Executive Licensing Panel - minutes

Centre 0321 (NewLife Fertility Centre)

Renewal Inspection Report

Change of Person Responsible

Change of Licence Holder

Tuesday, 9 July 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Anna Coundley Dan Howard	Director of Strategy and Corporate Affairs Policy Manager Chief Information Officer
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

- 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 NewLife Fertility Centre has held a treatment (including embryo testing) and storage licence with the HFEA since 2011 and provides a full range of fertility services.

1.3. The panel noted that, when considering this report and the licence renewal application, they were also requested to look at an application to vary the licence to change the Person Responsible (PR) and Licence Holder (LH) at the centre.

1.4. The panel noted that, in the 12 months to 31 December 2018, the centre provided 188 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small sized centre.

1.5. The panel noted that, HFEA register data, for the period 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.

1.6. The panel noted that, in 2018, the centre provided 78 cycles of partner inseminations, with twelve pregnancies, and this is in line with the national average.

1.7. 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 17%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.8. An inspection was carried out at the centre on 5 and 6 March 2019.

1.9. The panel noted that at the time of the inspection, there was one critical area of non-compliance concerning legal parenthood. There were also two major areas of non-compliance regarding donor assessment and screening, and medicines management. There were three 'other' areas of non-compliance relating to witnessing, quality management and record keeping. Since the inspection visit the PR has given a commitment to fully implement all the recommendations, providing evidence that actions have been taken and making a commitment, where required, to audit the effectiveness of those actions within the required timescales.

1.10. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a Quality Management System (QMS) and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients.

1.11. The panel noted that, at the time of the inspection, the centre's inspector advised the PR that he should take immediate action to review the case, noted in the report, as a critical non-compliance, regarding legal parenthood.

1.12. The panel noted that in view of the critical non-compliance identified at inspection, the executive held a management review meeting on 23 June 2019 with the Chief Inspector in accordance with the HFEA's Compliance and Enforcement Policy, to evaluate the centre's performance and to decide a proportionate licensing recommendation regarding the licence renewal application. The management review meeting found that the issues identified on inspection regarding legal parenthood were of concern. However, the PR had sought legal advice, spoken to the parties involved and taken action as described in his response to the inspection report.

1.13. The PR has stated in his response to the inspection report that they will continue to ensure that staff are suitably trained in consent to legal parenthood and that the centre's documents will be reviewed by a legal adviser. The centre's inspector discussed this further with the PR on 20 June 2019 and it was agreed that until such times as this has been completed the centre will not undertake any further treatments involving surrogacy arrangements

1.14. The panel noted that, the inspection team acknowledged the critical non-compliance concerning legal parenthood consenting, a major non-compliance related to donor screening (in 2016 the centre had a critical non-compliance related to donor screening) and the proposed change of PR and LH. The inspection team therefore recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of three years, rather than the usual four years, without additional conditions. This would allow the centre to be inspected within a year of the issue of the new licence, to closely look at the compliance of the areas of practice of concern in this inspection report and also to assess the leadership of the centre provided by the new PR and LH. This licensing recommendation is subject to the report's recommendations being implemented within the prescribed timescales.

1.15. The panel noted that due to the centre's licence expiring on 2 August 2019, there may not be enough time for the licensing administrative process to conclude prior to the expiry of the centre's licence. Therefore, the executive requested that the Executive Licensing Panel issue Special Directions, under Section 24 (5A) (b) of the HF&E Act 1990 (as amended), to permit the continuation of licensed activity at the centre from 2 August 2019 until such times at the offer of licence renewal is received and accepted by the PR.

1.16. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018; these certificates are generally synchronised to the centre's HFEA licence. The inspection team recommended the renewal of the centre's ITE import certificate in line with the centre's licence.

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 expressed major concerns regarding the range of non-compliances identified at the renewal inspection, particularly noting the critical non-compliance concerning legal parenthood. The panel also noted that the previous licence had been issued for three years (rather than the usual four) because of concerns about compliance at that stage.

2.5. The panel decided to adjourn renewal of the centre's licence, requesting the matter to be referred to the Licensing Committee for consideration. The panel noted that further updates on legal parenthood, medicines management, witnessing, quality management and record keeping, were due for receipt by 29 August 2019, requesting the inspector to provide the Licensing Committee with progress on these non-compliances.

2.6. The panel agreed to issue Special Directions under Section 24 (5A)(b) of the HF&E Act 1990 (as amended), to permit the continuation of licensed activity upon expiry of the centre's current licence, to allow time for the renewal to be considered by the Licence Committee and for the administration of the outcome of their consideration to be completed within the usual timeframe. These Special Directions would come into force on 3 August 2019 and would remain in force until any new licence comes into effect, or to 2 November 2019, whichever is sooner.

2.7. The panel decided that the renewal of the centre's ITE import certificate should be considered by the Licence Committee, in tandem with the renewal of the centre's licence.

3. Change of Person Responsible

3.1. The committee considered the papers, which included a completed application form and the CV of and confirmation of acceptance from the proposed new PR

3.2. The committee noted that the proposed PR, Mrs Visha Gloucester-Trotman (also referred to Mrs Bhavisha Gloucester-Trotman), is willing to assume the responsibility of the role of PR. The committee noted that the proposed PR has satisfactorily completed the PR Entry Programme (PREP) and the certificate number was provided.

3.3. The committee noted that Mrs Visha Gloucester-Trotman has suitable qualifications for the role of PR.

3.4. The committee noted from the information provided that the character, qualifications and experience of the proposed PR, Mrs Visha Gloucester-Trotman, are suitable to carry out a PR's duties under section 17 of the HFE Act 1990 (as amended).

3.5. The committee noted that all information required under General Directions 0008 had been provided.

3.6. The committee noted the inspectorate's recommendation to vary the centre's licence to appoint Mrs Visha Gloucester-Trotman as the PR.

4. Decision

4.1. The committee agreed it was in receipt of the appropriate documentation as required by the HFE Act 1990 (as amended) in relation to Section 16(2), which sets out the requirements with regard to the role of PR.

4.2. The committee endorsed the inspectorate's recommendation and agreed to vary the licence of the NewLife Fertility Centre (centre 0321), with immediate effect to reflect the change of Person Responsible to Mrs Visha Gloucester-Trotman, in accordance with Section 18A of the HFE Act 1990 (as amended).

5. Change of Licence Holder

5.1. The committee considered the papers, which included a completed application form and confirmation of acceptance from the proposed new LH

5.2. The committee noted that the proposed new LH, Mr Ahmed Gafar, is willing to assume the responsibility of the role of LH.

5.3. The committee noted that all information required under General Directions 0008 had been provided.

5.4. The committee noted the inspectorate's recommendation to vary the centre's licence to reflect the change of LH to Mr Ahmed Gafar.

6. Decision

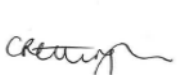
6.1. The committee agreed it was in receipt of the appropriate documentation as required by the HFE Act 1990 (as amended) in relation to Section 16(2), which sets out the requirements with regard to the role of the LH.

6.2. The committee endorsed the inspectorate's recommendation and agreed to vary the licence of the NewLife Fertility Centre (centre 0321), with immediate effect, to reflect the change of Licence Holder to Mr Ahmed Gafar, in accordance with Section 18A of the HFE Act 1990 (as amended).

7. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

16 July 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: 5 and 6 March 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 (lead), Sara Parlett, Nicola Lawrence and Polly Todd (observing).

Date of Executive Licensing Panel: 9 July 2019.

Centre name	NewLife Fertility Centre
Centre number	0321
Licence number	L/0321/3/c
Centre address	The Parade, The Pines, Epsom, Surrey, KT18 5DH
Person Responsible	Dr Amin Gafar
Licence Holder	Mrs Bhavisha Gloucester-Trotman
Date licence issued	03/08/2016
Licence expiry date	02/08/2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

NewLife Fertility Centre has held a treatment (including embryo testing) and storage licence with the HFEA since 2011 and provides a full range of fertility services.

The centre provided 188 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2018. In relation to activity levels this is a small centre.

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

This current licence has been varied three times since 2016 to reflect a change of Licence Holder (LH).

The Person Responsible (PR) and LH have requested that the licensing committee, when considering this report and the licence renewal application, also consider an application to vary the licence to change the PR and LH at the centre. The papers for this proposed variation are included with the papers for the licence renewal application.

Pregnancy outcomes[1]

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

In 2018 the centre reported 78 cycles of partner insemination with 12 pregnancies. This represents a clinical pregnancy rate of 15%, which 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 17% This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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

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

Summary for licensing decision.

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP) and standard licence conditions (SLCs), 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), (included with the report is an application to vary the licence to change the 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, two major and three 'other' areas of non compliance.

Since the inspection visit, the PR has given a commitment to fully implement all the recommendations, providing evidence that actions have been taken and making a commitment, where required, to audit the effectiveness of those actions within the required timescales.

Critical areas of non compliance:

- **The PR should ensure that consent to legal parenthood obtained and documented at the centre is valid.**

Major areas of non compliance:

- The PR should ensure that sperm donors are screened in accordance with standard licence conditions and professional body guidelines.
- The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance.

'Other' areas that require improvement:

- The PR should ensure that audits performed by the centre are comprehensive and robust.
- The PR should ensure that any risks associated with deviating from HFEA guidance on witnessing practices are properly assessed and documented.
- The PR should ensure that the staff member who verifies a patient's identity is documented in the patient's records.

Recommendation to ELP

The centre has one critical area of concern and two major areas of concern.

The inspection team notes that the success rates are consistent with the national average and the centre's multiple clinical pregnancy /live birth rates are not likely to be statistically different from the 10% multiple live birth rate target.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system (QMS) and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients.

At the time of the inspection the centre's inspector advised the PR that he should take immediate action to review the case noted in the report as a critical non compliance.

The centre's inspector contacted the centre on 29 March 2019 as she had reviewed some surrogacy documents submitted by the centre which she considered to contain some inaccuracies. She was informed by the lead nurse that no action had yet been taken regarding the non compliance identified on inspection regarding consent to legal parenthood in a surrogacy treatment. The centre's inspector discussed this with the HFEA's Chief Inspector and contacted the centre by email stressing the importance of the PR reviewing the patient's records to identify if there were discrepancies in the consents and if there may be, amongst the surrogate and commissioning couple some confusion as to their legal parenthood status. The inspector also suggested that the centre seek advice from a legal parenthood expert at their earliest opportunity.

On the 1 April 2019 the lead nurse submitted the centre's updated surrogacy information documents and confirmed that they were seeking legal advice about the case identified on inspection.

The draft inspection report was provided to the PR on 23 May 2019.The PR provided responses on 10 June confirming that the case identified had been reviewed, and that actions had been taken in accordance with the legal advice that he had received. The PR confirmed that no further action was needed in relation to this case.

With regards to the incorrect information in the centre's consent forms as described in the body of the report the PR informed the centre's inspector that these were due to cut and paste errors. He stated that he was grateful that the error was noted following the HFEA inspection and had been rectified. He further said that this had not translated into errors in using the WP and PP HFEA forms and that relevant staff were competent in the use of the WP and PP HFEA consent forms.

The PR has stated in his response to the inspection report that they will continue to ensure that staff are suitably trained in consent to legal parenthood and that the centre's documents will be reviewed by a legal adviser. The centre's inspector discussed this further with the PR on 20 June 2019 and it was agreed that until such times as this has been completed the centre will not undertake any further treatments involving surrogacy arrangements.

In view of the critical non compliance identified on inspection the executive held a management review meeting on 23 June 2019 with the Chief Inspector in accordance with the HFEA's Compliance and Enforcement Policy, to evaluate the centre's performance and to decide a proportionate licensing recommendation regarding the licence renewal application. The management review meeting found that the issues identified on inspection with regards to legal parenthood were concerning however the PR had sought legal advice, spoken to the parties involved and taken action as described in his response to the inspection report.

In relation to the inaccurate information in the centre's in house consent forms the PR has acted as documented above.

In conclusion, the inspection team notes the critical non compliance concerning legal parenthood consenting, a major non compliance related to donor screening (in 2016 the centre had a critical non-compliance related to donor screening) and the proposed change of PR and LH. The inspection team therefore recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of three years, rather than the usual four years, without additional conditions. A three year licence will allow the centre to be inspected within a year of the issue of the new licence, to closely look at the compliance of the areas of practice considered deficient in this inspection report and also to assess the leadership of the centre provided by the new PR and LH. This licensing recommendation is subject to the report's recommendations being implemented within the prescribed timescales.

The executive noted that the centre's licence is due to expire on 2 August 2019 and as this committee meeting is on 9 July 2019, there may not be enough time for the licensing administrative process to conclude prior to the expiry of the centre's licence. Therefore, the executive requests that the Executive Licensing Panel issue Special Directions to the Person Responsible (PR) at centre 0321 under Section 24 (5A) (b) of the HF&E Act 1990 (as amended), to permit the continuation of licensed activity at the centre from 2 August 2019 until such times at the offer of licence renewal is received and accepted by the PR.

Centre 0321 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

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 broadly compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better

Witnessing (Guidance note 18)
The centre uses an electronic witness system, however CoP Guidance 18.4 and HFEA model protocols detail critical points at which manual witnessing should still be performed. The centre does not perform manual witnessing at all of these required stages (e.g. at insemination, ICSI and disposal).

CoP guidance 18.2 allows for clinics to adapt the HFEA model protocols to take into account their local systems, however CoP guidance 18.27 and 18.28 states that centres should consider how witnessing guidance applies to their local environment, and the risks involved with departing from the guidance.

Consideration of the risks associated with the centre's departure from witnessing guidelines (including deviation from their own SOP) has not been documented.

SLC T71; see recommendation 4.

Donor selection criteria and laboratory tests

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

What the centre does well

Screening of donors (Guidance note 11)
It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos. The centre's procedures for screening donors are partially compliant with HFEA requirements.

Payments for donors (Guidance note 13; General Direction 0001)
We were informed that the centre has not recruited donors for the previous two years. The procedures relevant to payment of donors were however discussed and were considered to be compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

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

What the centre could do better

Screening of donors (Guidance note 11)
The records of one sperm donor (an intended parent in a surrogacy arrangement) indicated that the donor had not been screened in accordance with professional body guidelines; the donor had not had a physical genital examination.

The SOP for screening and assessment of sperm donors did not include that donors should have a physical examination as part of their assessment, as is recommended by professional body guidelines.

In 2016 the centre had a critical non-compliance related to donor screening. Whilst the actual non-compliance was different, it is a concern that a related non-compliance has recurred in this area of practice.

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

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

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

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

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable.

Written information provided to patients offered intralipid therapy is compliant with guidance.

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

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is a multiple pregnancy.

The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy.

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

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

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

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

Receipt of gametes and embryos (Guidance 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. This centre has been allocated an ITE import certificate and imports of gametes and embryos from TCSs outside the EU/EEA have been made in a manner 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 broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements, including those associated with ITE/TCS import certificates, are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have transport or satellite agreements and therefore this guidance note is not relevant.

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

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

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre has investigated 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)
In a review of ten patients records the inspection team identified the following issues related to medicines management practices:

- Several entries in the controlled drugs register were illegible.
- In five records the unit of measure of the controlled drug administered had not been recorded.
- In four records the amount of the controlled drug administered was illegible.
- In three records the patient's name or record number were illegible.
- The CD cupboard key could be accessed by the centre manager who did not require this access as part of his responsibilities.

SLC T2, The Association of Anaesthetists of Great Britain & Ireland (AAGBI) (2018)

‘Controlled Drugs in Peri-operative Care’; see recommendation 3.

Quality management system (QMS) (Guidance note 23)
The following issues were noted:

- The controlled drug audit did not identify illegible entries in the controlled drugs register.

SLC T36; see recommendation 5

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)

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

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

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

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

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

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

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

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

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

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Fourteen patients provided feedback between February 2018 and September 2018 giving an average 4.5-star rating to the clinic.

The website also gives the ability for patients to comment on the cost of treatment. Eight of the fourteen patients confirmed that they had paid what they expected to while four commented that it was more expensive.

Several patients provided individual comments to the HFEA which included:

- Professional staff, kind nurses and a good service;
- Very friendly and competent staff;
- The staff went above and beyond to help us, extremely empathetic, caring and professional.

The centre's own most recent patient survey responses were also reviewed. Feedback was comparable to that provided to the HFEA.

During the inspection the inspectors spoke to one patient who also provided positive feedback on their experiences.

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;
- treats patients with empathy and understanding.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
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 including consent to legal parenthood.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not provide treatment involving egg and/or sperm sharing arrangements. Therefore this guidance note is not 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. The inspection team did however identify an issue regarding consent to legal parenthood in a surrogacy arrangement. This is described below in 'Legal Parenthood (Guidance note 6)'.

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 on 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 are compliant with HFEA requirements. The inspection team did however identify an issue regarding the content of specific consent forms. This is described below in 'Legal Parenthood (Guidance note 6)'.

What the centre could do better
Nothing identified on 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. The inspection team did however identify an issue regarding consent to legal parenthood in a surrogacy arrangement. This is described below in 'Legal parenthood (Guidance note 6)'.

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 no couples were affected by legal parenthood consent anomalies.

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.

This centre has been inspected since 2014 and 2015. At that inspection in 2017 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 discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Four 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 partially compliant with HFEA requirements.

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

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

What the centre could do better

Legal Parenthood (Guidance Note 6)
In the records for a surrogacy case audited by the inspection team, the surrogate had completed a consent to nominate one of the commissioning couple to be the second legal parent, and this person had completed a consent to be the second legal parent. The surrogate was married and the husband of the surrogate had completed a withdrawal of consent to legal parenthood. The inspection team considered that the husband should have instead completed a 'lack of consent (LC)' form and those affected should have been advised that the legal power of the LC form was unclear, and that a court may still have to consider whether the surrogate's husband was in fact the father of the child conceived, before any consideration of parental orders occurs.

It was also noted that the centre's own consent form for treatment with IVF/ICSI includes the following statement: '*I/we understand that when using **donor eggs** in our treatment, the completion of additional consent forms to allow acknowledgement as 'legal parent' may be required (PP and WP).'* Consent to legal parenthood is only applicable when treatments involve the use of donor sperm, as the birth mother is always considered the legal parent in law, regardless whether donor eggs are used or not. Therefore, this information is not correct.

The form also states: *'I/we understand that when commissioning a surrogate in our treatment, the completion of additional consent forms to allow **acknowledgement** as 'legal parent' are required (HFEA PP and HFEA WP).'* The reference to the use of PP and WP forms is not correct, as specific consent to legal parenthood forms are in place for treatments involving surrogacy (SPP and SWP forms are). Furthermore, such forms are used to document consent to legal parenthood, rather than to 'acknowledge' it.

The inspection team were concerned that these statements indicate a lack of understanding of the legal parenthood regulations and requirements by centre staff.

The inspection team advised that immediately following the inspection the centre should seek legal advice regarding legal parenthood consents documented in the surrogacy case discussed above and, to discuss any legal advice received with the surrogate, her husband and the commissioning couple.

SLC T60; see recommendation 1.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

The centre's procedures for screening patients are 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)
From information provided by the centre to the HFEA, the register team was able to assess the following:

- All 93 IVF and 20 Donor insemination (DI) treatments in our sample reviewed post inspection, had been reported to the HFEA in accordance with General Direction 0005.
- Treatment reporting is timely, with 88% of the IVF and 10% of the donor insemination treatments in our sample reported to the HFEA within 10 working days.
- The clinic has a comprehensive data submission SOP in place and as well as evidence of periodic self-audit of data submission processes.

The centre's procedures for submitting information, about licensed activities, to the Authority, are compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents.

What the centre could do better

Record keeping and document control (Guidance note 31)
The centre does not document in patient records by whom a patient/donor has been reliably identified.

SLC T46, see recommendation 7.

Section 3: Monitoring of the centre's performance

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

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

It however is noted that in 2016 the centre had a critical non-compliance related to donor screening. Whilst the actual non-compliance was different, it is a concern that a related non-compliance has recurred in this area of practice.

On-going monitoring of centre success rates

In 2018 the centre did not receive any alerts from the HFEA with regards to the success rates of treatments provided.

Areas of practice requiring action

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

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non compliance requires immediate action to be taken by the Person Responsible.

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Legal Parenthood It was noted that the husband of a surrogate had completed a withdrawal of consent to legal parenthood, while the surrogate had consented to nominate one of the commissioning couple to be the second legal parent, and that person had completed a consent to be the second legal parent. In addition, it was noted that a	The PR should ensure that consent to legal parenthood obtained and documented at the centre is valid. The PR should keep the centre's inspector updated regarding the case identified on inspection. The PR should perform an audit of all cases involving surrogacy and the use of donor eggs to provide	Legal advice was sought. Commissioning couple, surrogate and her partner informed, statements signed & witnessed. No further action required. An audit of cases (2018 – 2019), of surrogacy undertaken has shown all other cases had correct consent forms signed. The consent and legal parenthood information provided to	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The PR has provided evidence of training and an audit report of surrogacy cases undertaken. With regards to the use of the SWC form we do acknowledge that the forms are necessarily

consent form for IVF/ICSI includes: • *'I/we understand that when using **donor eggs** in our treatment, the completion of additional consent forms to allow acknowledgement as 'legal parent' may be required (PP and WP).* • *'I/we understand that when commissioning a surrogate in our treatment, the completion of additional consent forms to allow **acknowledgement** as 'legal parent' are required (HFEA PP and HFEA WP)* The inspection team notes that it is not necessary to complete legal parenthood forms when using donor eggs, unless donor sperm is also used and the couple being treated are not married or in a civil partnership. In addition, the PP and WP forms document consent to legal parenthood not acknowledgement of legal parenthood, and WP and PP forms are not relevant in treatments involving surrogacy.	assurance that the correct consent forms have been completed. The audit should include whether the information given to patients regarding consent to legal parenthood is correct. The PR should inform the centre's inspector of the result of this audit prior to this report being presented to a licensing committee. The PR should seek legal advice regarding their consent forms and information regarding legal parenthood, to ensure that it is accurate. The PR should ensure that all staff are trained and competent to provide information regarding legal parenthood to those undertaking fertility treatments, prior to performing any further treatment cycles using donated eggs or involving surrogacy agreements. The PR should inform the	patients at the time was correct in all other cases. Audit report provided to inspector Documents being reviewed by fertility legal advisor as requested. IVF/ICSI consent form has been rectified All staff involved in the consenting process have completed training on surrogacy and legal parenthood as requested. One staff attended a legal parenthood workshop and processes changed after this	complex which reflect this complicated area of practice, however the PR has, as we have been informed, consulted with their own legal advisors and it is therefore difficult to understand some of the reasoning in his response. The executive does note the PR's observation that the HFEA surrogacy decision tree is missing box 6H. The situation he refers to is described in Code of Practice Guidance 6 I. The PR and his team must study the consent forms carefully and refer to the guide to consent. If he has any doubt about their completion or indeed who should complete the consent forms then he should seek advice from the centre's legal advisor. The PR has explained by email that the issue related to the information in the centre's own IVF/ICSI consent form was due to a cut and paste error and had not translated

The inspection team were concerned that these misinterpretations indicated a lack of understanding by centre staff of legal parenthood in treatment with donor eggs, and surrogacy cases. The inspection team advised the PR to seek legal advice immediately following the inspection regarding the legal parenthood consents documented in the surrogacy case discussed above and to discuss any advice received with the surrogate, her husband and the commissioning couple. SLC T61.	centre's inspector of how he intends to address this issue when responding to the inspection report.	and were implemented into practice since 3rd December 2018 (there have been no further surrogacy cases since processes have changed) All patients are now required to attend a nurse consultation to complete consent forms with a competent and trained member of the nursing team See above and the accuracy of legal parenthood and surrogacy will be addressed through further training, a check prior to embryo transfer and regular audits of these consent forms. The error occurred by the clinic due to the interpretation of the HFEA form; the SWC form stating at the beginning: *"Fill in this form if you are …….. a surrogate, or* ***the partner of a surrogate****, and you wish to withdraw your consent to:".* The HFEA surrogacy decision tree is missed box 6H which	into errors in using the WP and PP HFEA forms and that relevant staff were competent in the use of the WP and PP HFEA consent forms. However, the executive remains concerned that such an error was not identified by the centre and notes that the PR has provided assurance that the centre's documents will be reviewed by a legal advisor. The PR should investigate why this error occurred. The centre's inspector has discussed this with the PR and he has assured her that this error in the IVF/ICSI in house consent forms has been rectified with immediate effect and that the centre's inspector will be sent copy of the review of the surrogacy documents and centre consent forms outlining any actions the centre have taken by 29 August 2019. **Further action is required.**

		refers to the situation in question. If the surrogate is not married or in a civil partnership with her partner then it would appear the SWC form is not relevant as there would be no legal status and therefore the SWC form is for the married / civil partner of a surrogate. We understand this is not correct however. Legal advice was sought. Commissioning couple, surrogate and her partner informed, statements signed & witnessed. No further action required.	

Major area of non compliance

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

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

A major area of non compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Donor assessment and screening. The records of one sperm donor (intended parent in a surrogacy arrangement) indicated that the donor had not been screened in accordance with professional body guidelines; the donor had not had a physical examination. The SOP for screening and assessment of sperm donors did not include the need to perform a physical examination.	The PR should ensure that donors are screened in accordance with standard licence conditions and professional body guidelines. The PR should ensure that the relevant SOP is reviewed and shared with all relevant staff. The PR should ensure that staff are suitably trained and have been assessed as competent, prior to undertaking donor assessment and screening activities. The PR should perform an	Donor screening SOP has been reviewed and updated in accordance with standard licence conditions and professional body guidelines to add physical examination of males The SOP has been shared with all relevant staff Staff training not required as Consultants are already trained to perform physical examination and the blood screening was found to be compliant at inspection.	The inspector acknowledges the PR's response and receipt of audit of compliance of the screening and assessment of sperm donors who have been recruited by the centre. The inspector also notes the PR's comment that they do not feel that there are any risks from the omission to perform a physical examination but that they would consult with their urologist consultant. The inspector fully appreciates that consultants are trained to perform physical examinations.

In 2016 the centre had a critical non-compliance related to donor screening. Whilst the actual non-compliance was different it is a concern that a related non-compliance has recurred. SLC T52a, CoP 11.23 and UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008)	audit of the compliance of the screening and assessment of sperm donors who have been recruited by the centre. A report of the audit should be provided to the centre's inspector prior to this report being presented to a licensing committee. Where it is identified that donors have not been suitably screened, the PR should seek expert advice, to assess if there have been any risks to those treated with the donor's sperm or to other samples stored with the donor's sperm. The actions taken should be detailed when responding to the report.	We have provided you with this audit The clinic was compliant with the blood screening tests but not with the physical assessment of the potential donor	In 2016 the centre had a critical non-compliance related to donor screening. The reference to training in the recommendation is to ensure that staff are aware of professional bodies guidelines and any change to an SOP. In this instance the reference to training is with regards to training and competence in the recruitment and assessment of donors. Confirmation of this training to be received by the centre's inspector. **Further action is required.**
3. Medicines management In a review of ten patients records the inspection team identified the following issues related to medicines management practices: • Several entries in the controlled drugs register were illegible. • In five records the unit of	The PR should ensure medicines management practices are compliant with regulatory requirements and professional body guidance. The PR should inform the centre's inspector of the actions taken to address these non-compliances when	The staff involved have been informed by formal letter of the requirements and guidance expected of them. We are happy to undertake this audit. However, it is not feasible to provide a summary report by 6 June given the	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The inspector also acknowledges the limited time scale for the submission of a summary audit.

measure of the controlled drug administered to the patient had not been recorded. • In four records the amount of the controlled drug administered to the patient was illegible. • In three records the patient's name or record number was illegible. • The CD cupboard key could be accessed by the centre manager who did not require this access as part of his responsibilities SLC T2; The Association of Anaesthetists of Great Britain & Ireland (AAGBI) (2018) 'Controlled Drugs in Peri-operative Care.'	responding to this report. The PR should conduct an audit of the documentation in the controlled drug register, three months after the implementation of corrective actions, to see that they have been effective. A summary report of this audit should be provided to the centre's inspector by 6 June 2019.	report was received on 23rd May. Staff have just been informed and a reasonable number of cycles needs to occur to determine effectiveness. The CD cupboard key is now with a suitable person.	Audit to be received by 29 August 2019. **Further action is required.**

Other areas of practice that requires improvement

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

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
4. Witnessing The centre uses an electronic witness system, however CoP Guidance and HFEA model protocols detail critical points at which manual witnessing should still be performed. The centre does not perform double manual witnessing at all of these stages (e.g. insemination, ICSI and disposal) and the risks associated with this have not been assessed. SLC T71	The PR should ensure that any risks associated with deviating from HFEA guidance on witnessing practices are properly assessed and documented. The HFEA should be advised of the measures taken to ensure that this happens by the time this report is considered by a licensing committee. The PR should perform a review of witnessing protocols to ensure compliance with CoP guidance and HFEA model protocols. Within three months of the implementation of revised witnessing procedures, the centre should conduct an audit	Witnessing procedures are in place for all treatments. It is 4 manual witnessing steps that are being undertaken electronically instead of with a second person that is being questioned. As requested, we have undertaken a review of the witnessing protocol against the HFEA guidance / protocol by means of a risk assessment of each witnessing step. This showed the current system is effective, also confirmed by witnessing and tank audits. However, a few further improvements were identified and introduced	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The inspector also acknowledges the limited time scale for the submission of a summary audit. Audit to be received by 29 August 2019. **Further action is required.**

	of witnessing practice. A summary report of the findings of the audit should be provided to the HFEA by 6 June 2019	As discussed and agreed at the inspection. For steps that continue not to be double manual witnessed but are electronically witnessed they are now covered by a risk assessment. We are happy to undertake this audit. However, it is not feasible to provide a summary report by 6 June given the report was received on 23rd May. The changes have just been implemented and a reasonable number of cycles needs to occur to determine effectiveness.	
5. Quality Management The centre's controlled drug audit did not identify illegible entries in the controlled drugs register. SLC T36	The PR should ensure that audits performed by the centre are comprehensive and robust. The PR should review the methodology of the audit of medicines management to ensure that it includes the legibility of documentation within the controlled drugs register. The PR should perform an audit of medicines	Audit methodology reviewed and will be included in future audit checklist(s). We are happy to undertake this audit. However, it is not feasible to provide a summary report by 6 June given the report was received on 23rd May. The changes have just been implemented and a	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The inspector also acknowledges the limited time scale for the submission of a summary audit. Audit to be received by 29 August 2019.

	management practices since the inspection and provide the centre's inspector with the audit results by 6 June 2019.	reasonable number of cycles needs to occur to determine effectiveness.	**Further action is required.**
6. Record keeping The centre does not document in the patient record by whom the patient/donor has been identified. SLC T46	The PR should ensure that the identity of the staff member who verifies a patient's identity, is documented in the patient's records. The PR should inform the centre's inspector of the actions taken to address this non-compliance when responding to this report. Three months after corrective actions have been implemented, the PR should perform a records audit to ensure these actions have been effective. A summary report of this audit should be provided to the centre's inspector by 6 June 2019.	The identity of the staff member who verifies patient's ID is recorded on the lab sheet which is stored in the patients record. Identity of staff who check patient passports is recorded in patient's electronic notes. This can be demonstrated therefore no action is required. We are happy to undertake this audit. However, it is not feasible to provide a summary report by 6 June given the report was received on 23rd May.	The inspector acknowledges the PR's response and the actions he has taken towards compliance with this recommendation. The inspector also acknowledges the limited time scale for the submission of a summary audit. Audit to be received by 29 August 2019. **Further action is required.**

Reponses from the Person Responsible to this inspection report