Executive Licensing Panel - minutes

Centre 0208 (CARE Tunbridge Wells)

Renewal Inspection Report

Friday, 16 March 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Caylin Joski-Jethi (Chair) Anna Coundley Niamh Marren	Head of Intelligence Information Access & Policy Manager Regulatory Policy Manager
Members of the Executive	Bernice Ash	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 for the last three years.

1.2. The panel noted that CARE Tunbridge Wells is a stand-alone private IVF clinic based in Kent and is part of the CARE Fertility group. The centre currently holds a treatment (including embryo testing) and storage licence and has provided licensed treatments since 2004.

1.3. The panel noted that, in the 12 months to 31 October 2017, the centre provided 885 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels, this is a medium sized centre.

1.4. The panel noted that, in the year to 31 July 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 11%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.5. An inspection was carried out at the centre on 28 and 29 November 2017.

1.6. The panel noted that at the time of the inspection, there were two critical areas of non-compliance regarding the Person Responsible and legal parenthood. Six major areas of non-compliance surrounding safety and suitability of premises and facilities, payment of donor import/export, the Quality Management System (QMS) storage of gametes and embryos, screening of donors and adverse incidents were identified. The centre also had five 'other' areas of non-compliance concerning traceability, equipment and materials, staff, information and record keeping and document control.

1.7. The panel noted that, since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations concerning payment of donors/import and export, screening of donors and adverse incidents, traceability, equipment and materials, staff and record keeping and document control, and has committed, where required, to audit the effectiveness of these actions within the required timescales.

1.8. The panel noted that the PR has given a commitment to fully implement the critical non-compliance recommendations concerning the Person Responsible and legal parenthood, alongside those regarding the safety and suitability of premises and facilities, the QMS, the storage of gametes and embryos and information.

1.9. The panel noted that significant improvement is required in order for the centre to reflect suitable practices and the PR is encouraged to correct and use the centre's QMS to best effect to monitor and improve the services provided.

1.10. The panel noted that the inspection report was initially provided to the PR for comment without a licensing recommendation, because the inspection team considered that their recommendation would, in part, be determined by the PR's response to the report. After the PR had responded and provided the plans to implement the report's recommendations, the Executive undertook a management review, on 2 March 2018, in line with the HFEA Compliance and Enforcement Policy, to decide a proportionate licensing recommendation. As a result, the Executive recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of three years, rather than the usual four.

1.11. The panel noted that the licensing recommendation reflects concerns about the level of non-compliance found on inspection and that some recommendations, to address the critical and major non-compliances, remain to be fully implemented at the time the report will be considered by a licensing committee. It will allow a targeted interim inspection to be performed within one year of the licensing committee's decision, at which the centre's compliance generally, and with

regard to the implementation of this report's recommendations, will be assessed. The success, or otherwise, of the change of PR, which is being implemented by the centre to address a critical area of non-compliance, will also be determined at the targeted interim inspection.

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

1.13. The panel noted the Executive identified that the current PR has engaged effectively with the report's recommendations and has already taken actions to address some non-compliances, and has developed and began to implement plans to address the remainder. The Executive has responded to the PR's comments in the report, requesting regular fortnightly updates regarding the corrective and preventative actions to implement several recommendations. This is to ensure effective implementation, but also to foster more frequent and open communications between the centre and the HFEA.

2. Decision

2.1. The panel decided to defer the decision until reassurances are received that the new PR is effectively discharging their duties under Section 17 of the HF&E Act 1990 and showing early progress in addressing the non-compliances identified at the 28 and 29 November 2017 renewal inspection.

2.2. The panel agreed to issue a Special Direction under Section 24 (5A)(b) of the HF&E Act 1990 (as amended), to permit the continuation of the centre's treatment (including embryo testing) and storage licence from 1 May to 31 August 2018 to allow time for a new PR to provide evidence that progress is being made to address the non-compliances identified at the renewal inspection and for the administrative process of licence renewal to be completed within the usual timeframe.

3. Chair's signature

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

Signature

Name

Caylin Joski-Jethi

Date

22 March 2018

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 November 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: Grace Lyndon (lead), Karen Conyers, Polly Todd and Janet Anderson-Pearce (observer).

Date of Executive Licensing Panel: 16 March 2018

Centre name	CARE Tunbridge Wells
Centre number	0208
Licence number	L/0208/8/d
Centre address	Amberley House 9, Queens Road, Tunbridge Wells , Kent, TN4 9LL, United Kingdom
Person Responsible	Mr Michael Rimington
Licence Holder	CARE Fertility Group
Date licence issued	1 May 2014
Licence expiry date	30 April 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

CARE Tunbridge Wells is a stand alone private IVF clinic based in Kent which is part of the CARE Fertility group. The centre has held a treatment licence with the HFEA since 2004 and provides a full range of fertility services.

The centre provided 885 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2017. In relation to activity levels this is a medium-sized centre.

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

The centre's current treatment (with embryo testing) and storage licence has been varied to reflect the following changes:

- embryo testing was approved as a licensed activity in October 2016
- the Licence Holder was changed to the 'CARE Fertility Group' in July 2016.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year to 31 July 2017, show the centre's success rates are in line with national averages.

In 2016, the centre reported 15 cycles of partner insemination with two pregnancies. This pregnancy rate is in line with the national average.

Multiple births[2]

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

In the year to 31 July 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 11%. 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 Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the current PR had not discharged his duty under section 17 of the HF&E Act 1990 (as amended) but, since receiving the report, has discharged his duty and has also decided to stand down from the role. An application has been submitted to change the PR and is being processed;
- 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 two critical, six major and five '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 these actions within the required timescales:

Major areas of non compliance:

- The PR should ensure that money or other benefits provided to donors are compliant with General Direction 0001, notably if donated sperm is to be imported under the authorisation provided by General Direction 0006.
- The PR should ensure that an assessment is made during the recruitment of each donor of the need to screen for Zika and Ebola virus infection.
- The PR should ensure that all incidents are investigated thoroughly and that robust and effective corrective actions are taken to prevent recurrence.

'Other' areas that require improvement:

- The PR should ensure that relevant data is documented, to allow the traceability of gametes and embryos, and all devices which may affect their quality and safety.
- The PR should ensure that evidence is collected to support the testing and validation of all new, repaired or recommissioned equipment before use.
- The PR should ensure that all staff providing information to patients using donor gametes can provide evidence of training or competency assessment.
- The PR should ensure that note is kept in patient records of embryo use in training and the name of the staff member who verifies the identity of the patient against appropriate photo-identification documentation.

The PR has given a commitment to fully implement the following recommendations and has already commenced actions to achieve this:

Critical areas of non compliance:

- **The PR should discharge his duty as described by section 17 of the HF&E Act 1990 (as amended).**
- **The PR should ensure that effective consent to legal parenthood is obtained and that the four legal parenthood consent anomalies are investigated and addressed to the satisfaction of the patients concerned.**

Major areas of non compliance:

- The PR should submit a retrospective application to the HFEA to vary the licence to account for changes to the centre's premises made since the last inspection and should also develop and document a process to ensure that licence variation applications are submitted in future when necessary.
- The PR should ensure that the centre's quality management system (QMS) and audit processes are effective in identifying and implementing robust and effective corrective and preventative actions in response to audit findings.
- The PR should take appropriate actions to ensure all sperm samples are lawfully stored with effective consent from the gamete providers.

'Other' areas that require improvement:

- The PR should ensure that information provided to patients and donors is accurate and compliant with HFEA requirements, and it is clear from patient records what information has been provided.

Recommendation to the Executive Licensing Panel

The inspection team notes that there are two critical, six major and five 'other' areas of non compliance or poor practice, that the centre's success rates are consistent with the national averages and that their multiple clinical pregnancy rate meets the target.

Significant improvement is required in order for the centre to reflect suitable practices and the PR is encouraged to correct and use the centre's QMS to best effect to monitor and improve the services provided.

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

The report was initially provided to the PR for comment without a licensing recommendation, because the inspection team considered that their recommendation would, in part, be determined by the PR's response to the report. After the PR had responded and provided the plans to implement the report's recommendations, the Executive undertook a management review, on 2 March 2018, in line with the HFEA Compliance and Enforcement Policy, to decide a proportionate licensing recommendation. As a result, the Executive recommends the renewal of the centre's treatment (with embryo testing) and storage licence for a period of three years, rather than the usual four.

This licensing recommendation reflects concerns about the level of non compliance found on inspection and that some recommendations, to address critical and major non compliances, remain to be fully implemented at the time the report is considered by a licensing committee. It will allow a targeted interim inspection to be performed within one year of the licensing committee's decision, at which the centre's compliance generally, and with regard to the implementation of this report's recommendations, will be assessed. The success or otherwise of the change of PR, which is being implemented by the centre to

address a critical area of non compliance, will also be determined at the targeted interim inspection.

The Executive notes that the current PR has engaged effectively with the report's recommendations and has already taken actions to address some non compliance, and has developed and begin to implement plans to address the remainder. The Executive has responded to the PR's comments in the report and requests regular fortnightly updates regarding the corrective and preventative actions to implement several recommendations. This is to ensure effective implementation but also to foster more frequent and open communications between the centre and the HFEA.

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 partially 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 partially 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

Screening of donors (Guidance note 11)
The centre has not considered for all donors during their recruitment, the risk of Zika and Ebola virus infection (Recommendation 7; SLC T52h).

Payments for donors (Guidance note 13; General Direction 0001)
The centre has imported donor sperm from a sperm bank within the European Economic Area (EEA), with which it has a service level agreement which states concerning compensation arrangements for donors: 'irrespective of any actual expenses, loss of earnings and other costs or inconveniences incurred in connection with the donation.' Furthermore, the agreement describes a fixed rate payment scheme of 45 Euros per donation visit. General Direction 0001 requires that compensation is for reasonable expenses actually incurred by the donor and loss of earnings up to £61.28 per day or a total of £250 across the course of donation. General Direction 0001 also requires that the centre should be satisfied for each donor of the compensation provided and that any excess expenses have been incurred by the donor. Therefore it is likely that sperm has been used in treatment at the centre, from donors who have been compensated in a manner non compliant with General Direction 0001 (Recommendation 4).

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, with one exception. 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 and transport facilities and laboratories conducting tests that impact on the quality and safety of gametes and embryos 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 Clinical Pathology Accreditation (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 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 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 partially compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are broadly 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 partially 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. The inspection team were however concerned regarding a service level agreement with another centre within the EEA, which provides donor sperm, as discussed elsewhere in

this report.

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 broadly 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 broadly 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 and investigating adverse incidents are partially compliant with HFEA requirements. Reporting and investigating 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)
A room that was previously used as a consultation room with storage side room, has been refurbished and is now used as an andrology laboratory with en suite sperm production room. The PR has not however submitted an application to vary the licence to change the licensed premises to reflect this. In previous correspondence between the centre's inspector and the PR in June 2017, the PR discussed the potential need to vary the premises. However, on inspection it became clear that the actual changes to the premises were made in December 2016. The inspection team reviewed the changed premises and considered that they are suitable for use as an andrology laboratory and sperm sample production room. This does not however mitigate that the PR failed to apply to vary the licence to change the licensed premises (Recommendation 3; General Direction 0008).

Imports and exports (Guidance note 16; General Direction 0006)
The centre has imported donor sperm from a sperm bank within the EEA, with which it has a service level agreement which describes a fixed rate payment scheme of 45 Euros per donation visit, provided to donors 'irrespective of any actual expenses, loss of earnings and other costs or inconveniences incurred in connection with the donation.' As discussed in 'Payment for donors', the inspection team considers this compensation to be non compliant with General Direction 0001. These donor sperm samples have been imported into the UK under General Direction 0006. However General Direction 0006

requires that compensation to providers of gametes to be imported, should be compliant with General Direction 0001. The PR has no evidence that payments to sperm donors have been compliant with these requirements, indeed the inspection team consider the payment scheme to be non compliant with General Direction 0001. Therefore these imports of sperm under General Direction 0006 are non compliant with the terms of that direction (Recommendation 4).

Traceability (Guidance note 19)
Traceability records for five items in use in the laboratory were reviewed. Of these, one item was not recorded as 'in use' in the centre's traceability records (SLC T99; Recommendation 9)

Quality management system (QMS) (Guidance note 23)
Some of the centre's audits, for example 'Sperm donor compliance' and 'Stored sperm samples', noted non-conformances or failure to attain quality objectives, but did not document appropriate corrective and preventative actions or timescales for implementation. In other audits, corrective and preventative actions were documented but their implementation was not (SLC T36; recommendation 5).

Equipment and materials (Guidance note 26)
A gas analyser had been repaired but no documentation was present to support testing and re-validation of the instrument before its reintroduction back into service (SLC T25; Recommendation 10)

Adverse incidents (Guidance note 27)
A number of adverse incidents in the centre's incident recording system were reviewed. There was a succession of medicines management incidents in which patients had been given medication with the wrong label and the wrong instructions for use. The reason for these errors was identified as 'human error'. No meaningful investigation and root cause analysis had been performed, so the corrective actions taken were ineffective in preventing reoccurrence of similar incidents (SLC T118; Recommendation 8).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

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

Staff (Guidance note 2)
The centre is broadly 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

Person Responsible (Guidance note 1)
It can be questioned whether the PR has carried out his legal duties, because:

- Investigations into historic legal parenthood issues have not been completed and the legal parenthood consent anomalies have not been addressed despite the PR informing the HFEA that they had been;
- The centre premises have been significantly modified without the PR submitting an application to vary the licence to modify the licensed premises;
- Imports of donated sperm have been made under General Direction 0006 even though it is likely that the donors have been compensated in a manner non compliant with General Direction 0001.
- The Person responsible fails to respond to correspondence from the HFEA or a response is not given in an appropriate time frame.

(SLC T9; Recommendation 1).

Staff (Guidance note 2)
Staff who gave patients their information regarding their use of donated gametes in treatment, could not provide evidence of training or competence assessment to deliver this area of practice (SLC T15; Recommendation 11).

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

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

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

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

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

2. The experience of patients

Patient feedback

What the centre does well

The inspectors did not have the opportunity to speak to any patients during the inspection. The centre's most recent patient survey responses were reviewed. The patient experience indicator for October 2017 identified a 41% response rate after initial patient consultation and 95% of the responding patients rated the centre as excellent/very good, meeting the centres quality objective. The response rate for patients after treatment completed was 43% and 92% of these respondents rated their experience as either excellent or very good.

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

That 92% of respondents after treatment rated their experience as either excellent or very good, falls below the centre's quality objective for this indicator but corrective and preventative actions to improve the patient experience were not documented in the review (see QMS section and Recommendation 5).

Treating patients fairly

Counselling
Egg 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 and/or sperm 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 recipients.

Surrogacy (Guidance note 14)
The centre does not currently provide treatments regarding surrogacy so this was not an area of practice reviewed during this inspection.

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

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

What the centre could do better
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 donors are broadly 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

Information (Guidance note 4; Chair's Letter CH(11)02)
The 'consent to treatment information and guidance form' provided to egg sharers, states that if less than 8 eggs are collected in an egg sharing arrangement, HFEA regulations state the donor must keep all the eggs. This information is misleading in that HFEA regulations or guidance make no such reference.

In the sperm donor record reviewed, the information provided to the donor was not documented so it was unclear what information had been provided, notably about compensation arrangements and screening.

SLC T58; Recommendation 12

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.

In February 2014, the HFEA asked all center's 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 15 couples exhibited legal parenthood consent anomalies. After investigation, evidence was available for effective legal parenthood consent in eleven cases, but in four cases consent anomalies remained to be resolved. At this inspection, we reviewed the centre's audit from 2014 and found that it had been performed according to the method specified by the HFEA, however the centre has taken no further action to resolve the consent anomalies in the four cases identified and the cases were not reported to the HFEA in the form of an incident. The four cases are discussed below.

To provide assurance of the current compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Five sets of records where treatment with donor sperm had recently been provided and consent to legal parenthood was required, were audited by the inspection team. These activities enabled the inspection team to conclude that the process used to collect legal parenthood consent is 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)
The centre's legal parenthood consent audit in 2014 showed that 15 couples initially exhibited legal parenthood consent anomalies. After investigation, evidence was available for effective legal parenthood consent in 11 of these cases, but in four cases consent anomalies remained to be investigated and resolved. At this inspection, the inspection team identified that no further actions have been taken to resolve the consent anomalies in the four cases identified by the audit in 2014.

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 commenting: 'While we accept there are some paperwork errors, we do not believe any of the cases will present a problem in terms of legal parenthood either now or in future. Our 'in-house' consent forms which we used prior to the WP and PP cover most of the errors. We have subsequently carried out another audit of our WP and PP forms for all patients receiving treatment with donor sperm and no issues were identified. We have also put in place a further measure to ensure accurate completion. We have now completed our audit and would consider the matter closed'. The Executive now question whether this statement was justified because no further investigations or attempts to obtain legal advice regarding the four outstanding consent anomalies were made, until after this renewal inspection, despite the HFEA recommending in 2014 that centre's sought legal advice regarding any consent anomalies.

Since this renewal inspection, the centre has fully engaged with the HFEA and has committed to address the four cases in which consent to legal parenthood is not robust. The PR and Licence Holder (LH) have informed the HFEA of the actions taken so far, the contact or attempts at contact with the four patient couples affected, and what further actions are planned. The centre has committed to act in accordance with HFEA guidance to support couples affected by anomalies in consent to legal parenthood. On the basis of this information, the Executive is assured that the centre is taking action and is offering appropriate support and guidance to the couples affected. Progress with these actions will be followed up by the centre's inspector.

Chief Executive's Letters CE(14)01, CE(14)02 and CE(16)01; SLC T36;
(Recommendation 2)

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 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)

During an audit of records of stored samples, the following was noted:

- For one patient with sperm samples stored in 2000, consent for long term storage was documented on the (00)9 form which includes a medical practitioner's statement confirming that the patient's fertility was likely to be significantly impaired. In 2009, the patient completed a GS form under the 2009 regulations, consenting to

extended storage for the same period as originally indicated on his previous form. The 2009 regulations also require however that a written medical opinion concerning actual or potential premature infertility, should have been documented within the last 10 years, in order to meet the requirements for an extended storage period. An updated medical opinion was not noted in the records, meaning that extended storage could only be lawful for 10 years after the medical practitioner's statement was completed in 2000.

- For one patient with sperm samples stored in 2005, there was a gap of about 6 weeks in consent to storage, between the lapse of one period of consent and the commencement of the consent for an extended storage period. Centre staff explained that during this time they had been in discussion with the patient regarding the fees for long term storage, before the patient agreed to sign the consent forms. A medical practitioner statement was in place to comply with the requirements for extending storage.

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009; Recommendation 6.

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 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.

What the centre could do better

Record keeping and document control (Guidance note 31)
The name of the staff member who verifies the identity of a patient against appropriate photo-identification documentation is not recorded in the patient's records.

During an audit of the records of embryos used for training purposes, it was noted that in one case the use in training had not been documented on the patient's laboratory sheet, contrary to the centre's standard practice. The use of the embryo in training had been recorded in the training log book.

SLC T46; Recommendation 13.

Section 3: Monitoring of the centre's performance

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

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

On-going monitoring of centre success rates

Since the last inspection in 2015, the centre has not received any HFEA risk tool alerts in relation to their success rates.

Areas of practice requiring action

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

Critical 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. The Person Responsible It can be questioned whether the PR has carried out his legal duties, because: • Investigations into four historic legal parenthood issues have not been completed or legal advice sought, and the legal parenthood consent anomalies have not been resolved, despite the PR informing the HFEA that they had been;	The PR should ensure that he works closely with the HFEA and responds promptly to requests for information. The PR should note and reflect on the significant failings in his performance of the PR role listed in this report. The PR should review the barriers which have led to these failings. The PR should either commit	The PR notes that the inspection report was provided seven weeks late on 16th February 2018. The PR understands the HFEA has also been in contact with the CARE central team regarding the inspection report. The PR has responded to HFEA correspondence over the years but acknowledges this has not always been timely. This has sometimes been due to delays in seeking information from the appropriate staff to respond to	The Executive acknowledges the report was provided late but also that verbal feedback at the end of the inspection had identified the areas of non compliance so they could be addressed by the centre. The PR was kept informed of delay during report preparation, resulting from the complexity of the non compliances and other workload issues. The Executive acknowledges

• The centre's premises have been significantly modified without the PR submitting an application to vary the licence to modify the licensed premises; • Imports of donated sperm have been made under General Direction 0006 even though it is likely that the donors have been compensated in a manner non compliant with General Direction 0001. • The Person responsible fails to respond to correspondence from the HFEA or a response is not given in an appropriate time frame. SLC T9	to future compliance and improved performance or should seek to pass the PR role onto another staff member. In the former case, he should implement appropriate actions to remove barriers which limit his performance and should then take swift and effective corrective actions to address all non compliances listed in this report, and should communicate this to the centre's inspector. In the latter situation, the Licence Holder should submit an application to change the PR by the time this report is considered by a licensing committee.	the queries and at other times due to existing clinical commitments taking priority. Going forward, the PR accepts that there must be a change in work pattern to allow for the PR responsibilities to be appropriately discharged and issues to be addressed in a timely fashion. The PR has sought guidance from the CARE Group regarding how those barriers to performing the role might be lifted. The clinical activity of the PR is such that it is not possible to commit to a reduction in that clinical activity. Therefore, the PR will step down from the role. To maintain continuity within the clinic and to comply with the Code, the PR will only step down from the role once a suitable replacement has been made. See section two regarding legal parenthood below. See section three regarding the change in premises. See section four regarding the import of gametes.	the PR's decision to step down from the PR role and communications from the centre's Licence Holder confirming that a new PR is to be appointed and the CARE groups plans for doing this. An application to change the PR was received on 7 March 2018. The PR should provide fortnightly updates to the centre's inspector, regarding progress in appointing a new PR. The Executive encourages the PR to maintain fortnightly communication via email with the centre's inspector, to provide updates about the implementation of the report's recommendations, as requested in the 'Executive Review' comments. **Further action is required.**
2. Legal Parenthood The centre's audit of legal	The PR should ensure that effective consent to legal	The PR can confirm that at the current time the processes to	The Executive notes that the report found no concerns with

parenthood and investigations in 2014, found that four couples were affected by legal parenthood consent anomalies. The PR subsequently advised the HFEA that the anomalies had been resolved. At this inspection, the inspection team were advised that legal advice was not sought about these cases, contrary to what the HFEA had advised, so none of the cases have been resolved. The PR also provided assurances in 2015 that all non conformances found in the 2014 audit had been addressed. These assurances were not justified given the non compliance described above. Chief Executive's Letters CE(14)01, CE(14)02 and CE(16)01; SLC T36.	parenthood is obtained. The centre should immediately seek legal advice regarding the four legal parenthood consent anomalies identified by the 2014 audit. The PR should provide the centre's inspector with a summary of the legal advice when it is received and the actions planned in response to it, including how the centre intends to communicate with and support all couples affected. The PR should conduct a root cause analysis into the circumstances which led to the consent anomalies identified by the 2014 audit, why those anomalies have not yet been corrected, and why the PR provided assurances in 2015 regarding the resolution of the anomalies when legal advice had not been obtained so the cases could not be considered to be resolved. A copy of this root cause analysis should be provided	take consent to Legal Parenthood are in place and effective. Staff have received training and those staff taking consent have passed the appropriate competencies. This is documented on the staff training records which have previously been sent to the inspector. An audit of relevant treatments involving legal parenthood between 6 April 2009 and December 2017 has already been provided and is therefore not requested again. The historical cases regarding Legal Parenthood discussed at the inspection are acknowledged. Legal advice has already been sought regarding four cases where Legal Parenthood is an issue. Every effort has been made to reach the couples. Three have been successfully contacted. The PR can confirm that all the HFEA recommended actions in managing these couples will be complied with. The PR has sent a detailed summary of each case on progress to date to the inspector. The PR is pleased to update the	the centre's current legal parenthood consenting practices. The Executive acknowledges the PR's communications describing actions taken to contact the four couples with anomalous parenthood consents and the PR's confirmation that all HFEA required actions to manage these couples will be complied with. The PR should continue to make every effort to contact the one couple yet to be contacted, and to address the parenthood consent anomalies to the satisfaction of all the patients concerned. The Executive has agreed with the LH's request to submit the root cause analysis to the centre's inspector by 1 April 2018, rather than 1 March 2018. This is so that a thorough analysis can be performed by a team from outside the centre. This is thought reasonable as the centre's current consenting processes are considered

	to the centre's inspector by 1 March 2018. An audit of relevant treatments between 6 April 2009 and December 2017 has already been provided and is therefore not requested again. The PR should keep the executive updated with any progress made in all the cases and any potential court dates.	HFEA on the LP cases on a fortnightly basis as advised. The last update was sent to the inspector on 23rd February 2018. The next report will be sent on 7th March 2018. As a result of the very limited time available, the CARE Group Licence Holder has been in contact with the inspector seeking further time for an RCA to be carried out and the findings forwarded to the HFEA.	compliant. The PR should provide the centre's inspector with fortnightly updates regarding progress to address each of the four cases, including a summary of any legal advice received and the actions planned in response to it, how the centre intends to support the four couples affected, and any legal action proposed with court dates. **Further action is 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
3. Safety and suitability of premises and facilities A consultation room with storage side room, has been refurbished and is now used as an andrology laboratory with ensuite sperm production room. The PR has however failed to apply to the HFEA to vary the licence to change the licensed premises. General Direction 0008	The PR should submit an application to the HFEA to vary the licence to account for the changes to the centre's premises. The PR should investigate why the change to the premises was made without adhering to the requirements of General Direction 0008. This review should include suitable and appropriate corrective and preventative actions, with timescales for implementation, and should be provided to the centre's inspector with the PR's response to this report.	The application for a variation in premises was made on 5th December 2017, following the inspection. The PR acknowledges and apologises for the fact that the application was not made before the premises had been altered and before the new andrology laboratory came into use. The PR has reviewed the guidance notes and recognises this was an omission. Although the proposed change was pointed out to the inspection team at the Interim Inspection in November 2015 this was not followed through with the	The Executive acknowledges the PR's response but notes that the licensed activities in the room changed (clinical activity to laboratory activity) so a variation of the licence is required. The centre's inspector has received the variation application. The inspection team also recommended that an investigation be performed to find out how significant changes could be made at the centre without consideration of regulatory requirements. Such an investigation could follow the format of a root cause analysis and was expected to include suitable

	On balance, the inspection team do not consider there to be benefit in requiring the centre to suspend the use of the new andrology laboratory until the licence is formally varied, because of the disruption this may cause to patient treatment and because the team considered the revised premises were appropriate for licensed activities.	appropriate application for a change in premises. It should be noted that the existing sperm production room has not changed in design or location. The 'new' andrology laboratory was in fact an existing clinical area previously used for storage and not a consultation room. A new clinical sink was fitted and existing equipment moved from the laboratory to the new location. No new equipment was purchased and there was and is no change in the activity of the laboratory. In essence the andrology laboratory was moved from one clinical area to another.	and appropriate corrective and preventative actions, with timescales for implementation, and to be documented. No such investigation has been documented or provided to the centre's inspector. This non compliance suggests that the centre may not have an effective process to manage changes in the centre's fabric, equipment, processes and staff. The PR might wish to consider this possibility. A report of the investigation should be provided to the centre's inspector by 1 April 2018. **Further action is required.**
4. Payment of donors / Import and export The centre has imported donor sperm from a sperm bank within the EEA, with which it has a service level agreement which describes a fixed rate payment scheme of 45 Euros per donation visit, provided to donors 'irrespective of any actual expenses, loss of earnings and other costs or inconveniences incurred in	When importing sperm, the PR should ensure that money or other benefits provided to donors are compliant with General Direction 0001, if the import is to be undertaken under the authorisation provided by General Direction 0006. The PR should review documented procedures for importing sperm and the service level agreement with the	It is unfortunate that the printed third party agreement with the European Sperm Bank, which was shown to the inspector on the day, was not the approved version used by the CARE Group. The PR appreciates the concerns regarding payment of sperm donors. This has been escalated to the CARE Group who have been in contact with the provider. To reassure the	The Executive notes that an unauthorised version of the service level agreement should not have been present. The Executive notes the PR's response, commitment to compliance in this area of practice, and the evidence provided including a revised service level agreement, communication from the sperm bank regarding donor compensation and the centre's

connection with the donation.' This compensation scheme is non compliant with General Direction 0001. These donor sperm samples have been imported into the UK under General Direction 0006, which requires that compensation to providers of gametes to be imported, should be compliant with General Direction 0001. The PR has no evidence that payments to sperm donors have been compliant, indeed the inspection team consider the payment scheme to be non compliant, therefore these imports of sperm under General Direction 0006 are non compliant with the terms of that direction	overseas centre, to ensure the requirements of General Directions 0001 and 0006 are met in future. The PR should provide the centre's inspector with a summary of this review and any amended documents by 1 March 2018. The PR should review all imports of donated gametes since 1 December 2015, and should determine, with the overseas centre if necessary, the level of compensation provided to donors and whether it has been compliant with General Direction 0001. A report of this review should be provided to the centre's inspector by 1 March 2018.	HFEA the TPA has been updated to remove any uncertainty regarding payment and a statement from ESB regarding historical payments is attached. This hopefully reassures the HFEA that the provider complies with General Direction 0001 and 0006. As requested a review of donor sperm imported since 1st December 2015 has been made and is attached.('Donor Imports since December 2015')	review of imported donor sperm samples, indicating the nine donors imported since 1 December were appropriately compensated. The Executive considers the documents constitute reasonable evidence for compliance and the implementation of the recommendation. No further action is required but, going forward, the Executive suggests that the centre documents, for each donor imported, the actual amount of money provided to them in compensation during the cycle of donation for: a) loss of earnings b) reasonable expenses
5. QMS Some of the centre's audits, for example of 'sperm donor compliance' and 'stored sperm samples', note non-conformances and failure to meet quality objectives, but did not document appropriate corrective and preventative	The PR should ensure that the centre's audit processes are effective in identifying and implementing appropriate corrective and preventative actions in response to audit findings. These actions, with timescales for implementation, should be documented; as	The PR ensures the centre's audit processes are effective in identifying and implementing appropriate corrective and preventative actions by following and implementing the CARE Group rolling audit programme. The audit findings are all forwarded to the CARE	The Executive acknowledges the PR's comments, that the centre's audit programme is generally compliant and that, generally, audit findings and corrective and preventative actions are documented and reported monthly to the centre's management group meeting.

actions with timescales for implementation. Some audits recorded corrective and preventative actions, but did not record their implementation. SLC T36	should the fact the actions have been implemented. The actions taken to implement this recommendation should be documented in the PR's response to this report. The PR should review all audit reports since the last inspection in November 2015, to ensure the findings and appropriate corrective and preventative actions, with timescales for implementation, are clearly documented, along with the dates of implementation of the preventative and corrective actions. A summary report of the findings of this review should be provided to the centre's inspector by 1 March 2018. Three months after the implementation of corrective actions, the PR should audit the quality of audit reports to determine the effectiveness of the actions taken. A summary report of this audit should be provided to the centre's inspector by 1 June 2018	Governance and Quality Lead for review and quality assurance. Audit findings and CAPAs are presented in a written report and discussed at the monthly Operations Meeting and minuted. An example report is attached. During the period November 2015 to January 2017 CARE developed a robust audit programme to which all units are committed to following. The PR has reviewed 32 local and CARE-wide audits performed since November 2015 with the local Quality Manager. The PR will undertake to review the audits in the CARE audit programme from January 2017 onwards, to evidence that audits are closed off with CAPAs completed and information has been, or is being, discussed at meetings with staff. A report will be sent to the HFEA by 1st June 2018. The PR will ensure that departmental meeting agendas will include a standing agenda item to update staff on completed audits and the	This inspection report makes clear however that this non compliance relates to some (occasional) audits in which non conformances have not been properly investigated, so appropriate corrective and preventive actions have not been documented and/or clearly implemented. The Executive expects there to be effective root cause analysis of non conformances found during audit, so appropriate corrective and preventative actions can be implemented to prevent recurrence. This expectation will hopefully be facilitated by the PR's actions to ensure non conformances and corrective and preventative actions are discussed in departmental meetings. The PR states he has reviewed the completion of corrective and preventative actions in 32 audits performed since November 2015. A summary report of this review was requested by 1 March 2018, but has not been provided. The PR should do so on receipt of this

		resultant non-conformances and actions. The Tunbridge Wells Operational meeting will include a report (rolling action plan) of all non-conformances and resulting actions for audits completed since January 2017. Responsible managers will be required to provide assurance in minutes that actions have been completed or escalated. Change control processes will be implemented for changes in process or procedures.	finalised report. A summary report of the follow up audit to ensure the recommendation has been effective implemented, should be provided to the centre's inspector by 1 June 2018. **Further action is required**.
6. Storage of gametes and embryos During an audit of records of stored samples, the following was noted: • For one patient with samples stored in 2000, consent for long term storage was documented on the (00)9 form, which includes a medical practitioner's statement confirming that the patient's fertility was likely to be significantly impaired. In 2009, the patient completed	The PR should take appropriate actions to ensure all sperm samples are lawfully stored with effective consent from the gamete providers. The PR should provide the centre's inspector with a summary of any legal advice obtained regarding the two cases identified, as well as with the centre's intended actions and anticipated timescales for their implementation, when responding to this report.	In the first case with sperm stored in 2000, there are two HFEA consents to storage (form (00)9 consent to long term storage and a GS form completed in 2009). The case has been discussed at a local multidisciplinary meeting and with the CARE Group. In the absence of an updated medical opinion, it was concluded that the samples should be removed from storage. Historically the patient has not been in contact in any way with the centre for more	The Executive acknowledges the PR's commitment to fully implement this recommendation. One sample has been allowed to perish while the other has been discussed with the CARE legal team. The PR should ensure a summary of any legal advice obtained (on a case by case basis) is provided to the centre's inspector, as well as the intended actions and timescales for implementation, as is stated in the recommendation.

a GS form under the 2009 regulations, consenting to extended storage for the same period as originally indicated on his previous form. The 2009 regulations also require that a medical opinion concerning actual or potential premature infertility, should have been documented within the last 10 years, in order to meet the requirements for an extended storage period. An updated medical opinion was not noted in the records, meaning that extended storage could only be lawful for 10 years after the medical practitioner's statement was completed in 2000 • For one patient with samples stored in 2005, there was a gap of approximately 6 weeks between two periods of consent to storage. Centre staff explained that during this time they had been in discussion with the patient regarding the fees for long term storage, before the	The PR should also review all long term stored samples to ensure that all appropriate consents and written medical opinions are in place. A summary of the findings of the review, including any corrective actions with timescales for implementation, should be provided to the centre's inspector by 1 March 2018.	than five years despite attempts by the centre to contact him. He moved to Slovakia. The PR contacted the patient after the inspection and received verbal telephone confirmation to dispose of the samples followed up by an e-mail from the patient confirming the same. The PR can confirm that the samples have been removed from storage. In the second case regarding the gap in continuous consent, as matters stand, the consent form is current, acknowledging that there was a gap of a few weeks while the man was deciding whether he wished to continue storage. Communication with the patient during the gap is well documented. It was considered unreasonable to have removed the samples from storage for a short period of time while he was considering his options. It should also be noted that there is a Medical Practitioners Statement in the records to	The Executive expects the PR to provide fortnightly updates, via email to the centre's inspector, regarding the actions taken to address the one sample in storage for which storage consent has not been continuous, and the review of all long term stored samples to ensure that all appropriate consents and written medical opinions are in place. It is agreed that the review of stored material can be completed by 1 June 2018, as requested by the PR, rather than the 1 March 2018. The inspection team accept that they underestimated the number of samples to be audited when drafting the original deadline. **Further action is required.**

patient agreed to sign the consent forms. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 Paragraph 4		support extended storage which predates the expiry of the original consent to storage. CARE has previously sought legal advice on a similar case from Sheffield and sent it to the HFEA on 29th September 2017 but as yet an answer on the matter has not been received. The CARE legal team has advised the centre to wait for that response as the case sited in this report is similar. The long term storage of samples has been reviewed and with the exception of the above two cases the PR is assured all consents to storage are in place and correct with none requiring a Medical Practitioners Statement at this point in time. The PR has asked for this to be audited again and would ask that this audit can be reported to the HFEA by 1st June 2018.	
7. Screening of donors The centre has not considered for all donors during their recruitment, the risks of Ebola	The PR should ensure that an assessment is made during the recruitment of each donor of the need to screen for Zika and	The inspection team noted that the EBOLA and ZIKA risk appeared not to be documented in the records for	The Executive acknowledges the PR's response. The actions which the PR describes would seem to ensure that appropriate

or Zika virus infection. SLC T52(h)	Ebola virus infection. Documentation of this assessment should be present in the records. The PR should inform the centre's inspector of the actions taken to comply with this recommendation when responding to this report. Three months after the implementation of the corrective actions, the PR should conduct an audit of donor records to ensure actions implemented have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 1 June 2018.	gamete donors. However, this is documented for egg donors in the female history sheet in the electronic records. All egg donors complete a current ZIKA questionnaire which is stored in their electronic records and this is confirmed in the nurse checklist. For sperm donors, the EBOLA risk assessment is made at several stages. The travel history is taken by telephone in the first instance and recorded on the 'Sperm Donor Telephone Checklist.' This is checked again when the potential donor comes to the clinic and is recorded on the 'Potential Sperm Donor Consultation' checklist. The donors are asked about their travel history which specifies countries where EBOLA is a risk. Again all sperm donors complete the current ZIKA questionnaire. For the sperm donor record reviewed at the inspection, this was shown to the inspector on the day. For the sake of clarity, this will be raised with the CARE Group to decide whether any change in	consideration is given to the risks of Ebola or Zika virus infection during donor recruitment, and that the consideration is recorded. The PR should confirm that the SOPs guiding the sperm and egg donor recruitment processes include Zika and Ebola risk assessments. No further actions are required beyond submission of the report of the audit to ensure Zika and Ebola risk assessments are performed and documented, which should be provided to the centre's inspector by 1 June 2018.

		documentation is required. CARE Ebola Policy attached for information.	
8. Adverse incidents Effective investigation and root cause analysis of incidents is not always performed. Thus in some cases, corrective actions have not prevented the recurrence of similar incidents. SLC T118	The PR should ensure that all incidents are investigated thoroughly and that corrective and preventative actions are robust and effective in reducing the risk of recurrence. The PR should review the process for investigating incidents to ensure the procedure is effective and is always fully implemented. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 1 March 2018.	The centre has a robust system for the reporting of incidents (DATIX). This system covers all incidents at the clinic including those which are reportable to the HFEA and other external agencies. The PR confirms that the centre has an excellent culture amongst the staff for reporting incidents. Therefore there is an extensive list of incidents which are delegated to the appropriate senior staff member for investigation. That staff member must then decide upon the level of investigation and whether a root cause analysis is required. Incidents are not closed until the Clinic Director has been assured of a robust investigation. The PR acknowledges that a more robust system of assurance of completion of actions arising from incidents should be enforced. Incidents graded as Moderate or High risk generate a Shared Learning tool which	The Executive acknowledges the PR's commitment to fully implement this recommendation and notes that the centre's incident reporting and investigation processes, as described by the PR, are generally compliant. This inspection report makes clear however that some (occasional) incident investigations, have not been robust, so appropriate corrective and preventive actions have not been implemented so that incidents have recurred. The Executive expects there to be, for all incidents where necessary, effective root cause analysis, so appropriate corrective and preventative actions can be implemented to prevent recurrence. The Executive is therefore reassured to see that the 'CARE Incident reporting and management procedure' includes that root cause analysis should be performed for all incidents except those graded green with a risk level of 1-3 out of 25.

		is escalated throughout the organisation and is presented to the local monthly Operations meeting as part of the Quality Managers report. The PR has reviewed the incident log and can report that there are currently 51 clinical and non-clinical incidents which require investigation or review and closure. There are two in the severe category, seven moderate and seven of low severity. The remaining 34 are classed as having not caused any harm .Once the incident is closed, the outcome is shared with the reporter. The actions/non conformances are disseminated by the investigating officer to the appropriate departments and reported to both the Operations meeting and the Quarterly Quality and Governance meetings. The PR acknowledges that incidents must be reviewed in a timely fashion and that reporting the learning from incidents is valuable for all staff to try to avoid repetition and improve the service and	The PR's stated actions to: • investigate incidents and take appropriate actions in a timely manner • implement a robust way of assuring the completion of corrective and preventative actions in response to incidents; • discuss incidents and corrective and preventative actions at departmental meetings and at the monthly Operations meeting will assist the centre in meeting the Executive's expectation. The PR states he has reviewed 51 recent incidents which remain open. The PR also discusses providing an update to the centre's inspector by 1 June 2018 regarding how these incidents have been processed. This will be useful but the review must include whether the incidents have been investigated in line with the 'CARE Incident reporting and management procedure', i.e. whether root cause analysis has been performed where required and if appropriate corrective and

		quality of care. The departmental managers will be expected to cascade learning to their staff at regular meetings or, in the case of urgent change, through written instructions. In some case, a change control process may be required which will be documented in the incident record on Datix Moving forward, the PR will undertake to ensure all currently open incidents will be investigated and managed appropriately by 1st June 2018. The PR will then confirm to the Inspector that this has been done and provide an update of the current situation. Of course there will always be open incidents as the process of incident reporting is an ongoing one but the PR commits to completing incident investigation in a timely fashion. The PR will add a specific 'Investigations Update' agenda point to the monthly Operations Meeting which will document which incidents are outstanding and which	preventative actions have been implemented. No further action is required beyond completion of the proposed review of active incidents and submission of the report to the HFEA by 1 June 2018.

		member of staff is responsible together with a report of incidents which have been investigated and the ensuing actions. Please see the attached CARE 'Incident Reporting, Management and Procedure Policy'.	

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
9. Traceability One item in use in the laboratory was not recorded as 'in use' in the centre's traceability records. SLC T99.	The PR should ensure that relevant data is documented, to allow the traceability of gametes and embryos, and all devices which may affect their quality and safety. The PR should review the traceability processes and ensure they are fully implemented. A summary of the findings of the review, including corrective and preventative actions with timescales for implementation, should be provided to the centre's inspector by 1 March 2018. Within three months of the implementation of any changes, the traceability processes should be audited to	The PR acknowledges that one item in use in the laboratory was not recorded as 'in use' in the traceability records which was an error. The traceability processes have been reviewed with the Laboratory Manager. It must be pointed out in response that this error would however have been picked up before the end of the week the inspection took place by the existing safeguarding mechanism. On the week of 4th December 2017, an extra checklist was implemented which records a weekly traceability and batch control check. The batch control record is checked against all consumables currently in use in the Laboratory. This is in	The Executive acknowledges the PR's response and the actions taken to implement this recommendation. No further action is required beyond the completion of the audit to verify the actions taken have been effective, a summary of which should be submitted to the centre's inspector by 1 June 2018.

	ensure the actions taken have been effective. A summary report of the findings of the audit should be submitted to the centre's inspector by 1 June 2018.	addition to existing monthly traceability audit. Attached is an example of the monthly audit from November 2017, an audit confirming the weekly checks have been performed and the end of day checklist. ('Audit tool - Monthly Traceability Witnessing and Mismatch', 'Audit of weekly traceability check', 'Embryology End of Day Checklist'). The centre would be pleased to send a further audit by 1st June 2018.	
10. Equipment and Materials A gas analyser had been repaired but no documentation was present to support testing and re-validation of the instrument before its reintroduction back into service. SLC T25.	The PR should ensure that evidence is collected to support the testing and validation of all new, repaired or recommissioned equipment before use. The PR should ensure that the testing and re-validation of the gas analyser is documented by 1 March 2018. The PR should confirm to the centre's inspector when this has been completed.	The PR can confirm that the repaired gas analyser has been tested, revalidated and is functional. The record of this is held by the Laboratory. Attached 'G100 Gas Analyser revalidation' and 'CORP LAB 1a new and repaired equipment'.	The Executive acknowledges the PR's response and supporting evidence for the revalidation for the gas analyser. No further action is required.

11. Staff Staff providing information to patients using donor gametes could not provide evidence of training or competency assessment. SLC T15	The PR should ensure that all staff providing information to patients using donor gametes can provide evidence of training or competency assessment. This recommendation should be implemented by 1 March 2018 and evidence of implementation provided to the centre's inspector.	The appropriate nursing staff (nurse donation team) had training before the inspection in the recruitment and matching of donors. This included a Powerpoint presentation and a group discussion. The Powerpoint presentation is attached. The relevant Laboratory staff are scheduled to receive this training from the Nurse Manager by 9th March 2018. The clinicians have been trained in the provision of information to patients using donor gametes. Each clinician has their clinical competency checked and signed off every two years as part of their assessment of fitness to practice. The centre has been updated with a specific CARE donation nurse competence which the Nurse Manager is scheduled to implement. For completeness the relevant Laboratory Staff will have the same assessment to cover sperm donation. Again this will be completed by 9th March 2018.	The Executive acknowledges the PR's response and actions already taken to implement this recommendation No further actions are required beyond those already planned by the PR. Confirmation should be provided to the centre's inspector when all training and competence assessment has been completed.

		Please see the attached competency document and CARE EBOLA Policy.	
12. Information The 'consent to treatment information and guidance form' provided to egg sharers, states that if less than 8 eggs are collected in an egg sharing arrangement, HFEA regulations state the donor must keep all the eggs. This information is misleading in that HFEA regulations or guidance make no such reference. In the sperm donor record reviewed, the information provided to the donor was not documented so it was unclear what information had been provided, notably about compensation arrangements and screening. SLC T58	The PR should ensure that information provided to patients and donors is accurate and compliant with HFEA requirements, and it is clear from records what information has been provided. The inspection team considered that the information documents available are generally compliant and a wholesale review is not required. However the PR should ensure that the specific concerns expressed in this report are addressed. This recommendation should be implemented by 1 March 2018 and the centre's inspector provided with evidence of the actions taken.	The PR is pleased the inspection team found the patient information to be generally compliant. The inspection team queried the consent form for egg recipients taking part in the egg share scheme. It stated that if less than eight eggs were collected then all of the eggs would be given to the egg share donor. The inspection team were concerned the consent form implied the number of less than eight eggs was a regulatory direction from the HFEA and not a CARE Group policy. This has been discussed within the CARE Group and the consent form has been amended within the CARE Group to clarify the situation. The new wording is as follows: 'In the unlikely event that too few eggs are collected for sharing (at CARE this number is fewer than 8), under current	The Executive acknowledges the PR's response and efforts to implement this recommendation Concerns related to sperm donor information have been addressed. The revised text provided to egg sharer providers and recipients remains problematic however because it still states that 'if fewer than 8 eggs are collected…under current HFEA guidelines…the donor must use all the eggs herself.' HFEA CoP guidance does not state this so the information remains inaccurate. The PR should review CoP guidance 12.20 and should ensure that information provided to patients and donors reflects this guidance and is accurate and therefore compliant with HFEA requirements. **Further action is required.**

		HFEA guidelines only one option is available. The donor must use all the eggs herself. CARE undertakes to take reasonable efforts to arrange a rematch (subject to a suitable donor being available) as soon as possible. In these circumstances a treatment refund will be made'. Regarding sperm donor information recorded in the records, it is recorded in the electronic patient records at the Laboratory 'Potential Sperm Donor consultation' checklist that the donor information leaflet was given to the donor in question. This contains the details about compensation and screening. Attached is a copy of that information. To avoid any confusion about the information provided, the date information is given to a potential donor will now be recorded on the electronic records on the 'Potential Sperm Donor Consultation' checklist.	

13. Record keeping and document control The name of the staff member who verifies the identity of a patient against appropriate photo-identification documentation is not recorded in the patient's records. During an audit of the records of embryos used in training, it was noted that in one case, the use in training had not been documented on the patient's laboratory sheet, contrary to the centre's standard practice. The use of the embryo in training had been recorded in the training log book. SLC T46.	The PR should ensure that note is kept in patient records of embryo use in training and the name of the staff member who verifies the identity of the patient against appropriate photo-identification documentation. This recommendation should be implemented by 1 March 2018 and the centre's inspector provided with evidence of the actions taken. Three months after the implementation of preventative actions, the PR should audit patient records to ensure the actions have been effective. A report of the audit should be provided to the centre's inspector by 1 June 2018.	The inspection team noted that although photographic identification is recorded in the notes, there was no record of which staff member verified that information. However it is possible to identify which member of staff entered the information into the electronic records. This has been discussed at the centre and additional measure has been implemented whereby the reception staff now verify patient identity electronically when scanning in the ID document. See section 5.8 of the attached document 'Obtaining and Verifying ID'. An audit of the completeness of verification of patient identification will be sent to the HFEA by 1st June 2018. The PR acknowledges the incomplete record regarding embryos used in training. The information was recorded on the training records but not on the patient laboratory record. As such traceability was not compromised.	The Executive acknowledges the PR's response and actions taken to implement this recommendation. No further action is required beyond the completion of the audit to verify the actions taken have been effective, a summary of which should be submitted to the centre's inspector by 1 June 2018.

		However, going forwards, the relevant laboratory treatment cycle records have been updated to include a summary section detailing any gametes or embryos used for training. The centre will audit both the laboratory treatment cycle records against the training record spreadsheet by 1st June 2018. Attached 'TW Lab 04 Form for Laboratory Record'.	

Reponses from the Person Responsible to this inspection report
The PR thanks the Inspection Team for their time and guidance at the Inspection in November 2017. The centre would be delighted to provide and any further information required to resolve any concerns raised at the inspection.