Executive Licensing Panel Minutes

Centre 0076 (NUTURE Fertility)

Interim Inspection Report

Date:	10 August 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Richard Sydee (Chair) Helen Crutcher Dina Halai	Director of Finance and Resources Risk and Business Planning Manager Senior Scientific Policy Manager
Executive:	Bernice Ash	Secretary
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 noted that NURTURE Fertility is located in Nottingham and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services and is part of The Fertility Partnership group.

1.2. The panel noted that, in the 12 months to 30 April 2021, the centre had provided 1289 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a large sized centre.

1.3. The panel noted that, HFEA register data, for the period March 2020 to February 2021, show the centre's success rates for IVF and ICSI are in line with the national averages with the following exceptions:

- The clinical pregnancy rates following ICSI in women aged under 38 years are higher than average at a statistically significant level.
- The clinical pregnancy rates following ICSI in women aged 38 years and over are higher than average at a statistically significant level.
- The clinical pregnancy rates following FET in women aged under 40 years are higher than average at a statistically significant level.

1.4. The panel noted that, in 2020, the centre reported 6 cycles of partner insemination, with two pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.5. The panel noted that, HFEA register data, between March 2020 and February 2021, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 11%. This represents performance that is not likely to be statistically different to the 10% multiple live birth rate target for this period.

1.6. The panel noted that, in March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented. These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

1.7. The panel noted that HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

1.8. The panel noted that this centre was last inspected in February 2019; therefore, an on-site inspection should usually have occurred by February 2021. However, due to the Covid-19 pandemic, a DBA/RBA was conducted for the centre's interim inspection. Following this, it was concluded that any items of concern identified during the DBA were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site inspection. This

removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

1.9. The panel noted the centre's interim inspection was conducted by a DBA, followed by a virtual inspection, on 12 May 2021, which included videoconferencing with key members of staff. The centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and the on-going monitoring of the centre's performance, was also taken into account.

1.10. The panel noted that at the time of the inspection, there were two major areas of non-compliance identified concerning medicines management and legal parenthood. There was also one 'other' area of non-compliance regarding premises and facilities. Since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations surrounding medicines management and premises and facilities, committing, where required, to audit the effectiveness of those actions within the required timescales. The PR has given a commitment to fully implementing the non-compliance regarding legal parenthood.

1.11. The panel noted the centre is well led and provides a good level of patient support.

1.12. The panel noted that the inspection team recommends the continuation of the centre's treatment (including embryo testing) and storage licence, particularly noting progress made by the centre in meeting the HFEA multiple birth rate targets, the above average success rates and the positive comments made by patients in relation to their experiences.

2. Decision

2.1. The panel particularly noted that the non-compliance surrounding medicines management was also identified at the centre's last renewal inspection, conducted in February 2019, acknowledging that an audit of practices was due for submission to the HFEA by 12 November 2021.

2.2. The panel noted that, in the last 12 months, only 22 patients had provided feedback through the 'Choose a Fertility Clinic' facility, available on the HFEA website, giving the centre an average 4.5 rating. The panel endorsed the inspector's suggestion that the centre should actively encourage patients to use this mechanism to provide feedback, noting this would be followed up at the next inspection.

2.3. The panel congratulated the centre on its progress made in meeting the HFEA's multiple birth rate targets.

2.4. The panel was satisfied the centre was fit to have its treatment (including embryo testing) and storage licence continued.

3. Chair's signature

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

Signature

Name

Richard Sydee

Date

17 August 2021

Interim Licensing Report

Centre name: NURTURE Fertility
Centre number: 0076
Date licence issued: 1 June 2019
Licence expiry date: 31 May 2023
Additional conditions applied to this licence: None
Date of inspection: 12 May 2021
Inspectors: Bernadette O'Leary, Polly Todd and Louise Winstone
Date of Executive Licensing Panel: 10 August 2021

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law). The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an interim inspection, at the mid-point of the licence period.

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

This centre was last inspected in February 2019, therefore an on-site inspection should usually be conducted by February 2021. However, following the DBA/RBA for this clinic, it was concluded that any items of concern identified during the DBA were of relatively low

risk and could be reviewed effectively using virtual technology rather than on-site inspection. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

This inspection was therefore carried out by desk based assessment followed by a virtual inspection, which included videoconferencing with key members of centre staff.

The current foci for an interim inspection are:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

Summary for licensing decision – post review of draft by PR
The inspection team recommends the continuation of the centre's licence. In particular we note the progress made by the centre in meeting the HFEA multiple birth rate targets, the above average success rates and the positive comments made by patients in relation to their experiences.

The centre is well led and provides a good level of patient support.

The ELP is asked to note that this report makes recommendations for improvement in relation to two major and one 'other' area of non compliance or poor practice.

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 entries into the controlled drugs register are compliant with regulatory and best practice requirements.

'Other' areas of non compliance:

- The PR should ensure that all medical gases are stored appropriately.

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

Major areas of non compliance:

- The PR should ensure that legal parenthood processes are robust.

Information about the centre

NURTURE Fertility is located in Nottingham and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services and is part of The Fertility Partnership group.

The centre provided 1289 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2021. In relation to activity levels this is a large centre**.**

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[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 $p \leq 0.002$.

For IVF and ICSI, HFEA held register data for the period March 2020 to February 2021 show the centre's success rates are in line with national averages with the following exceptions:

- The clinical pregnancy rates following ICSI in women aged under 38 years are higher than average at a statistically significant level.
- The clinical pregnancy rates following ICSI in women aged 38 years and over are higher than average at a statistically significant level.
- The clinical pregnancy rates following FET in women aged under 40 years are higher than average at a statistically significant level.

In 2020, the centre reported six cycles of partner insemination with two pregnancies which is in line with the national average.

Multiple births[2]

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

Between March 2020 to February 2021, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 11%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur.

The inspection team was not able to observe any laboratory activities during the virtual inspection but was able to discuss witnessing with staff and review the centre's own audit of witnessing. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

During the inspection process, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

[2]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 $p \leq 0.002$.

The inspection team considered that staffing levels in the clinic were suitable for the activities being carried out, following assessment of information provided as part of the DBA and discussions with the PR during the virtual inspection.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: medicines management; infection control; legal parenthood; witnessing and consent to storage.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements with the exception noted in the legal parenthood section of this report.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- Extension of storage consent.
- Ovarian hyperstimulation syndrome.
- Data protection and confidentiality.
- The use of CE marked medical devices.
- HFEA Clinic Focus articles regarding safeguarding.

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be partially compliant with guidance because the following issues were identified during the review of the centre's controlled drugs (CD) register:

- The carry-over of stock from one page to another was not signed or witnessed.
- In four entries the witness signature was not recorded for the destruction of the drug.
- The majority of entries did not have the time of administration (A) recorded.
- In several entries, the unit of drug was not recorded for the supply (S), administration (A), or destruction (D) of the drug.
- Overwriting was used to amend the date of two entries, and the stock balance of three consecutive entries.

See recommendation 1.

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.

Infection Control
It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, we reviewed infection control practices and found them to be compliant with guidance.

Equipment and Materials
It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

As part of the DBA, the inspection team reviewed the centre's own audit of CE marked equipment and materials. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support
New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

Patient feedback
The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only 22 patients have provided feedback in the last 12 months, giving an average 4.5 star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it is important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection. The centre's own most recent patient survey responses were therefore reviewed. Feedback was comparable to that provided to the HFEA. 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 and communication at the clinic.

On the basis of this feedback 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.

Monitoring of the centre's performance

In addition to commenting on evidence gathered during the DBA and virtual inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the DBA and virtual inspection, indicate that the centre is non-compliant with the following HFEA requirement:

- The gas store outside housed several large empty cylinders but one of these was not chained and was therefore standing unsecured. There were also over a dozen small empty cylinders which were not stored in a rack, and some appeared to be rusty.

See recommendation 3.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2019, recommendations for improvement were made in relation to one critical, three major and three 'other' areas of non compliance.

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

On-going monitoring of centre success rates

Since the last renewal inspection in February 2019, the centre has received two risk tool alerts related to the multiple pregnancy rate, to which the PR has responded appropriately, providing evidence and information that the issue has been addressed.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The clinic is compliant with requirements to submit information to the HFEA.

Legal parenthood

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

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the inspection in February 2019, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team reviewed the results of a recent legal parenthood consenting audit and discussed these procedures with staff during the virtual inspection. Six 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 using screenshare technology. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are partially compliant with HFEA requirements because:

- In two of the six records reviewed the marital status of the couple could not be determined. In both cases a PBR ('Posthumous birth registration') consent form had been completed and there was no WP consent form ('Your consent to your partner being the legal parent') or PP consent form ('Your consent to being the legal parent'), therefore it could be assumed that the couples were married, however, this could not be determined from the records. Both treatments resulted in live births. After the inspection, the PR contacted the patients and confirmed that in each case the couple was married at the time of their treatment. The inspection team was concerned that the process for documenting marital status is not robust and failure to accurately record this information could undermine the effectiveness of the consents provided.
- In one case, an unmarried couple had had a frozen embryo transfer following a split cycle (some of the woman's eggs were fertilised with the partner's sperm, and some were fertilised with donor sperm). There was no evidence that WP or PP consent forms had been completed. Staff indicated that WP and PP forms were not required as the embryo transferred was created using the partner's sperm, however this would not have been known at the start of the patient's treatment cycle. This finding raises concerns that staff may not understand legal parenthood consent processes.
- The centre's audit had not been performed according to the method specified by the HFEA.

See recommendation 2.

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

Annex 1

Areas of practice that require the attention of the Person Responsible

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, 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 made.

Critical areas 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 child who may be born as a result of treatment services. A critical 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’ areas 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 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;
- which can comprise 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. Medicines Management The following issues were identified on review of the centre’s controlled drugs (CD) register: • The carry-over of stock from one page to another was not signed or witnessed. • In four entries the witness signature was not recorded for the destruction of the drug. • The majority of entries did not have the time of administration (A) recorded.	The PR should ensure that entries into the controlled drugs register are compliant with regulatory and best practice requirements. The PR should review medicines management practices and ensure that all relevant staff are aware of the correct procedures for recording information and making corrections in the CD register. A summary report of the review, including corrective actions taken, should be provided to the	The findings of the report were shared with the lead for sedation services (Dr D Harvey) and disseminated widely through the anaesthetic team. The findings were of great disappointment to the SMT at NURTURE having taken steps previously to make sure the CD Book was correct and filled in correctly. As PR I have expressed my frustration to the anaethetists and explained that there must be an immediate improvement towards full compliance.	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. No further action is required beyond the audit of practices due by 12 November 2021.

• In several entries, the unit of drug was not recorded for the supply (S), administration (A), or destruction (D) of the drug. • Overwriting was used to amend the date of two entries, and the stock balance of three consecutive entries. SLC T2. The Misuse of Drugs Regulations (2001). Regulations 19(1)(a) and 20(c). DH (2007) Safer Management of Controlled Drugs: a guide to good practice in secondary care (England). Sections 4.7.1.3 and 4.11.1.3. NICE (2016) Controlled drugs: safe use and management (NG46). Recommendations 1.7.4,1.8.3 and 1.8.4. The Association of Anaesthetists of Great-Britain	centre's inspector by 12 August 2021. Three months after the date of this review the PR should conduct an audit of CD register entries to ensure corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 12 November 2021.	A full Audit will be completed in July 2021 and a report provided to the HFEA in the requested time frame.	

and Ireland (AAGBI) Controlled Drugs in Perioperative Care 2019. Recommendations 4 and 5, and Page 7.			
2. Legal parenthood Several concerns related to legal parenthood were noted by the inspection team. These are described in the main body of the report. Human Fertilisation and Embryology Act 2008. SLC T2 and T36. Clinic Focus (April 2021) Legal parenthood article.	The PR should ensure that legal parenthood processes are robust. The PR should review legal parenthood consenting processes including, but not limited to, the issues identified in this report. A summary report of this review, including actions taken to ensure that proper consent to legal parenthood is obtained for all patients, should be provided to the centre's inspector by 12 August 2021. To provide assurance of the validity of all legal parenthood consents currently documented, the PR should conduct a full audit, using previously supplied HFEA methodology, of all records of patients treated since the renewal inspection in 2019 (6	The process for assessing marital status on Day 1 Booking forms has been amended to capture data which will improve the ability to audit. A review will be completed to assess the effects of this going forward. an audit of patient records will be completed as requested and provided to the inspectors within the requested time frames and any errors will be reported	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. No further action is required beyond the audit of legal parenthood consents due by 12 November 2021.

	February), using donor sperm or embryos (including embryos created with donor sperm or donor eggs), to ensure that the correct legal parenthood consents are in place (where applicable). The executive acknowledges that a robust audit of all relevant consents will take a period of time, therefore the PR should provide a report of this audit to the centre's inspector by 12 November 2021. If any anomalies with legal parenthood consents are found, the PR must inform the HFEA immediately.		

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require improvement are any areas of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate 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
3. Premises and facilities The gas store outside housed several large empty cylinders but one of these was not chained and was therefore standing unsecured. There were also over a dozen small empty cylinders which were not stored in a rack, and some appeared to be rusty. SLC T17. DH (2006) Medical gases – Health Technical Memorandum 02-01 Medical gas pipeline systems – Part B: Operational Management. Section 8.	The PR should ensure that all medical gases are stored appropriately. The PR should inform the centre’s inspector of the actions taken to comply with this recommendation when responding to the inspection report.	All members of the laboratory team have been refreshed on correct storage of medical gases. BOC have been contacted to remove the old gas bottles seen at inspection. This was an error on their behalf	The executive acknowledges the PR’s response and the prompt actions taken to address the issues identified on inspection. No further action is required.

Additional information from the Person Responsible
The Team at NURTURE found the inspection process fair and comprehensive. The amount of preparation and provision ofdocumentation required prior to inspection is significant, but resulted in a straight forward remote inspection.