Executive Licensing Panel - minutes

Centre 0076 (NUTURE Fertility)

Renewal Inspection Report

Tuesday, 23 April 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Richard Sydee (Chair) Joanne Anton Kathleen Sarsfield-Watson	Director of Finance and Resources Policy Manager Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

Declarations of interest

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

The panel had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel considered the papers, which included a completed application form, inspection report and licensing minutes for the last four years.

1.2. The panel noted that NURTURE Fertility has been licensed by the HFEA since 1992 and provides a full range of fertility treatments. The centre is part of The Fertility Partnership group and has satellite agreements in place with Burton Fertility Clinic, Burton on Trent and NURTURE Fertility at Chesterfield.

1.3. The panel noted that, in the 12 months to 31 December 2018, the centre provided 1150 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large sized centre.

1.4. The panel noted that HFEA register data, between 1 October 2017 to 30 September 2018, show the centre's pregnancy outcomes for IVF and ICSI success rates, in terms of clinical pregnancy outcomes, are in line with the national averages, with the following exceptions:

- Success rates following IVF treatment in women over 38 years old are higher than the national average at a statistically significant level.
- Success rates following FET treatment in women of all ages are higher than the national average at a statistically significant level.

1.5. The panel noted that, for the year ending 31 December 2017, the centre provided 15 cycles of partner inseminations, with one pregnancy, and this is in line with the national average.

1.6. The panel noted that, between 1 October 2017 and 30 September 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 22%. This represents performance that is likely to produce a multiple live birth rate statistically greater than the 10% multiple live birth rate target.

1.7. An inspection was carried out at the centre on the 6 and 7 February 2019.

1.8. The panel noted that at the time of the inspection there was one critical area of non-compliance concerning multiple births. Three major areas of non-compliance were identified regarding the screening of donors, medicines management and equipment and materials, alongside three 'other' areas in connection to the disclosure of information held on the HFEA Register for use in research, record keeping and obligations and reporting requirements.

1.9. The panel noted that, since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations regarding the screening of donors, medicines management, equipment and materials, the disclosure of information held on the HFEA Register for use in research and record keeping, and where required, will audit the effectiveness of these actions within the required timescales. The PR has given a commitment to fully implement the recommendations made in the report in relation to multiple births and obligations and reporting requirements.

1.10. The panel noted that at the interim inspection in 2017, the centre's multiple clinical pregnancy rate was 22%. The complications of multiple pregnancy are the biggest risks associated with fertility treatment to the health of patients and children conceived through that treatment, so the interim inspection report recommended that actions were taken to reduce the multiple clinical pregnancy rate.

1.11. The panel noted that the PR had reviewed and monitored the centre's multiple births minimisation strategy since the interim inspection; however, there is no evidence of a reduction in the number of multiple births. The PR must continue to review and monitor the effectiveness of the strategy to reduce multiple birth rates to meet the 10% live birth rate target. The inspector will work with the

PR to drive a reduction in the multiple clinical pregnancy rate and ensure that he continues to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

1.12. The panel noted that the inspection team considered the continued high multiple clinical pregnancy rate and the risks this carries for patients and children conceived; a three year licence term was contemplated. However, the inspection team also noted the generally good level of compliance at the centre, the treatment success rates above the national averages, and the positive patient feedback about the centre. Due to these positive factors, and on the basis that the centre's inspector will work with the PR to drive a reduction in the multiple clinical pregnancy rate, the inspection team recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

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

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

2.4. The panel noted the actions, taken by the PR, to address a majority of the non-compliances identified in the renewal inspection report, alongside the good patient feedback.

2.5. The panel expressed particular concern regarding the centre's high multiple pregnancy rate, identifying that despite the PR's review and monitoring of the multiple births minimisation strategy, since the interim inspection conducted in 2017, there had been no reduction in the number of multiple births. However, the panel was pleased to note that actions had been taken, following the renewal inspection report, encouraging the PR to work closely with the inspectorate to decrease the number of multiple pregnancies over time and looked forward to a reduction being reported at the interim inspection.

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

3. Chair's signature

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

Signature

Name

Richard Sydee

Date

30 April 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: 6 and 7 February 2019.

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

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

Inspectors: Janet Kirkland MacHattie, Louise Winstone, Grace Lyndon and Nicola Lawrence (observer).

Executive Licensing Panel: 23 April 2019

Centre name	NURTURE Fertility
Centre number	0076
Licence number	L/0076/15/c
Centre address	The East Midlands Fertility Centre, Bostock's Lane, Sandiacre, Nottingham, NG10 5QG, United Kingdom.
Person Responsible	Mr James Hopkisson
Licence Holder	Ms Jude Fleming
Date licence issued	1 June 2015
Licence expiry date	31 May 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

NURTURE Fertility has been licensed by the HFEA since 1992 and provides a full range of fertility treatments. The centre is part of The Fertility Partnership group.

NURTURE Fertility was last inspected for licence renewal in January 2015 and a four year licence was subsequently granted. An interim inspection was performed in March 2017.

The current licence was varied to reflect a change of Licence Holder in March 2018 and to include embryo testing as a licensed activity in September 2018.

The centre provided 1150 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2018. In terms of activity, this is a large centre.

The centre has satellite agreements in place with Burton Fertility Clinic, Burton on Trent and with NURTURE Fertility at Chesterfield.

Pregnancy outcomes[1]

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

- success rates following IVF treatment in women over 38 years old are higher than the national average at a statistically significant level;
- success rates following FET treatment in women of all ages are higher than the national average at a statistically significant level.

For the year ending 31 December 2017, the centre reported 15 cycles of partner insemination with one pregnancy. This is in line with the national average.

Multiple births[2]

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

Between 1 October 2017 and 30 September 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 22%. This represents performance that is likely to produce a multiple live birth rate statistically greater than the 10% multiple live birth rate target (recommendation 1).

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged 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 one critical, three major and three 'other' areas of non compliance.

Since the inspection visit the PR has provided evidence that actions have been taken to implement the following recommendations and has committed where required to audit the effectiveness of those actions within the required timescales:

Major areas of non compliance:

- The PR should ensure that donors are screened in accordance with professional body guidelines.
- The PR should ensure that medicines management practices are in accordance with guidance and good practice guidelines.
- The PR should ensure that CE marked medical devices are used where possible and that equipment on the emergency resuscitation trolley is fit for purpose and within its' specified expiry date

Other' areas that require improvement:

- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately communicated to the HFEA register.
- The PR should ensure that proper patient records are kept in line with SLC T46.

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

Critical areas of non compliance:

- **The PR should keep the effectiveness of the centre's multiple birth minimisation strategy and its implementation under review to ensure that the 10% multiple live birth rate target is not exceeded.**

'Other' areas that require improvement:

- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

Recommendation to the Executive Licensing Panel

The centre has one critical area of concern and three major areas of concern. The centre's success rates are above the national average for IVF treatment in patients over 38 years and for frozen embryo transfer in all age groups. The centre's multiple clinical pregnancy rate is however currently 22% so the centre is highly unlikely to meet the 10% multiple live birth rate target.

At the interim inspection in 2017, the centre's multiple clinical pregnancy rate was 22%. The complications of multiple pregnancy are the biggest risks associated with fertility treatment to the health of patients and children conceived through that treatment, so the interim inspection report recommended that actions were taken to reduce the multiple clinical pregnancy rate.

The PR has reviewed and monitored the centre's multiple births minimisation strategy since that interim inspection, however there is no evidence of a reduction in the number of multiple births. The PR must continue to review and monitor the effectiveness of the strategy to reduce multiple birth rates to meet the 10% live birth rate target.

The inspector will work with the PR to drive a reduction in the multiple clinical pregnancy rate and ensure that he continues to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

In considering the term of licence to recommend, the inspection team had regard of the continued high multiple clinical pregnancy rate and the risks this carries for patients and children conceived. A three year licence term was considered. However the inspection team also noted the generally good level of compliance at the centre, the treatment success rates above the national averages, and the positive patient feedback about the centre. Because of these positive factors and on the basis that the centre's inspector will work with the PR to drive a reduction in the multiple clinical pregnancy rate, the inspection team recommends the renewal of the centre's Treatment (including embryo testing) and Storage licence for a period of four years without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

The HF&E Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. Centre 0076 has not been issued with an ITE import certificate by the HFEA, so has no certificate to be renewed at this juncture.

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 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)
Two issues were identified on inspection:

- The centre's SOP for screening sperm donors does not describe the requirement for a physical examination for herpes and genital warts or the consideration of screening for Hepatitis A. One sperm donor has completed his course of donation and a review of his records showed that there was no consideration of the need for screening for Hepatitis A.
- The competence of staff to undertake sperm donor recruitment, assessment and screening has not been assessed.

See recommendation 2. SLC T52a, CoP 11.23 and UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008).

Suitable premises and suitable practices

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

What the centre does well

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

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

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

The centre is compliant with HFEA requirements to process gametes and/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 UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

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

Prescription of intralipid 'off label'
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. The strategy however is not effective as the centre's current multiple pregnancy rate is 22%.

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

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

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

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

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

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

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. The centre has not yet been granted an ITE import certificate however the centre has not undertaken any imports of gametes and embryos from TCS since 1 April 2018. The centre is therefore compliant with General Direction 0006.

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

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

Quality management system (QMS) (Guidance note 23)

The centre has a QMS that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage the 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 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

Medicines management (Guidance Note 25)
Two issues were identified on inspection:

- In two out of the three patient records reviewed, the amount of medication administered to the patient documented in the controlled drugs register did not correspond with the amount documented in the patient record;
- Some entries in the patient records were illegible.

See recommendation 3. NICE Guideline [46] April 2016 'Controlled drugs; safe use and management' (section 1.7.4); 'Controlled drugs in Perioperative Care', The Association of Anaesthetists of Great Britain and Ireland 2006.

Multiple births (Guidance note 7; General Direction 0003)

The centre's multiple clinical pregnancy rate is currently 22% and the centre is highly unlikely to meet the 10% multiple live birth rate target.

At the interim inspection in 2017 the multiple clinical pregnancy rate was also 22% and the inspection team documented this as a major non compliance. This situation has not improved despite the PR reviewing the centre's multiple birth minimisation strategy and 'monitoring' its implementation in response to the interim inspection report's recommendation; several risk tool alerts from the HFEA highlighting the issue to the PR; and assurances from the PR that the multiple pregnancy rate was being monitored and addressed.

The inspection team noted that the patient information regarding treatment with frozen embryos stated that the centre normally replaces two embryos in a frozen embryo treatment cycle. It was considered by the inspection team that this statement is likely to influence patients' decisions regarding how many embryos they wish to have replaced. It also causes the inspection team to question the thoroughness and focus of the centre's efforts to achieve the 10% multiple live birth rate target.

The centre recently reported to the HFEA that a patient, who had received a double embryo transfer, unfortunately suffered a complicated emergency delivery of twins. The team reviewed this case and found that the centre has investigated it appropriately. It has emphasised, to all, the risks of multiple births and the need to take action and better control the multiple pregnancy and birth rates.

See recommendation 1. SLC T2; General Directions 0003.

Equipment and materials (Guidance note 26)
Two issues were identified on inspection:

- The specimen containers used to collect semen samples are not CE marked at the appropriate level;
- A review of the contents of the centre's emergency trolley identified two items that were past their expiry date. The centre team said that they were aware of this but there was no documentation to alert staff to these items being beyond their expiry date.

See recommendation 4. SLCs T30, T2, T23; Resuscitation Council 2015.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

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

The PR has academic qualifications in the field of 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's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

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

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

What the centre could do better

Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. 495 patients have provided feedback in the last 12 months about this fertility clinic, giving an average five-star rating. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting the staff at the clinic on their helpfulness, good communication, friendliness and professionalism.

There were no patients available during the inspection to feedback to the inspectors about their experiences at the centre.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

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

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

Counselling (Guidance note 3)

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

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

- care is taken when selecting egg providers donating for benefits in kind;
- egg providers are fully assessed and medically suitable; and
- the benefit offered is the most suitable for the egg 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. An incident involving the care and assessment of a surrogate was discussed at inspection with the PR. At the time of the inspection the centre was unable to provide evidence of an appropriate assessment of this patient. However, subsequent to the inspection, the PR provided information to the inspection team which demonstrated that an assessment of the surrogate had taken place, therefore no recommendation has been made at this time.

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.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that four couples were affected by legal parenthood consent anomalies.

At the licence renewal inspection in January 2015, this audit was reviewed and found to have been performed per the method specified by the HFEA and that appropriate actions had been taken in response to the audit findings. All couples were informed of the anomalies and had been provided with support and advice in accordance with the expectations of the HFEA. There are no ongoing actions regarding these couples.

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.

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 performed by the centre. Ten 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 broadly

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

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
An audit of 10 patient records found that in seven records, discrepancies occurred between completed patient/partner disclosure consent forms and the related consent data submitted for inclusion on the register. Therefore, the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure to researchers.

The inspection team noted that in one case, the patient had not consented to contact research, however, the decision submitted to the HFEA indicated that they had consented. This discrepancy could pose a risk that the HFEA may inadvertently release patient identifying information to researchers against the patient's wishes.

See recommendation 5. Chair's Letter (10)05 and General Direction 0005.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

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

Storage of gametes and embryos (Guidance note 17)

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

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff

What the centre does well

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

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

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

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

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are broadly compliant with HFEA requirements. 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)
In one record reviewed, the welfare of the child assessment form indicated that the patient had a condition relevant to the assessment but there was no evidence that this had been discussed or taken in to account in the consideration of whether treatment should be provided. The PR later provided evidence that the condition had been considered.

See recommendation 6. SLC T46(e).

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The quality of data submissions to the HFEA Register requires improvement. At the time of post inspection review by the HFEA register team, missing and incomplete submissions and uncorrected submission errors were noted in the centre's register dataset. This affects the ability of the HFEA to fulfil its statutory 'opening the register' duties and adversely affects the effectiveness of processes which monitor centre activity.

The audit found that 9% (12/138) of the IVF treatments reviewed had not been reported to the HFEA in accordance with General Direction 0005. All four of the DI treatments reviewed had been reported.

5% (6/125) of the IVF treatments reviewed at inspection had been reported to the HFEA outside the 10-working day period allowed by General Direction 0005.

See recommendation 7. General Direction 0005; SLC T41.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2017, recommendations for improvement were made in relation to two areas of major non compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales. However, the following recommendation was not effectively implemented because the non compliance it sought to address has re-occurred:

- The PR should keep the effectiveness of the centre's multiple birth minimisation strategy and its implementation under review to ensure that the no greater than 10% multiple live birth rate is not exceeded.

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
1. Multiple births The multiple clinical pregnancy rate at the time of this inspection was 22%, as it was at the interim inspection in 2017. The centre has received several alerts from the HFEA risk tool regarding this issue since the 2017 inspection. The centre has reviewed their multiple births minimisation	The PR should review the centre's multiple birth minimisation strategy and the centre's multiple pregnancy and birth rate and make appropriate and necessary changes to ensure that significant progress towards the 10% multiple live birth rate target is made. The PR should perform quarterly audits, until further notice, to monitor the use of	Multiple Birth Minimisation Strategy revised 17/12/18 and implemented as of 1/1/19. Age limits for eSET criteria have been lifted by 3 years for frozen cycles. Age limit for eSET for fresh cycles were lifted in September 2018. Patient information updated to include latest eSET policy criteria and up to date success	Whilst the inspection team notes the PR's response, review of processes and actions taken in implementing this recommendation, the multiple pregnancy rates at this centre have, on a year on year basis since 2017, been significantly above the performance required to meet the 10% target for live births. The centre's inspector will closely monitor the PR's

strategy however there is no evidence of a reduction in the number of multiple clinical pregnancies and births. It was noted that the patient information regarding treatment with frozen embryos stated that the centre normally replace two embryos in a frozen embryo treatment cycle. It was considered by the inspection team that this statement may influence prospective patients' decisions regarding how many embryos they wish to have replaced. SLC T2; General Direction 0003. This non compliance has been graded as a critical non compliance. This is because of the failure of the centre to take effective action in response to the previous inspection recommendation and several risk tool alert emails and because multiple pregnancies are considered to pose a direct and avoidable risk to patients.	eSET recommendations and their acceptance by patients, and the multiple clinical pregnancy rate generally and in each treatment pathway, to identifying where improvements may be made and the effectiveness of changes to the centre's multiple birth minimisation strategy. The review of the centre's multiple birth minimisation strategy, including the changes to be made, and reports of the quarterly audits, should be provided to the centre's inspector by 7 May 2019 and then henceforth. The audit reports should include detail of revisions to the strategy where required. The centre's frozen embryo replacement patient information should be amended. The centre's inspector will continue to monitor the centre's progress.	rates for FET's. (NF01-INF-NUR6) Action: MPR for the period 1/1/19-31/3/19 will be performed once all clinical outcomes are confirmed. This is expected around end of April. Audit is scheduled on Q Pulse. Report to be submitted to HFEA Inspector for review.	progress in reducing the multiple pregnancy rates and may consider further regulatory action if improvements are not achieved. **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 partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Screening of donors Two issues were identified on inspection: • The centre's SOP for screening sperm donors does not describe the requirement for a physical examination for herpes and genital warts or the consideration of screening for Hepatitis A. A review of a donor's record showed that there was no consideration of the need for Hepatitis A screening. • The competence of staff to undertake sperm	The PR should ensure that sperm donors are screened in accordance with regulatory requirements and professional body guidelines. The PR should provide the centre's inspector with confirmation of revised sperm donor screening practices, evidence of relevant staff training and a summary of the changes made to the sperm donation and related SOPs when responding to this report.	A gentleman donating sperm in August 2017 around the time of the suggestion to screen for Hepatitis A was not screened. SOP did not include the need for physical examination of sperm donors **Action:** The donor has been invited back, to undergo a Hep A test. This was carried out and he has screened Negative. Updated SOP NF01-SOP-EMB-0041 to include the requirement to perform Hep A screening if sperm	The inspection team acknowledges the PR's response, review of processes and actions taken in implementing this recommendation. No further action is required beyond submission of the audit due by 7 August 2019.

donor recruitment, assessment and screening has not been assessed. See recommendation 2. SLC T52a, CoP 11.23 and UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008).	The PR should audit the treatments carried out with the sperm donor to assess the number of recipients potentially affected by the non compliant screening. A summary of the findings of the audit should be provided to the centre's inspector by 7 May 2019. The PR should ensure that the competence of relevant staff to undertake donor recruitment, assessment and screening, is assessed and documented. Evidence of this should be provided to the centre's inspector by 7 May 2019. It is acknowledged that the centre do not routinely recruit sperm donors however, where possible, 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 7 August 2019.	donor has sex with other men. Clinician's progress note also amended to include this. The donor in question has been used for 3 patients, 2 have an ongoing clinical pregnancy. No embryos remain in storage. A fourth patient is matched but has not yet used it, they have been informed and wish to carry on. The donor had no signs or symptoms of Hepatitis A at time of donation. As PR I have contacted the University of Nottingham, Professor of Virology for advice his reply: "We could test that for IgG and IgM anti-HAV, which would tell us if he has had HAV in the past (or been vaccinated) or if he had evidence of recent HAV infection." He has subsequently come to NURTURE for screening as recommended by the Professor of Virology, results awaited. "There are labs that can look for HAV RNA in a biological sample – if you thawed a sample of sperm out, I'm sure that could be arranged	

		– if you want to sort that out at your end I suggest contacting Micropathology - https://www.micropathology.com – or otherwise you could send us the sample and we would forward it to Micropath. The one problem with that approach is that strictly speaking, it only tells you that the sperm are HAV RNA free on the day of the sample – in other words, if there are multiple samples, you'd need to test each one of them. Having serological results would help to mitigate that – if he was HAV IgG pos, IgM neg and RNA neg at the time of first donation, then all subsequent donations would be safe." **Action:** Updated the SOP NF01-SOP-EMB-0041 to include the requirement for a physical examination of prospective donors. Clinician's progress note also amended to include this. Both of the NURTURE recruited donors were examined.	

		A doctors meeting has been held on the 27th March and the issue of examining donors was brought up. Every doctor was aware of the need to examine sperm donors and how to carry this out. As PR I am confident and happy that all doctors are aware of the need to examine sperm donors. An audit will be carried out if we have other donors that are recruited. However no timeline can be placed on this as we do not actively recruit. If an audit was performed on the two donors it would be 100% correct.	
3. Medicines management Two issues were identified on inspection: • In two out of the three patient records seen, the amount of medication administered to the patient documented in the controlled drugs register did not correspond to that documented in the patient's record.	The PR should ensure that medicines management practices are in accordance with guidance and good practice guidelines. The PR should review the centre's medicines management practices including the issues identified in this report. This review should also encompass any training and	After the last inspection it was noted that Medicines Management was an issue with distribution of top up drugs to patients by nursing staff. A new protocol, training and assessment was implemented and there were no concerns at inspection. The ordering, storage and prescription of controlled drugs was subject to an onsite Home Office Inspection. The Controlled drugs documentation of receipt, storage	The inspection team acknowledges the PR's response, review of processes and actions taken in implementing this recommendation. No further action is required beyond submission of the audit due by 7 August 2019.

• Some entries in the patient records were illegible. NICE Guideline [46] April 2016 'Controlled drugs; safe use and management' (section 1.7.4). 'Controlled drugs in Perioperative Care' The Association of Anaesthetists of Great Britain and Ireland 2006.	competency requirements identified. Three months after the implementation of corrective actions, the PR should perform an audit to ensure that these corrective actions have been effective. A summary report of this audit should be provided to the centre's inspector by 7 August 2019.	and use was passed by the Home Office. The assessment of notes at inspection was a concern, however a subsequent audit showed inconsistencies but not at the level of 2/3 as documented. The lead for Sedation Services has cascaded out to all the anaesthetists the need for accurate recording of drug administration both in the notes and the Controlled Drugs Book. A further audit has been scheduled in Q pulse and will be forwarded in August 2019. A new drug book has been sourced. A new anaesthetic sheet has been assessed and will go into use on the 1st of May 2019, this will standardise the record keeping of all anaesthetists performing sedation.	
4. Equipment and materials Two issues were identified on inspection:	The PR should ensure that CE marked medical devices are used where possible.	Non-CE marked sperm pots were being used. This was a genuine mistake, brought about by incorrect information being given by a supplier.	The inspection team acknowledges the PR's response, review of processes and actions taken

• The specimen containers used to collect semen samples are not CE marked at the appropriate level. • A review of the contents of the centre's emergency trolley identified two items that were past their expiry date. SLC T2; T23, T30.	During the inspection, CE marked containers were sourced. When responding to this report, the PR should state when it is intended for these to be in use. The PR should ensure that equipment on the emergency resuscitation trolley is fit for purpose and within the specified expiry date. The PR should inform the centre's inspector of the measures taken to address this non-compliance when responding to this report.	Action: Non-CE marked sperm pots have been replaced with CE marked sperm pots. The CE marked pots were sourced during the inspection and immediately went into the laboratory for use. Two Nasopharangeal tubes were found to be "out of date" on the resuscitation trolley. These were in the process of being sourced, however no alert had been placed. Action: Now sourced. Element of risk considered very low as have never been needed in the last 18 years at NURTURE.	in implementing this recommendation. No further action is required.

Other areas of practice that require 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
5. Disclosure of information, held on the HFEA Register, for use in research. In seven of ten records audited, discrepancies were found between completed patient/partner disclosure consents and the related consent data submitted for inclusion on the register. Therefore, the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure to researchers. The inspection team noted that in one case, the patient had not consented to contact research, however, the decision submitted to the HFEA indicated that they had consented. This discrepancy	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register. The PR should confirm that the incorrect submissions identified have been corrected when responding to this report. The PR should review the centre's systems and processes to ensure that going forward, the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms. A summary of the	Action: Samples of inaccurate submissions of consents to research provided in your email have been amended on the HFEA register. SOP NF01-SOP-ADM-0014 has been changed to ensure that the process is in place for reporting any consent variations for research to the HFEA in timely manner. The team will conduct a robust audit on Consents to Research submissions. We will check ever cycle submitted from 01/04/2018 to 31/03/2019 to ensure that patient/partner consents to disclosure of identifying information to researchers are	The inspection team acknowledges the PR's response, review of processes and actions taken in implementing this recommendation. No further action is required beyond submission of the audit due by 7 August 2019.

could pose a risk that the HFEA may inadvertently release patient identifying information to researchers against the patient's wishes. Chair's Letter (10)05 and General Direction 0005.	findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 7 August 2019.	accurately recorded on the HFEA register. This will be forwarded to the HFEA with corrective actions in due course. A reply was sent to the HFEA to you with the findings of our investigation on 7th of March. The cycles deemed as unreported were actual cancelled cycles which under the HFEA criteria are not reportable. This is due to the fact that cancellation of fresh cycles occurred prior to starting stimulation phase (this is the trigger for reporting cycles started) and cancellation of FER cycles occurred prior to embryo thaw. As such this cycles should not have been reported to the HFEA and I do not think they should be included in our action required plan. We have reviewed cycles provided in your email and the outcome of that review has	

		been added explaining the cancellation stage.	
6. Record keeping In one record reviewed in the course of the inspection the welfare of the child assessment form indicated that the patient had a condition relevant to the assessment. There was no evidence in the patient record that this had been discussed or taken into account in the assessment of whether treatment should be provided. SLC T46(e).	The PR should ensure that proper patient records are kept in line with SLC T46. Where a completed welfare of the child form highlights a possible concern, evidence within the patients records should indicate that the concern has been addressed prior to the offer of treatment. The PR should provide a summary of immediate actions to be taken to address the issue identified during the inspection when responding to this report.	Welfare of the child review: there has been extensive discussion surrounding the case of surrogacy where it was noted that the Surrogate was taking a low dose of Citalopram. As the clinician involved in this case I take full responsibility, I have overseen all aspects of care at the request of the IP. The information was covered at time of consultation and documented that there had been no previous pregnancy problems (postnatal depression). It was extensively covered in the Surrogacy agreement between IP and surrogate that we have on file. We had seen the IP and Surrogate through a number of fresh and frozen cycles and no concerns were raised by staff members from a safeguarding point of view. To reassure the Unit and HFEA we have made contact with the Surrogate post-	The inspection team acknowledges the PR's response, review of processes and actions taken in implementing this recommendation. No further action is required.

		delivery and she is recovering well A number of emails have been sent from me to the HFEA with regard this case. **Action:** We have amended our electronic notes to include direct questions for the Surrogate on their mental health to flag concerns (Whooley Test)	
7. Obligations and reporting requirements The quality of data submissions to the HFEA Register requires improvement. At the time of post inspection review there were missing and incomplete submissions and uncorrected submission errors in the centre's register dataset. The audit found that 9% (12/138) of the IVF treatments reviewed post inspection had not been reported to the HFEA in accordance with General Direction 0005.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for non-reporting and delayed submissions. This recommendation should be implemented by the time the inspection report is considered by a licensing committee and the inspector informed of the	A request has been made to the HFEA for the raw data to facilitate investigation into incorrect and late reporting, so far we have only received data on the 12 patients. Regular timetabled audits on data submission are carried out as part of our QM system and will be forwarded when completed. The data set below were incorrectly assessed by the HFEA and an apology has been received, after it was pointed out that there was an	The inspection team acknowledges the PR's response. The register team and centre's inspector will continue to monitor the centre's progress. Further action is required.

5% (6/125) of the IVF treatments reviewed at inspection had been reported to the HFEA outside the 10-working day period allowed by General Direction 0005. General Direction 0005; SLC T41	results of the review and actions taken. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the Authority. The PR must ensure that register data submissions are completed in accordance with the guidance issued by the Authority and where an error is identified it must be corrected within 2 calendar months in accordance with the requirements of General Direction 0005.	error at the HFEA's end and the cycles should not have been registered as stimulation had not started. We are always reviewing our reporting timelines to make sure correct data is provided in a timely manner to the HFEA and have been in correspondence with the HFEA to get more information so as to set continual improvement targets.	

Responses from the Person Responsible to this inspection report