]

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

Between 1 March 2016 and 28 February 2017 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 5%: this represents performance that is likely to be statistically lower than the 10% multiple live birth rate target, for which the centre should be commended.

[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 Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their 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 following recommendations have been fully implemented:

'Other' areas that requires improvement:

- The PR should ensure that gas cylinders are stored securely.
- The PR should ensure patient information describing intralipid therapy makes clear that the administration of intralipid is not evidence based.

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

Major areas of non compliance:

- The PR should take appropriate actions to ensure that all gametes and embryos are stored lawfully.
- The PR should ensure that prior to giving consent to use embryos in training, each gamete provider is provided with the necessary information
- The PR should ensure that the prescription generation system is secure.

'Other' areas that requires improvement:

- The PR should ensure that suitable flooring and hand washing facilities are present in all clinical areas.
- The PR should ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have three major 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 are below the target, this achievement is to be commended. Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system (QMS) and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients. The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

The 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.

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

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

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

by CPA (UK) Ltd or another body 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 partially 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 a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The centre use the services of a third party to administer the intralipid to patients in their own home. Centre staff interviewed on inspection assured the inspection team that they had assessed the service and were satisfied that the infusions are being administered safely.

Written information provided to patients offered intralipid therapy is not compliant with guidance

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

Multiple births (Guidance note 7; General Direction 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been

transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

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

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

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

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

Receipt of gametes and embryos (Guidance 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.

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 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 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)
Some gas cylinders in the gas store were not secured.
(SLC T17, Health Technical Memorandum.02-01: medical gas pipeline systems part B: Operational management). See recommendation 5.

Infection control (Guidance Note 25)
Floors in some clinical areas were not sealed. 'Hands free' operated soap dispensers are not in use in all clinical areas (SLC T17, Health Building Note 00-10: Part A, 2.4, Infection control in the built environment 2013 3.5). See recommendation 4.

Medicines management (Guidance Note 25)
The centre use an electronic system to generate prescriptions from a drop down list. The centre have procedures in place to ensure generated prescriptions are checked and signed by clinician. However, there remains a risk that this system could be abused and unauthorised prescriptions generated (SLC T2, SLC T44a). See recommendation 3.

Prescription of intralipid 'off label'
Patient information describing intralipid therapy does not make it clear that the administration of intralipid is not evidence based (Clinic Focus July 2015). See recommendation 6.

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 (with an exception noted in the counselling section of this report), in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

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

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

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing

Preimplantation genetic screening

What the centre does well

Preimplantation genetic screening (Guidance note 9);
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 embryo is at a significant risk of having a serious 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
During the inspection visit the centre's own patient feedback was reviewed. Feedback from 72 responses was fairly positive, with 30 of the individuals providing written feedback to CARE Sheffield commenting that they have compliments about the care that they received.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

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

- care is taken when selecting egg and sperm providers donating for benefits in kind
- egg and sperm providers are fully assessed and medically suitable, and

- the benefit offered is the most suitable for the egg or sperm provider and recipients.

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
Counselling (Guidance note 3)
Nothing identified at this inspection.

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 / or donors are compliant with HFEA requirements (with the exception of intralipid as described elsewhere in this report). 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 its effectiveness and, in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that one couple were affected by legal parenthood consent anomalies. This case was concluded in May 2016 following a declaration of parenthood being made by the Family Division of the High Court.

At the inspection on 21 July 2015, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA. Actions had been taken in response to the audit findings.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

Inspectors also visited the centre on 3 May 2016, the focus of which was learning from legal parenthood consent anomalies. The centre engaged fully with this process. A full route cause analysis was performed by the centre with relevant changes to practice implemented.

As part of this renewal inspection, to provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed nine sets of records where treatment with donor sperm had recently been provided. Effective consent to legal parenthood with a prior offer of counselling was seen to be in place before treatment in all circumstances where consent to legal parenthood was required.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be compliant with HFEA requirements.

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

The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

What the centre could do better

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Two discrepancies were found between 10 completed patient disclosure consents on the patient files and the related consent data submitted for inclusion on the register. The patients had provided consent to disclosure, however data submitted to the register was recorded as the patients had not provided consent to disclosure Therefore the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure. (CH(10)05 and General Direction 0005). See recommendation 7.

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
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 partially 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

Storage of gametes and embryos (Guidance note 17)

A review of the centre's own extended storage audit showed that there were three instances where there was a period of lapsed consent, between the expiry of the original storage consents and the signing of storage extension consents. Although the centre have taken corrective actions, the inspection team believe further legal considerations of these complex issues is warranted (The Human Fertilisation and Embryology (Statutory Storage

Period for Embryos and Gametes) Regulations 2009 and SLC T79). See recommendation 1.

Use of embryos for training staff (Guidance note 22)

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 partially 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
Consent to training
Patients can consent to donating their embryos to training prior to being given specific information on that training. Prior to the embryos being used in training, specific information is sent by post to the patients. Centre staff cannot be assured that both gametes providers have seen this information and only the signature of one gamete provider, to document further consent, is required before embryos are used in training (SLC T97). See recommendation 2.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

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

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

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

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

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2015, recommendations for improvement were made in relation to two areas of major non compliance and one 'other' area of non compliance.

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

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.

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

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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. **Storage of gametes and embryos** A review of the centre's own extended storage audit showed that there were three instances where there was a period of lapsed consent, between the expiry of the original storage consents and the signing of storage extension consents (The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009, (SLC T79).	The PR should ensure storage is only extended beyond the statutory storage period when there is compliance with the 2009 storage regulations, both in relation to patient consent and evidence of either premature infertility or of likely premature infertility in the future. In all cases where there has been a failure to comply with the 2009 storage regulations, the PR should seek independent legal advice on how to proceed, including whether affected patients ought to be informed. Proposed actions in response to this advice should be	A report has been forwarded to the legal team with supporting evidence for each patient. Response will be communicated by the Licence Holder to the report and full investigation findings to be forwarded to HFEA prior to 29th September.	The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation. Further action required.

	forwarded to the HFEA for review prior to any action being taken. The outcome of this investigation, including the centre's intended actions and the timescales for their implementation should be submitted to the HFEA by 29 September 2017.		
2. Consent to training There is no process to ensure that consent to donating embryos to training is given by both gamete providers after receiving the specific information on the proposed training activities. SLC T97.	The PR should review the process for obtaining consent to use embryos in training to ensure that prior to giving consent each gamete provider is provided with the necessary information described in SLC T97. The PR should provide the centre's inspector with confirmation of how this will be achieved by 29 August 2017. Six months after the implementation of the new process the PR should audit the process and provide the centre's inspector with a summary of the results of that audit.	Patient information is to be sent with Cryobilling letters see patient information and consent ; training using gametes and embryos (15746). Cryobilling decision form wording altered to confirm this documentation has been sent with letters and read before patient signs for training. Corp lab PW 57 (16030) is to be used in clinic for recording the use of the frozen embryos For fresh donations this checklist is used in conjunction with doc 15746 . All proceudres follow SOP 58	The Executive acknowledges the PR's response and evidence of compliance provided. The PR has committed to provide the requested audit. Further action required.

		See attached docs. Re -Audit to be scheduled for Jan 18 and supplied to HFEA inspector.	
3. Medicines management Staff are able to generate and print completed electronic prescriptions in an uncontrolled and unsecure manner. SLC T2, SLC T44a.	The PR should review the security of the electronic system used to generate electronic prescriptions, to ensure that unauthorised or incorrect prescriptions cannot be generated. A report of this review along with proposed corrective actions should be provided to the centre's inspector when returning this report.	The CARE Head of IT will restrict access to the system, only allowing permissions to specified members of staff. An update will be provided to the HFEA when this is complete.	The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation. The PR has committed to providing an update report. Further action required.

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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. Infection control Floors in some clinical areas were not sealed. 'Hands free' operated soap dispensers are not in use in all clinical areas. (SLC T17). Health Building Note 00-10: Part A, 2.4 Infection control in the built environment 2013 3.54.	The PR should ensure that the flooring in clinical areas is suitable and is sealed to allow appropriate cleaning in the event of spillages of bodily fluids. The PR should ensure that suitable hand washing facilities are available in all procedural areas. The PR should provide the centre's inspector with confirmation of how this will be achieved by 29 August 2017.	The proposal for the flooring is as follows:- Recovery room 1 and 2 to be done on 27.7.17 Theatre and laboratory floors are required to be completed when the clinic is not processing cycles and therefore will be completed Dec 17/Jan 18.	The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation. Further action required.
5. Safety and suitability of premises and facilities Some gas cylinders in the gas store were not secured. (SLC T17, Health Technical Memorandum.02-01: medical gas pipeline	The PR should ensure that gas cylinders are secured in accordance with compressed gas safe storage guidance. The PR should provide confirmation of the action taken when responding to this report.	5.6.17 Cage reviewed by BOC advised to use one chain for all cylinders 6.7.17 Estates personel reviewed cage to add one chain. Chain to be supplied and fitted on 20.7.17	The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation. No further action required.

systems part B: Operational management).			
6. Prescription of intralipid 'off label' Patient information describing intralipid therapy does not make it clear that the administration of intralipid is not evidence based. Clinic Focus July 2015	The PR should review the information about intralipid treatments provided to patients to make sure it is easy to understand, and makes clear that the administration of intralipid in fertility treatment is not evidence based. Copies of the revised patient information should be submitted to the centre's inspector by 29 September 2017.	The patient information has been revised and has been submitted with this renewal application Doc ID 12655	The Executive acknowledges the PR's response and evidence of compliance provided. No further action required.
7. Disclosure of information, held on the HFEA Register, for use in research Two discrepancies were found between 10 completed patient disclosure consents on the patient files and the related consent data submitted for inclusion on the register. CH(10)05, GD 0005	The PR should correct the submissions that have been identified as being incorrect and provide confirmation to their inspector by 29 September 2017. The PR should review the procedures for checking and submitting consent to ensure that consent to disclosure decisions made by patients are accurately reported to the HFEA. This should include any variations to consent previously given by patients. A summary of the findings and any corrective	To indentify these patients and confirm changes made. A review of the pathway with any suggestions for improvement to the recording of the consent to disclosure information and any changes will be completed for submission prior to 29th September 17	The Executive acknowledges the PR's response and evidence of compliance provided. The PR has committed to provide the requested audit. Further action required.

	actions identified should be submitted to the centre's inspector by 29 September 2017. Three months after the implementation of corrective action, the centre should perform an audit to ensure that these corrective actions have been effective. This audit should be submitted by 29 December 2017.		

Reponses from the Person Responsible to this inspection report
Found the inspection process and feedback on the day was very positive but the comments made on the day in response to good practice are not commended in the report. We feel therefore that the report is unfairly biased towards non compliance whereas the inspection was very balanced on the day.