Executive Licensing Panel - minutes

Centre 0030 (Herts and Essex Fertility Centre)

Executive Update

Tuesday, 11 December 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Lisa Whiting Helen Crutcher	Director of Strategy and Corporate Affairs Research Manager Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Senior Governance Manager

Declarations of interest

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

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

1.1. The panel noted that the Herts and Essex Fertility Centre is located in Cheshunt, Essex and has held a treatment and storage licence with the HFEA since 1992. The centre was formerly known as the Essex Fertility Centre, which was located at Holly House Hospital. The current licence has not been varied since it was issued on 26 November 2014.

1.2. The panel noted that a renewal inspection was carried out at the centre, on 17 and 18 July 2018 and was considered by the Executive Licensing Panel at its meeting on 26 September 2018.

1.3. At the meeting on 26 September 2018, the panel noted that actions concerning the five major and three 'other' non-compliances identified at the renewal inspection remained outstanding. The panel particularly noted the reoccurring non-compliance concerning the safety of gas storage, which was also identified at the 2016 interim inspection and the 2014 renewal inspection.

1.4. The 26 September 2018 Executive Licensing Panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years, without additional conditions, subject to the recommendations being implemented within the prescribed timescales. Acknowledging that further information, in relation to all the identified non-compliances, was due for receipt later this year, the panel requested that the executive submit an update report to a panel meeting, prior to the end of 2018, to ensure that the non-compliances were being effectively addressed.

2. Consideration of Progress Update

2.1. The panel considered the papers, which included an executive update, inspection report, update on recommendations made in the report and licensing minutes for the last three years.

2.2. The panel noted the update on the implementation of the recommendations made in the renewal inspection report.

2.3. The panel noted that the Person Responsible (PR) had fully engaged with the recommendations made and all of these had now been closed, with the exception of the follow up audits for donor screening and screening of patients, due by 18 January 2019, and confirmation from the manufacturer of the 4-well dishes that CE marking had been achieved.

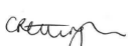
3. Decision

3.1. The panel noted the positive progress made by the PR in addressing the non-compliances identified during the renewal inspection, noting these had all been rectified, with the exception of the follow up audits for donor screening and screening of patients, alongside confirmation from the manufacturer of the 4-well dishes regarding CE marking.

4. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

14 December 2018

Executive Licensing Panel
7 December 2018

Centre number	0030
Centre name	Herts and Essex Fertility Centre
Person Responsible	Mr David Ogutu

Update to renewal inspection report

1. The renewal inspection report for Herts and Essex Fertility Centre was considered by the Executive Licensing Panel on 26 September 2018.

2. The panel noted that action concerning the five major and three 'other' non-compliances, identified at the renewal inspection, remained outstanding. Acknowledging that further information, in relation to all the identified non-compliances, was due for receipt later this year, the panel requested that the executive submit an update report to a panel meeting prior to the end of 2018 to ensure that the non-compliances are being effectively addressed.

3. The panel particularly noted the reoccurring non-compliance, concerning the safety of gas storage, which was also identified at the 2016 interim inspection and the 2014 renewal inspection.

4. Annex 1 provides an update on the implementation of the recommendations made in the renewal inspection report.

5. In summary, the PR has engaged fully with the recommendations made in the renewal inspection report. All recommendations have now been closed with exception to the follow up audits for donor screening and screening of patients due by 18 January 2019 and confirmation from the manufacturer of the 4-well dishes that CE marking has been achieved.

Louise Winstone
Inspector

Annex 1: Recommendations that required further action

Major area of non-compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Donor screening The following issues were noted regarding the centre's practices of screening gamete donors: • The centre does not screen egg donors for syphilis at the time of donation. • The centre's SOP for screening egg donors does not describe the requirement to screen egg donors at the time of donation, or the screening tests required.	The PR should ensure that gamete donors are screened in accordance with regulatory requirements and professional guidelines. Immediately after the inspection the PR provided updated SOPs to confirm that revised screening practices had been implemented. The PR should audit the treatments carried out with donor gametes or embryos created with donated gametes, since the last renewal inspection in 2014, to	All egg donors at Herts and essex Fertility Centre are screened for Syphillis at the time of recruitment. Only Syphillis negative donors are recruited. The donors are also screened for Chlamydia and Gonorrhea in addition to HIV, Hepatitis B and C viruses. Due to wrong interpretation of the guidelines, we have not routinely repeated Syphillis test when we perform repeat screening tests for screening donors just before their egg donation.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The audit of treatments carried out with donor gametes or embryos created with donated gametes, since the last renewal inspection in 2014 and a summary of the findings of the review assessing the risks to the recipients, is to be provided by 18 October 2018. Evidence of staff training is to be provided by 18 October 2018 and a follow up audit by 18 January 2019.

• A physical examination for herpes and genital warts is not carried out for sperm donors prior to donation (this was an area for improvement identified at the previous licence renewal inspection in 2014). SLC T52a, T52b, T53b, T33b, UK Guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008).	assess the number of recipients affected by the use of non-compliantly screened donors. The PR should assess the risks to the recipients and provide a summary of the findings of the review, including corrective actions with timescales for implementation, to the centre's inspector by 18 October 2018. It is noted that the requirement for a physical examination of sperm donors was referenced at the last renewal inspection at this centre and the PR subsequently provided evidence that this requirement was implemented. The PR is asked to review how and why there was a return to non-compliant practice and to provide an explanation to the centre's inspector by 18 October 2018. The PR should ensure that the competence of relevant staff to undertake donor recruitment, assessment and screening, is assessed and	We have since changed our SOP and fully implemented the guidelines, with all donors having repeat screening for: -HIV 1 and 2: Anti-HIV – 1, 2 -Hepatitis B: HBsAg and Anti-HBc -Hepatitis C: Anti-HCV-Ab -Syphilis -Gonorrhoea The repeat tests are performed maximum two weeks before commencing stimulation. We will audit treatments carried out with donor gametes or embryos since the last inspection in 2014 and update the inspector by 18th October 2018. The requirement for a physical examinantion was instituted after the last inspection. Unfortunatley the SOP changes were not very clear and the requirement was not added to the screening checklist. This resulted with some some occassions when	Further action is required. **Progress update, 22 October 2018:** The PR has provided an audit of treatments carried out with donor gametes or embryos created with donated gametes, since the last renewal inspection in 2014 and a summary of the findings of the review assessing the risks to the recipients. The risk to recipients was considered low, with no corrective action required. Evidence of staff training has also been provided. The PR has confirmed that the follow up audit will be provided to the centre's inspector by 18 January 2019. Further action is required.

	documented. Evidence of this should be provided to the centre's inspector by 18 October 2018. The PR should audit the effectiveness of changes introduced in this area of practice within six months. A copy of the audit should be provided to the centre's inspector by 18 January 2019.	patients were not examined or where examined, this was not clearly documented. The SOP has been updated and physical examination results added to screening checklist. Relevant staff have been informed of the requirement and procedure for physical examination and their competency confirmed. An audit of the effectiveness of these changes will be provided to the clinic's inspector not later than 18th January 2019.	
2. Safety and suitability of premises and facilities Six small cylinders in the gas cylinder cupboard were unsecured. In addition, large cylinders were secured to the wall of the cupboard but had additional cylinders secured to them. The inspection team was	The PR should take immediate action to ensure that medical gases are stored appropriately and that patients have the ability to summon help at any time in the recovery area. The PR should perform a risk assessment regarding the number of cylinders in the	Medical gases are stored in a secure cupboard within the clinic. Annual health and safety inspections have not flagged up any concerns about the smaller, medical gas cylinders attached to the larger secured cylinders as a risk factor. We agree that if centre staff had to access one of the cylinders, it could lead	The executive acknowledges the PR's response and commitment to implementing this recommendation. The PR is asked to forward the input received from the medical gas health and safety expert by 18 October 2018. Further action is required.

concerned that if centre staff had to access one of these cylinders it would result in the others being unsecure for a short period during the manipulation of the cylinders leading to a significant risk of a cylinder becoming unstable and either falling over or on to the other cylinders. Concerns regarding the safety of gas storage were identified as a major non-compliance in the interim inspection in 2016 and the renewal inspection in 2014. The patient emergency buzzer was out of reach of the bed trolley on which the patients recover following their procedures. Department of Health (2006) 'Medical Gases Health Technical Memorandum (HTM) 02- 01: Medical gas pipeline systems; Operational management. SLC T2, T17.	storage cupboard and ensure that all cylinders are appropriately secured from falling over. The PR should inform the centre's inspector of the actions taken to comply with this recommendation when responding to the inspection report. The PR should ensure that patients have the ability to summon help at any time in the recovery area. The PR should inform the centre's inspector of the actions taken to comply with this recommendation when responding to the inspection report.	to the other being unsecure during the time. We will add more secured storage space, as well as get input from a health and safety expert to ensure safe gas storage. Patients are admitted to the recovery area for egg collection and embryo transfer. There are two call buttons to summon help in each patient bay. One is attached to a string above the patients bed, and a second one on the wall which the patient's partner can reach (though patient cannot reach this second button, it is meant for the partner). Recovery area staff have been informed to ensure that the moveable patient trolleys are positioned above the patient call buttons to ensure patients can reach the buttons and this has been implemented. The position of the trolley in relation to the call	**Progress update, 22 October 2018:** The PR has confirmed the actions taken to ensure the safe storage of medical gases and has provided the input received from the medical gas health and safety expert. The PR has acted to ensure that the moveable patient trolleys are positioned above the patient call buttons to ensure patients can reach the buttons. No further action is required.

		button has also been added to the recovery area check list to ensure that this is not overlooked.	
3. Medicines management In two patient records observed on inspection the documentation of the controlled drug medication prescribed and administered by the anaesthetist was unclear. In one instance the name of the drug had been abbreviated and the unit of measure administered was not documented. In another record the unit of measurement was unclear. In two patient prescriptions observed on inspection the frequency of administration was unclear. Controlled Drugs in Perioperative Care 2006, section 18:16.	The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance. The PR should with immediate effect ensure that all prescriptions of medication are clear. The PR should inform the centre's inspector of the actions taken to comply with this recommendation when responding to the inspection report. The PR should audit the completion of prescriptions after a period of three months and provide the audit result to the centre's inspector by 18 October 2018.	All members of staff (anaesthetists included) have been informed of the importance and need to clearly document prescriptions. We will audit completion of prescriptions and send a report to the clinic's inspector by18th october 2018	The executive acknowledges the PR's response and commitment to implementing this recommendation. The audit is to be provided by 18 October 2018. Further action is required. **Progress update, 22 October 2018:** The PR has detailed the improvements that have been made to ensure clear documentation of name and dose of drugs. An audit of the completion of prescriptions has been provided. No further action is required.

NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'. NMC (2015) 'Standards for medicines management'.			
4. CE marking The flush media used during egg collection is not CE marked. Although the 4-well culture dishes used for embryo culture are CE marked, this is for in vitro diagnostic use only and not for their designated use, i.e. as class II medical devices. SLC T30. This was an area for improvement identified at previous inspections in 2016 and 2014.	The PR should ensure that CE marked medical devices are used where possible. We would not recommend precipitous changes that might impact on the quality of treatment, however the PR should ensure that a plan is developed and implemented so that appropriately CE marked medical devices are used. This plan should be provided to the centre's inspector by 18 October 2018 and should include the timescales by which products identified in this report will either be replaced with a suitably CE marked alternative or will obtain CE mark certification.	The clinic introduced a CE marked flush media after our last inspection. This was followed by a significant drop in our clinical pregnancy rates. We informed our inspectors of this and they agreed that we revert to our previous products as we continue investigating CE marked alternatives. We have been in discussions with other clinics using a different CE marked flush media and will trial this. A comprehensive report with trial dates will be sent to our inspectors by 18th October 2018. Sparmed, the manufacturers of OOsafe 4-well culture dishes have confirmed that their class 2 CE mark application has been submitted and should hopefully be in place by	The executive acknowledges the PR's response and commitment to implementing this recommendation. The plan including timescales is to be provided by 18 October 2018. Further action is required. **Progress update, 22 October 2018:** The PR has confirmed that CE marked flush media was introduced on 1 October 2018. The manufacturer of the 4 well dish has applied for CE marking for their product, this is expected to be granted in 2019. The PR has committed to keep the centre's inspector informed. Further action is required.

	The plan should be fully implemented by 18 January 2019.	September 2018. We are keen to continue using this product if CE mark is granted. However, we will consider alternative products if CE application is unsuccessful.	
5. Storage of gametes and embryos On the day of the inspection the centre did not have effective consent for the storage of cryopreserved sperm for one gentleman and embryos for two couples. The inspection team noted that one of these sets of embryos has been in storage for longer than the statutory storage period of 10 years but evidence of compliance with the 2009 storage regulations is not in the patient records. Schedule 3, 8(1) HF&E Act 1990 (as amended). The Human Fertilisation and Embryology (Statutory Storage Period for Embryos	The PR should ensure that effective consent to storage is in place for all gametes and embryos that are in storage. The PR should develop an action plan to resolve these cases and advise the centre's inspector of this when responding to this report. The PR should also confirm whether any further gametes or embryos are in storage without effective consent when responding to this report. The PR should conduct a review to identify why the bring forward system has not been fully effective in ensuring that effective consent to storage is in place for all gametes and embryos that are in storage. A summary of the	A comprehensive audit and review of all stored gametes and embryos is underway. A full report of the audit as well as policy review will be submitted to the inspector by 18th october 2018.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The review and audit are to be provided by 18 October 2018. Further action is required. **Progress update, 22 October 2018:** The PR has provided evidence that there are no gametes or embryos currently in storage beyond their consent periods. The PR has provided a summary of the review of the centre's bring forward system. A new cryopreservation bring forward SOP has been provided.

and Gametes) Regulations 2009 and SLC T79.	findings of the review should be provided to the centre's inspector by 18 October 2018. The PR is reminded of guidance issued by the HFEA in CH (03)03 in relation to the timely disposal of cryopreserved material where there is consent to do so, and actions should there be a possibility of legal challenge to the disposal of cryopreserved material. The PR should ensure storage is only extended beyond the statutory storage period when there is compliance with the 2009 storage regulations, both in relation to patient consent and evidence of either premature infertility or of likely premature infertility in the future. In any cases where there has been a failure to comply with the 2009 storage regulations, the PR should seek independent legal advice on how to proceed. Proposed		No further action is required.

	actions in response to this advice should be forwarded to the HFEA for review prior to any action being taken. The outcome of this investigation, including the centre's intended actions and the timescales for their implementation should be submitted to the centre's inspector by 18 October 2018. It is expected that the PR should aim to resolve these issues by 18 January 2019.		

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
6. Infection control The following issues were noted: • Not all chairs in the consulting rooms that are used for clinical activities have an impermeable cover or are 'wipe clean'; • Audits of infection control performed by the infection control lead were not documented; • Cleaning schedules were not documented for all areas; • Minor surgical procedures were being performed in a clinical/consultation room. The room appeared to be cluttered and therefore difficult to clean; • In some clinical areas the floor sealant was peeling;	The PR should ensure that infection control measures and practices are compliant with regulatory requirements and best practice. The PR should, in consultation with the infection control lead and relevant infection control advisors, perform a risk assessment of the issues identified in the report and provide the centre's inspector with a summary of how these concerns will be addressed by 18 October 2018.	A risk assessment in collaboration with the infection control lead as well as advisors will be performed and a report submitted to the inspector by 18th october 2018	The executive acknowledges the PR's response and commitment to implementing this recommendation. The risk assessment is to be provided by 18 October 2018. Further action is required. **Progress update, 22 October 2018:** The PR has provided evidence that the issues identified in this report have now been addressed and an audit has been provided. No further action is required.

• Clinical trolleys were in some instances positioned under air conditioning units. The clinical inspector believed this introduced unnecessary risk of contamination from dust or condensation produced by the unit. SLC T2. Department of Health: Health Building Note 00-09: Infection control in the built environment (2013) section 3.105. Healthcare-associated infections: prevention and control in primary and community care 2017, section 1.1.4.4.			
7. Quality management system The centre has not implemented learning issued by the HFEA and/or other sources because of the following: • The laboratory is using the WHO 1999 criteria for the	The PR should ensure that learning from guidance provided by the HFEA and/or other sources is implemented. The PR should undertake a review to identify why the learning from this guidance was not implemented.	A review of the quality management system, specifically looking at learning and dissemination of guidance will be reviewed and lessons learnt shared. A summary report of the review findings will be	The executive acknowledges the PR's response and commitment to implementing this recommendation. The updated legal parenthood SOP has been provided. The summary report and audit are to be provided by 18 October 2018.

assessment of semen parameters and not the most recent guidelines from 2010; • Actions required from previous inspections had not been fully implemented (gas storage area, CE marking and physical examination of sperm donors, see 'safety and suitability of premises and facilities, equipment and materials and 'screening of donors'). • The centre does not consider the need for additional screening tests which may be required because of patients and donors travel and/or exposure history, with regards to Ebola and Zika information on posters on display in the centre did not reflect current guidelines. • The centre's legal parenthood SOP does not reflect practice and is not compliant with guidance as it states that the PP	A summary report of the findings of this review including corrective actions and the timescale for their implementation should be provided by 18 October 2018. The PR should conduct an audit to evaluate whether guidance and advice issued by the HFEA and other sources has been acted on and submit a summary report of the audit findings by 18 October 2018. The PR should forward a copy of the updated legal parenthood SOP when responding to this report.	submitted to the HFEA inspectors by 18th October 2018 with the updated legal parenthood SOP.	Further action is required. **Progress update, 22 October 2018:** The PR has reviewed all guidance and advice issued by the HFEA and other sources and has updated procedures, information and SOPs where relevant to ensure compliance. The PR has stated that all new guidance will be included on the centre's quality improvement log to ensure implementation. No further action is required.

consent form should be completed if the couple are married or in a civil partnership and not the PBR form. SLC T32.			
8. Screening of patients The centre does not consider the need for additional screening tests which may be required because of patients and donors travel and/or exposure history, with regards to Ebola. On inspection, Ebola questionnaires were seen in some patient records however staff seemed unaware of the centre's processes to assess this risk. The inspection team noted that the centre assesses patient and donors travel history in relation to Zika virus exposure or infection, however information on posters on display in the centre did not reflect current guidelines.	The PR should ensure that the risks of Ebola infection are considered prior to patients and donors being treated and that Zika information reflects current guidance. The PR should provide a copy of the revised procedure to the centre's inspector by 18 October 2018. Three months after implementing the revised procedure, the PR should audit patient and donor history and screening procedures to ensure that corrective actions implemented have been effective.	.Revised policy will be submitted to the HFEA by 18th October An audit will also be conducted and report submited by the 18th of january 2019	The executive acknowledges the PR's response and commitment to implementing this recommendation. The revised procedure is to be submitted by 18 October 2018 and the follow up audit by 18 January 2019. Further action is required. **Progress update, 22 October 2018:** The PR has provided updated patient information leaflets, health questionnaires and screening checklists. The follow up audit will be provided by 18 January 2019. Further action is required.

SLC 50(d). European Tissues and Cells Directive (EUTCD) 2017. Advisory Committee on Dangerous Pathogens (ACDP) 2017.	A summary report of the audit should be provided to the centre's inspector by 18 January 2019.		

Inspection report

Purpose of the inspection report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high-quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 17 and 18 July 2018

Purpose of inspection: Renewal of a licence to carry out Treatment and Storage.

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

Inspectors: Louise Winstone, Karen Conyers, Janet Kirkland-MacHattie and Katie Best (observer)

Date of Executive Licensing Panel: 26 September 2018

Centre name	Herts and Essex Fertility Centre
Centre number	0030
Licence number	L/0030/17/a
Centre address	Bishops' College, Churchgate, Cheshunt, EN8 9XP, United Kingdom
Person Responsible	Mr David Ogutu
Licence Holder	Mr Michael Ah-Moye
Date licence issued	26 November 2014
Licence expiry date	25 November 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Herts and Essex Fertility Centre is located in Cheshunt, Essex and has held a Treatment and Storage licence with the HFEA since 1992. The centre was formerly known as the Essex Fertility Centre which was located at Holly House Hospital. The current licence has not been varied since it was issued on 26 November 2014.

The centre provided 673 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2018. In relation to activity levels this is a medium sized centre.

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

In May 2017, the Herts and Essex Fertility Centre featured in a newspaper report, making allegations with regards to egg sharing and donation, counselling and costs of medication. Subsequently, the centre was inspected on 18 May 2017, during which its practices, policies and documentation surrounding 'egg sharing' and sperm/egg donation and the costs of medication were reviewed. The PR engaged effectively with this investigation. A report was presented to the Authority's ELP in August 2017 and the panel expressed concern regarding information on the centre's website about the marketing of egg sharing and/or egg donation and undue emphasis on financial incentives. The panel also highlighted the importance of undertaking a shift in culture at the centre, ensuring more attention is given to the tone used in marketing materials for patients. The centre's website and egg sharing and donation practices were a focus of this inspection. The Executive was reassured that the centre's website has been revised and there is now no emphasis on financial incentives to patients to donate eggs.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period March 2017-February 2018 show the centre's success rates are in line with national averages.

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

Multiple births[2]

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

Between March 2017-February 2018 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17%. 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, Standard Licence Conditions (SLCs), and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

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

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

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

Major areas of non-compliance:

- The PR should ensure that gamete donors are screened in accordance with regulatory requirements and professional body guidelines.
- The PR should take immediate action to ensure that medical gases are stored appropriately and that patients have the ability to summon help at any time in the recovery area.
- The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance.
- The PR should ensure that CE marked medical devices are used where possible.
- The PR should ensure that effective consent to storage is in place for all gametes and embryos that are in storage.

'Other' areas that require improvement:

- The PR should ensure that infection control measures and practices are compliant with regulatory requirements and best practice.
- The PR should ensure that learning from guidance provided by the HFEA and/or other sources is implemented.
- The PR should ensure that the risks of Ebola infection are considered prior to patients and donors being treated and that Zika information reflects current guidance.

Recommendation to the Executive Licensing Panel

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

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/live birth rates meet the target. The PR is encouraged to continue to use the quality management system (QMS) to best effect to monitor and improve their success rates and the quality of the service offered to patients.

The centre is to be commended on their proactive approach to collecting patient feedback.

In considering the length of licence to recommend, the inspection team have taken into account the non-compliances identified in previous inspections that have reoccurred. The PR has provided explanations for these and the implementation of the recommendations will be continuously monitored by the centre's inspector. The inspection team recommends the renewal of the centre's Treatment and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

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

What the centre does well

Screening of donors (Guidance note 11)
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. The centre's procedures for screening donors are partially compliant with HFEA requirements.

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

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

donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

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

What the centre could do better

Screening of donors (Guidance note 11)
The following issues were noted regarding the centre's practices of screening gamete donors:

- The centre does not screen egg donors for syphilis at the time of donation (SLC T52b, T53b).
- The centre's SOP for screening egg donors does not describe the requirement to screen egg donors at the time of donation, or the screening tests required (SLC T53b, T33b).
- A physical examination for herpes and genital warts is not carried out for sperm donors prior to donation (SLC T52a; guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008)).
- The centre does not consider the need for additional screening tests which may be required because of patients and donors travel and/or exposure history, with regards to Ebola and Zika information on posters on display in the centre did not reflect current guidelines (see 'screening of patients' and recommendation 8).

See recommendation 1.

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

What the centre does well

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

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

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

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

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

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

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

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to 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 single biggest risk of fertility treatment is a multiple pregnancy. The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy.

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

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;

- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

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

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

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements.

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

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

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

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

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

The centre does not currently undertake satellite activities therefore requirements relating to this were not relevant at this inspection.

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

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

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

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

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
Six small cylinders in the gas cylinder cupboard were unsecured.

In addition, large cylinders were secured to the wall of the cupboard but had additional cylinders secured to them. The inspection team was concerned that if centre staff had to access one of these cylinders it would result in the others being unsecure for a short period during the manipulation of the cylinders leading to a significant risk of a cylinder becoming unstable and either falling over or on to the other cylinders.

Concerns regarding the safety of gas storage were identified as a major non-compliance in the interim inspection in 2016 and the renewal inspection in 2014.

The patient emergency buzzer was out of reach of the bed trolley on which the patients recover following their procedures.

SLC T2, T17; see recommendation 2.

Infection control (Guidance Note 25)
The following issues were noted:

- Not all chairs in the consulting rooms that are used for clinical activities have an impermeable cover or are 'wipe clean';
- Audits of infection control performed by the infection control lead were not documented;
- Cleaning schedules were not documented for all areas;

- Minor surgical procedures were being performed in a clinical/consultation room. The room appeared to be cluttered and therefore difficult to clean;
- In some clinical areas the floor sealant was peeling;
- Clinical trolleys were in some instances positioned under air conditioning units. The clinical inspector believed this introduced unnecessary risk of contamination from dust or condensation produced by the unit.

SLC T2; Department of Health: Health Building Note 00-09: Infection control in the built environment (2013) section 3.105; Healthcare-associated infections: prevention and control in primary and community care 2017, section 1.1.4.4; see recommendation 6.

Medicines management (Guidance Note 25)
The following issues were noted:

- In two patient records observed on inspection the documentation of the controlled drug medication prescribed and administered by the anaesthetist was unclear;
- In one instance the name of the drug had been abbreviated and the unit of measure administered was not documented. In another record, the unit of measurement was unclear;
- In two patient prescriptions observed on inspection the frequency of administration was unclear.

Controlled Drugs in Perioperative Care 2006; NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'; NMC (2015) 'Standards for medicines management'; see recommendation 3.

Quality management system (QMS) (Guidance note 23)
The findings on inspection indicate that the centre has not implemented learning issued by the HFEA and/or other sources, for example:

- The laboratory is using the WHO 1999 criteria for the assessment of semen parameters and not the most recent guidelines from 2010;
- Actions required from previous inspections have not been fully implemented (gas storage area, CE marking and physical examination of sperm donors, see 'safety and suitability of premises and facilities', **'**equipment and materials' and 'screening of donors').
- The centre does not consider the need for additional screening tests which may be required because of patients and donors travel and/or exposure history, with regards to Ebola and Zika information on posters on display in the centre did not reflect current guidelines (see 'screening of patients' and recommendation 8).
- The centre's legal parenthood SOP does not reflect practice and is not compliant with guidance as it states that the PP consent form should be completed if the couple are married or in a civil partnership and not the PBR form.

SLC T32; see recommendation 7.

Equipment and materials (Guidance note 26)
The flush media used during egg collection is not CE marked. Although the 4-well culture dishes used for embryo culture are CE marked, this is for in vitro diagnostic use only and not for their designated use, i.e. as class II medical devices. We acknowledge that appropriately CE marked flush media and culture dishes were put into use following the interim inspection in 2016. However, the PR was concerned that following the introduction of these products the centre noted a reduction in success rates. The PR then made the decision to revert to using the previously used non-CE marked flush and dishes which

remain in use. The inspectors were concerned that no further actions had been taken to source alternative CE marked items.

SLC T30; see recommendation 4.

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

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

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

Welfare of the child and safeguarding

What the centre does well

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

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 does not perform embryo testing therefore requirements relating to this are not relevant to this inspection.

What the centre could do better
Not applicable.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit, no patients were available to speak to the inspectors. However, the centre's own patient feedback was discussed, and the results were reviewed. The centre actively collects feedback on patient experience and acts on any negative comments received. Any risks identified from this feedback are incorporated into the centre's risk and opportunities register. Between 1 January 2018 and 31 March 2018, 83 patients completed an electronic questionnaire and it was noted that all of this feedback was positive. A further 287 patients had provided feedback directly to the HFEA via the HFEA website. This feedback was generally positive however there were 11 patient comments regarding the cost of medication. This was discussed at length with the clinic manager and the inspector was informed that patients are advised that they can receive their medication cheaper elsewhere, evidence was provided on the consultants' checklist which states that patients have been informed that medication can be purchased externally.

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)

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

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg and/or sperm 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 and/or sperm providers are fully assessed and medically suitable; and
- the benefit offered is the most suitable for the egg or sperm provider and recipient(s) (where relevant).

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

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

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

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and / or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

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

Consent and disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

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

Following the inspection in June 2016, the centre conducted an audit of consent to legal parenthood for all patients who had received treatment with donor sperm or with embryos created with donor sperm (fresh or frozen) from February 2014 to June 2016. This audit identified one case where a patient had entered her date of birth instead of date of signing on the declaration section of the WP form. The couple have since been informed and offered support and legal advice has been obtained. The legal advice has stated that this anomaly is unlikely to affect legal parenthood status however the clinic have made it clear to the couple that they will support the couple and cover all legal costs should a court declaration be required in the future.

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

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

The centre's procedures for screening patients are broadly 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 are important to ensure that the gametes and embryos are stored appropriately to maintain their quality and safety and are stored 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

Screening of patients (Guidance note 15)

The centre does not consider the need for additional screening tests which may be required because of patients (and donors) travel and/or exposure history, with regards to Ebola. On inspection, Ebola questionnaires were seen in some patient records however staff seemed unaware of the centre's processes to assess this risk. The inspection team noted that the centre assesses patient (and donors) travel history in relation to Zika virus

exposure or infection, however information on posters on display in the centre did not reflect current guidelines.

SLC 50(d); European Tissues and Cells Directive (EUTCD) 2017; Advisory Committee on Dangerous Pathogens (ACDP) 2017; see recommendation 8.

Storage of gametes and embryos (Guidance note 17)
On the day of the inspection the centre did not have effective consent for the storage of cryopreserved sperm for one gentleman and embryos for two couples. Regarding the cryopreserved sperm, the inspection team was informed that the gentleman has confirmed verbally that he does not want to continue storage of the sample, but the centre is requesting written confirmation before they discard. For one set of embryos, the couple are living abroad, and the PR is trying to establish contact.

The other set of embryos, has been in storage for longer than the statutory storage period of 10 years but evidence of compliance with the 2009 storage regulations is not in the patient records.

Schedule 3, 8(1) HF&E Act 1990 (as amended); The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009; SLC T79; see recommendation 5.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority. However, potential issues with recording the traceability of embryos used in training were noted, see 'Traceability' above.

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

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

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

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

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

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

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2016, recommendations for improvement were made in relation to one area of critical non-compliance and four areas of major non-compliance.

The PR provided information and evidence that all the recommendations were fully implemented within the prescribed timescales, notwithstanding the reoccurring non-compliances in relation to the gas storage area, CE marking and physical examination of sperm donors, see 'safety and suitability of premises and facilities, equipment and materials and 'screening of donors'.

During this inspection, it was noted that the centre has a high proportion of ICSI usage. This was discussed at length with the clinic staff and the inspectors were advised that this is something that they are aware of and are currently working towards reducing the number of ICSI cycles. The inspectors reviewed five records where patients were having ICSI and noted that centre staff were able to explain why the use of ICSI was indicated in these cases. The use of ICSI will continue to be monitored by the centre's inspector and no recommendation is considered necessary at this stage.

On-going monitoring of centre success rates

Since the last renewal inspection in 2016, the centre has received one risk tool alert relating to the multiple pregnancy rate. The PR responded appropriately and provided a commitment to keep the multiple pregnancy rate under review.

Areas of practice requiring action

This 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
None identified.			

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 partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Donor screening The following issues were noted regarding the centre's practices of screening gamete donors: • The centre does not screen egg donors for syphilis at the time of donation. • The centre's SOP for screening egg donors does not describe the requirement to screen egg donors at the time of donation, or the screening tests required.	The PR should ensure that gamete donors are screened in accordance with regulatory requirements and professional guidelines. Immediately after the inspection the PR provided updated SOPs to confirm that revised screening practices had been implemented. The PR should audit the treatments carried out with donor gametes or embryos created with donated gametes, since the last renewal inspection in 2014, to	All egg donors at Herts and essex Fertility Centre are screened for Syphillis at the time of recruitment. Only Syphillis negative donors are recruited. The donors are also screened for Chlamydia and Gonorrhea in addition to HIV, Hepatitis B and C viruses. Due to wrong interpretation of the guidelines, we have not routinely repeated Syphillis test when we perform repeat screening tests for screening donors just before their egg donation.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The audit of treatments carried out with donor gametes or embryos created with donated gametes, since the last renewal inspection in 2014 and a summary of the findings of the review assessing the risks to the recipients, is to be provided by 18 October 2018. Evidence of staff training is to be provided by 18 October 2018 and a follow up audit by 18 January 2019.

• A physical examination for herpes and genital warts is not carried out for sperm donors prior to donation (this was an area for improvement identified at the previous licence renewal inspection in 2014). SLC T52a, T52b, T53b, T33b, UK Guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008).	assess the number of recipients affected by the use of non-compliantly screened donors. The PR should assess the risks to the recipients and provide a summary of the findings of the review, including corrective actions with timescales for implementation, to the centre's inspector by 18 October 2018. It is noted that the requirement for a physical examination of sperm donors was referenced at the last renewal inspection at this centre and the PR subsequently provided evidence that this requirement was implemented. The PR is asked to review how and why there was a return to non-compliant practice and to provide an explanation to the centre's inspector by 18 October 2018. The PR should ensure that the competence of relevant staff to undertake donor recruitment, assessment and screening, is assessed and documented. Evidence of this	We have since changed our SOP and fully implemented the guidelines, with all donors having repeat screening for: -HIV 1 and 2: Anti-HIV – 1, 2 -Hepatitis B: HBsAg and Anti-HBc -Hepatitis C: Anti-HCV-Ab -Syphilis -Gonorrhoea The repeat tests are performed maximum two weeks before commencing stimulation. We will audit treatments carried out with donor gametes or embryos since the last inspection in 2014 and update the inspector by 18th October 2018. The requirement for a physical examinantion was instituted after the last inspection. Unfortunatley the SOP changes were not very clear and the requirement was not added to the screening checklist. This resulted with some some occassions when patients were not examined or	Further action is required.

	should be provided to the centre's inspector by 18 October 2018. The PR should audit the effectiveness of changes introduced in this area of practice within six months. A copy of the audit should be provided to the centre's inspector by 18 January 2019.	where examined, this was not clearly documented. The SOP has been updated and physical examination results added to screening checklist. Relevant staff have been informed of the requirement and procedure for physical examination and their competency confirmed. An audit of the effectiveness of these changes will be provided to the clinic's inspector not later than 18th January 2019.	
2. Safety and suitability of premises and facilities Six small cylinders in the gas cylinder cupboard were unsecured. In addition, large cylinders were secured to the wall of the cupboard but had additional cylinders secured to them. The inspection team was concerned that if centre staff had to access one of these	The PR should take immediate action to ensure that medical gases are stored appropriately and that patients have the ability to summon help at any time in the recovery area. The PR should perform a risk assessment regarding the number of cylinders in the storage cupboard and ensure that all cylinders are	Medical gases are stored in a secure cupboard within the clinic. Annual health and safety inspections have not flagged up any concerns about the smaller, medical gas cylinders attached to the larger secured cylinders as a risk factor. We agree that if centre staff had to access one of the cylinders, it could lead to the other being unsecure during the time.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The PR is asked to forward the input received from the medical gas health and safety expert by 18 October 2018. Further action is required.

cylinders it would result in the others being unsecure for a short period during the manipulation of the cylinders leading to a significant risk of a cylinder becoming unstable and either falling over or on to the other cylinders. Concerns regarding the safety of gas storage were identified as a major non-compliance in the interim inspection in 2016 and the renewal inspection in 2014. The patient emergency buzzer was out of reach of the bed trolley on which the patients recover following their procedures. Department of Health (2006) 'Medical Gases Health Technical Memorandum (HTM) 02- 01: Medical gas pipeline systems; Operational management. SLC T2, T17.	appropriately secured from falling over. The PR should inform the centre's inspector of the actions taken to comply with this recommendation when responding to the inspection report. The PR should ensure that patients have the ability to summon help at any time in the recovery area. The PR should inform the centre's inspector of the actions taken to comply with this recommendation when responding to the inspection report.	We will add more secured storage space, as well as get input from a health and safety expert to ensure safe gas storage. Patients are admitted to the recovery area for egg collection and embryo transfer. There are two call buttons to summon help in each patient bay. One is attached to a string above the patients bed, and a second one on the wall which the patient's partner can reach (though patient cannot reach this second button, it is meant for the partner). Recovery area staff have been informed to ensure that the moveable patient trolleys are positioned above the patient call buttons to ensure patients can reach the buttons and this has been implemented. The position of the trolley in relation to the call button has also been added to the recovery area check list to	

		ensure that this is not overlooked.	
3. Medicines management In two patient records observed on inspection the documentation of the controlled drug medication prescribed and administered by the anaesthetist was unclear. In one instance the name of the drug had been abbreviated and the unit of measure administered was not documented. In another record the unit of measurement was unclear. In two patient prescriptions observed on inspection the frequency of administration was unclear. Controlled Drugs in Perioperative Care 2006, section 18:16. NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'.	The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance. The PR should with immediate effect ensure that all prescriptions of medication are clear. The PR should inform the centre's inspector of the actions taken to comply with this recommendation when responding to the inspection report. The PR should audit the completion of prescriptions after a period of three months and provide the audit result to the centre's inspector by 18 October 2018.	All members of staff (anaesthetists included) have been informed of the importance and need to clearly document prescriptions. We will audit completion of prescriptions and send a report to the clinic's inspector by18th october 2018	The executive acknowledges the PR's response and commitment to implementing this recommendation. The audit is to be provided by 18 October 2018. Further action is required.

NMC (2015) 'Standards for medicines management'.			
4. CE marking The flush media used during egg collection is not CE marked. Although the 4-well culture dishes used for embryo culture are CE marked, this is for in vitro diagnostic use only and not for their designated use, i.e. as class II medical devices. SLC T30. This was an area for improvement identified at previous inspections in 2016 and 2014.	The PR should ensure that CE marked medical devices are used where possible. We would not recommend precipitous changes that might impact on the quality of treatment, however the PR should ensure that a plan is developed and implemented so that appropriately CE marked medical devices are used. This plan should be provided to the centre's inspector by 18 October 2018 and should include the timescales by which products identified in this report will either be replaced with a suitably CE marked alternative or will obtain CE mark certification. The plan should be fully implemented by 18 January 2019.	The clinic introduced a CE marked flush media after our last inspection. This was followed by a significant drop in our clinical pregnancy rates. We informed our inspectors of this and they agreed that we revert to our previous products as we continue investigating CE marked alternatives. We have been in discussions with other clinics using a different CE marked flush media and will trial this. A comprehensive report with trial dates will be sent to our inspectors by 18th October 2018. Sparmed, the manufacturers of OOsafe 4-well culture dishes have confirmed that their class 2 CE mark application has been submitted and should hopefully be in place by September 2018. We are keen to continue using this product if CE mark is granted. However, we will consider	The executive acknowledges the PR's response and commitment to implementing this recommendation. The plan including timescales is to be provided by 18 October 2018. Further action is required.

		alternative products if CE application is unsuccessful.	
5. Storage of gametes and embryos On the day of the inspection the centre did not have effective consent for the storage of cryopreserved sperm for one gentleman and embryos for two couples. The inspection team noted that one of these sets of embryos has been in storage for longer than the statutory storage period of 10 years but evidence of compliance with the 2009 storage regulations is not in the patient records. Schedule 3, 8(1) HF&E Act 1990 (as amended). The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 and SLC T79.	The PR should ensure that effective consent to storage is in place for all gametes and embryos that are in storage. The PR should develop an action plan to resolve these cases and advise the centre's inspector of this when responding to this report. The PR should also confirm whether any further gametes or embryos are in storage without effective consent when responding to this report. The PR should conduct a review to identify why the bring forward system has not been fully effective in ensuring that effective consent to storage is in place for all gametes and embryos that are in storage. A summary of the findings of the review should be provided to the centre's inspector by 18 October 2018.	A comprehensive audit and review of all stored gametes and embryos is underway. A full report of the audit as well as policy review will be submitted to the inspector by 18th october 2018.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The review and audit are to be provided by 18 October 2018. Further action is required.

	The PR is reminded of guidance issued by the HFEA in CH (03)03 in relation to the timely disposal of cryopreserved material where there is consent to do so, and actions should there be a possibility of legal challenge to the disposal of cryopreserved material. The PR should ensure storage is only extended beyond the statutory storage period when there is compliance with the 2009 storage regulations, both in relation to patient consent and evidence of either premature infertility or of likely premature infertility in the future. In any cases where there has been a failure to comply with the 2009 storage regulations, the PR should seek independent legal advice on how to proceed. Proposed actions in response to this advice should be forwarded to the HFEA for review prior to any action being taken.		

	The outcome of this investigation, including the centre's intended actions and the timescales for their implementation should be submitted to the centre's inspector by 18 October 2018. It is expected that the PR should aim to resolve these issues by 18 January 2019.		

Other areas of practice that requires improvement

Other areas of practice that require 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
6. Infection control The following issues were noted: • Not all chairs in the consulting rooms that are used for clinical activities have an impermeable cover or are 'wipe clean'; • Audits of infection control performed by the infection control lead were not documented; • Cleaning schedules were not documented for all areas; • Minor surgical procedures were being performed in a clinical/consultation room. The room appeared to be cluttered and therefore difficult to clean; • In some clinical areas the floor sealant was peeling;	The PR should ensure that infection control measures and practices are compliant with regulatory requirements and best practice. The PR should, in consultation with the infection control lead and relevant infection control advisors, perform a risk assessment of the issues identified in the report and provide the centre's inspector with a summary of how these concerns will be addressed by 18 October 2018.	A risk assessment in collaboration with the infection control lead as well as advisors will be performed and a report submitted to the inspector by 18th october 2018	The executive acknowledges the PR's response and commitment to implementing this recommendation. The risk assessment is to be provided by 18 October 2018. Further action is required.

• Clinical trolleys were in some instances positioned under air conditioning units. The clinical inspector believed this introduced unnecessary risk of contamination from dust or condensation produced by the unit. SLC T2. Department of Health: Health Building Note 00-09: Infection control in the built environment (2013) section 3.105. Healthcare-associated infections: prevention and control in primary and community care 2017, section 1.1.4.4.			
7. Quality management system The centre has not implemented learning issued by the HFEA and/or other sources because of the following: • The laboratory is using the WHO 1999 criteria for the assessment of semen	The PR should ensure that learning from guidance provided by the HFEA and/or other sources is implemented. The PR should undertake a review to identify why the learning from this guidance was not implemented.	A review of the quality management system, specifically looking at learning and dissemination of guidance will be reviewed and lessons learnt shared. A summary report of the review findings will be submitted to the HFEA	The executive acknowledges the PR's response and commitment to implementing this recommendation. The updated legal parenthood SOP has been provided. The summary report and audit are to be provided by 18 October 2018.

parameters and not the most recent guidelines from 2010; • Actions required from previous inspections had not been fully implemented (gas storage area, CE marking and physical examination of sperm donors, see 'safety and suitability of premises and facilities, equipment and materials and 'screening of donors'). • The centre does not consider the need for additional screening tests which may be required because of patients and donors travel and/or exposure history, with regards to Ebola and Zika information on posters on display in the centre did not reflect current guidelines. • The centre's legal parenthood SOP does not reflect practice and is not compliant with guidance as it states that the PP consent form should be completed if the couple	A summary report of the findings of this review including corrective actions and the timescale for their implementation should be provided by 18 October 2018. The PR should conduct an audit to evaluate whether guidance and advice issued by the HFEA and other sources has been acted on and submit a summary report of the audit findings by 18 October 2018. The PR should forward a copy of the updated legal parenthood SOP when responding to this report.	inspectors by 18th October 2018 with the updated legal parenthood SOP.	Further action is required.

are married or in a civil partnership and not the PBR form. SLC T32.			
8. Screening of patients The centre does not consider the need for additional screening tests which may be required because of patients and donors travel and/or exposure history, with regards to Ebola. On inspection, Ebola questionnaires were seen in some patient records however staff seemed unaware of the centre's processes to assess this risk. The inspection team noted that the centre assesses patient and donors travel history in relation to Zika virus exposure or infection, however information on posters on display in the centre did not reflect current guidelines. SLC 50(d).	The PR should ensure that the risks of Ebola infection are considered prior to patients and donors being treated and that Zika information reflects current guidance. The PR should provide a copy of the revised procedure to the centre's inspector by 18 October 2018. Three months after implementing the revised procedure, the PR should audit patient and donor history and screening procedures to ensure that corrective actions implemented have been effective. A summary report of the audit should be provided to the centre's inspector by 18 January 2019.	.Revised policy will be submitted to the HFEA by 18th October An audit will also be conducted and report submited by the 18th of january 2019	The executive acknowledges the PR's response and commitment to implementing this recommendation. The revised procedure is to be submitted by 18 October 2018 and the follow up audit by 18 January 2019. Further action is required.

European Tissues and Cells Directive (EUTCD) 2017. Advisory Committee on Dangerous Pathogens (ACDP) 2017.			

Responses from the Person Responsible to this inspection report
Herts and Essex fertility Centre team found the inspection process very fair, open and informative. The inspection team was approcahble, clear but firm in their approach which we appreciated. We were provided with ample notice of the inspection, and provided with a detailed inspection progarmme. A number of areas for concern / improvement have been highlighted in this inspection report. We already resolved majority of these before the inspection report was availed. We will review our practice and ensure that all the concerns are addressed within the specified time frame. We will continue to learn from the process to ensure that we continue to improve, providing a safe and high quality service for our patients, whilst meeting our legal and regulatory obligations.