Licence Committee - minutes

Centre 0327 (Boston Place)

Renewal Licence

Thursday, 7 March 2019

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Jonathan Herring	
Members of the Executive	Dee Knoyle Moya Berry	Committee Secretary Committee Secretary (Observer)
Legal Adviser	Gerard Hanratty	Browne Jacobson LLP
Specialist Adviser		
Observers		

Declarations of interest:

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

The committee had before it:

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

The following papers were considered by the committee:

Papers enclosed:

- Executive Update
- Renewal inspection report
- Application form
- Email from Person Responsible confirming licence type applied for.
- Previous licensing minutes up to the last licence renewal:
    - May 2018 - Change of Person Responsible
    - December 2017 - Change of Licence Holder
    - January 2017 - Interim Inspection Report
    - February 2015 - Renewal Inspection Report

1. Background

1.1. Boston Place, centre 0327 is located in central London and has held a licence with the HFEA since May 2013. The centre provides a full range of fertility services including embryo testing. The centre is part of The Fertility Partnership, a group of fertility centres, not currently operating under common practices and procedures.

Current Licence

1.2. The current licence has been varied to reflect a change of Licence Holder (LH) in December 2017 and a change of Person Responsible (PR) in May 2018. The centre's current licence is due to expire on 24 May 2019.

Renewal Licence

1.3. Due to concerns raised about the level of non-compliance, outlined in the centre's renewal inspection report, the Executive decided to refer this renewal application to the Licence Committee for consideration, rather than the Executive Licensing Panel.

2. Consideration of application

Renewal Inspection

Application

2.1. The committee noted that the Person Responsible (PR) has submitted an application for the renewal of a treatment and storage licence, however since submission, he has confirmed that this was an error and that he wishes to renew the centre's current licence to carry out treatment (including embryo testing) and storage.

2.2. The committee noted that the application contains the supporting information required by General Direction 0008 and that the appropriate fee has been paid.

2.3. The committee noted that the centre also holds an ITE import certificate in accordance with the HF&E Act 1990 (as amended). Amendment made on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018 (the '2018 Regulations').

Inspection Process

2.4. The committee noted that in the 12 months to 31 October 2018, the centre provided 486 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

2.5. The committee noted that for IVF and ICSI, HFEA-held register data for the year ending 31 July 2018 showed the centre's success rates were in line with national averages.

2.6. The committee noted that for the year 2017, the centre reported 24 cycles of partner insemination with two clinical pregnancies. This represented a clinical pregnancy rate which was comparable to the national average.

2.7. The committee noted that for the year ending 31 July 2018, HFEA-held register data showed the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 6%. This represents performance that is not likely to be significantly different to the 10% maximum multiple live birth rate target for this period.

2.8. The committee noted that the renewal inspection took place on 4 and 5 December 2018. The renewal inspection report covers the performance of the centre since the last inspection, the findings from the renewal inspection visit and communications received from the centre. The committee noted that at the time of the renewal inspection there were two critical, six major and nine 'other' areas of non-compliance identified:

Critical area of non-compliance:

- The PR should ensure that proper consent to legal parenthood is obtained.
- The PR should ensure that there is effective written consent in place for all stored gametes and embryos.

Major areas of non-compliance:

- The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice guidance.
- The PR should ensure written agreements with all third parties who provide goods or services that influence the quality and safety of gametes and embryos are compliant with requirements.
- The PR should ensure that written agreements with satellite services are compliant with requirements and that the satellite activities are audited against the specifications detailed in the satellite agreements.
- The PR should ensure that staff are available in sufficient number and are suitably trained and assessed as competent to undertake their roles.
- The PR should ensure that a woman is not provided with treatment services unless account has been taken of the welfare of the child.
- The PR should ensure that patients and donors are provided with a suitable opportunity to receive proper counselling and that this offer is documented.

'Other' area that requires improvement:

- The PR should ensure that the centre's facilities are suitable for patients and staff.
- The PR should ensure that all clinical areas of the centre meet the requirements of infection prevention and control regulations.
- The PR should ensure that the centre's quality management system (QMS) and auditing processes are effective in identifying and implementing appropriate corrective actions in response to audit findings.
- The PR should ensure that all critical equipment is subject to ongoing monitoring.
- The PR should ensure that appropriate safeguarding processes are in place.
- The PR should take appropriate action to ensure that the centre's website is compliant with requirements.
- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.
- The PR should ensure that the centre's document control procedures are effective.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

2.9. The committee noted that since the inspection visit, the PR has committed to fully implementing all of 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.

2.10. The committee noted that evidence of progress in implementing these recommendations was due to be submitted to the Executive by 5 March 2019, two days before the Licence Committee meeting on 7 March 2019. The committee received an Executive update which confirmed that submissions were provided by the PR, however they arrived outside of the set deadline, not allowing sufficient time for the Executive to review them in detail.

2.11. The committee noted that significant improvement is required in order for the centre to reflect suitable practices. The centre has a Quality Management System (QMS) and the PR is encouraged to continue to use it to monitor and improve their success rates and the quality of the service offered to patients.

Recommendations

2.12. Due to the issues identified during the renewal inspection, the Executive held a management review meeting on 20 December 2018 in accordance with the HFEA Compliance and Enforcement Policy to evaluate the centre's performance and to decide a proportionate licensing recommendation for the licence renewal application. The Executive concluded that the non-compliances seen on inspection were significant and reflected direct and indirect risks to patients and to the centre's compliance with the HF&E Act 1990 (as amended) and other relevant legal requirements. As a result, the Executive considered recommending the renewal of the centre's treatment (with embryo testing) and storage licence for a period of three years, rather than the usual four, with a targeted interim inspection to be performed within one year of renewal.

2.13. The Executive reported that a further meeting took place with the PR on 14 January 2019 and after review of the centre's action plans to address the non-compliances the Executive considered that the proposed actions demonstrated the PR's commitment to attaining compliance and good governance and would thereby mitigate risks identified at the centre.

2.14. The committee noted that the Executive is closely monitoring the centre's performance and the PR is providing regular updates regarding corrective and preventative actions. The Executive reported that it is assured that the PR will fully discharge his duties.

3. Decision

3.1. The committee noted that the Executive is assured that the PR will fully discharge his duties and strive to demonstrate better leadership in driving the centre to achieve and maintain compliance with regulatory requirements with the support of the Licence Holder, who is also the Chief Operating Officer for The Fertility Partnership group.

3.2. However, the committee considered the information provided in this application and still has concerns about the number and nature of non-compliances identified at the renewal inspection. The committee also noted that the Executive had considered adding a further non-compliance regarding poor leadership by the PR, however on this occasion the Executive decided that this was not necessary, given the engagement and commitment of the PR to ensure compliance at the centre.

3.3. The committee acknowledged that the PR is engaging with the Executive and has committed to implementing the recommendations outlined in the renewal inspection report. However, the committee deliberated on the lack of evidence of progress in implementing the Executive's recommendations, as the PR's submissions arrived outside of the set deadline, not allowing sufficient time for the Executive to review these submissions in detail to provide a satisfactory update to the Licence Committee to make a decision on the renewal of the centre's licence.

3.4. The committee agreed to adjourn its decision on the renewal of the centre's treatment (including embryo testing) and storage licence until the Executive has had the opportunity to review, in detail, the evidence of progress in implementing these recommendations and submitted a progress report to the Licence Committee.

3.5. The committee requested an Executive update for consideration at the Licence Committee meeting scheduled in May 2019.

4. Chair’s signature

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

Signature

Name

Kate Brian

Date

4 April 2019

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high-quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Licence Committee 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: 4 and 5 December 2018

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: Karen Conyers, Polly Todd, Mhairi West and Stevan Cirkovic (HFEA observer, 4 December 2018 only)

Date of Licence Committee: 7 March 2019

Centre name	Boston Place
Centre number	0327
Licence number	L/0327/2/c
Centre address	16-20 Boston Place, London, NW1 6ER, United Kingdom
Person Responsible	Dr Antonios Vlismas
Licence Holder	Ms Judith Fleming
Date licence issued	24 May 2015
Licence expiry date	24 May 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Boston Place is located in central London and has held a licence with the HFEA since May 2013. The centre provides treatment to self-funded patients and is part of 'The Fertility Partnership' group of fertility centres. The centres within The Fertility Partnership group do not currently operate under common practices and procedures, therefore this inspection was not undertaken using the HFEA's 'group approach' methodology.

The centre provides a full range of fertility services including embryo testing. Other licensed activities of the centre include storage of gametes and embryos. The Person Responsible (PR) has submitted an application to renew a licence for treatment and storage, however he has confirmed that this was an error and that he wishes to renew the centre's current licence to carry out treatment (including embryo testing) and storage.

The current licence has been varied to reflect a change of Licence Holder in December 2017 and a change of PR in May 2018.

The centre provided 486 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2018. In relation to activity levels this is a small centre.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year ending 31 July 2018 show the centre's success rates are in line with national averages.

For the year 2017 the centre reported 24 cycles of partner insemination with two clinical pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

Multiple births[2]

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

HFEA held register data for the year ending 31 July 2018 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR will discharge his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable with the exceptions noted in this report;
- the centre's practices are suitable with the exceptions noted in the body of the report;
- 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 Licence Committee is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including two critical, six major and nine 'other' areas of non-compliance or poor practice that require improvement.

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.

Evidence of progress with implementing a number of these recommendations is due to be submitted to the executive two days before the Licence Committee meets. The executive will provide confirmation of receipt of this evidence to the committee.

Critical area of non-compliance:

- **The PR should ensure that proper consent to legal parenthood is obtained.**
- **The PR should ensure that there is effective written consent in place for all stored gametes and embryos.**

Major areas of non-compliance:

- The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice guidance.
- The PR should ensure written agreements with all third parties who provide goods or services that influence the quality and safety of gametes and embryos are compliant with requirements.
- The PR should ensure that written agreements with satellite services are compliant with requirements and that the satellite activities are audited against the specifications detailed in the satellite agreements.
- The PR should ensure that staff are available in sufficient number and are suitably trained and assessed as competent to undertake their roles.
- The PR should ensure that a woman is not provided with treatment services unless account has been taken of the welfare of the child.

- The PR should ensure that patients and donors are provided with a suitable opportunity to receive proper counselling and that this offer is documented.

'Other' area that requires improvement:

- The PR should ensure that the centre's facilities are suitable for patients and staff.
- The PR should ensure that all clinical areas of the centre meet the requirements of infection prevention and control regulations.
- The PR should ensure that the centre's quality management system (QMS) and auditing processes are effective in identifying and implementing appropriate corrective actions in response to audit findings.
- The PR should ensure that all critical equipment is subject to ongoing monitoring.
- The PR should ensure that appropriate safeguarding processes are in place.
- The PR should take appropriate action to ensure that the centre's website is compliant with requirements.
- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.
- The PR should ensure that the centre's document control procedures are effective.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

Recommendation to the Licence Committee

The centre has two critical and six major areas of non-compliance. There are also nine 'other' areas of non-compliance or poor practice.

The inspection team notes that the success rates are consistent with the national average and its multiple clinical pregnancy rate meets the target. The PR is encouraged to continue to use the QMS to best effect to monitor and improve their success rates and the quality of the service offered to patients.

Significant improvement is required in order for the centre to reflect suitable practices.

Given the issues identified during this inspection, the executive held a management review meeting in accordance with the HFEA Compliance and Enforcement Policy to evaluate the centre's performance and to decide a proportionate licensing recommendation regarding the licence renewal application. The meeting on 20 December 2018 found that the non-compliances seen on inspection were significant and reflected direct and indirect risks to patients and to the centre's compliance with the HF&E Act 1990 (as amended) and other relevant legal requirements. As a result, the executive considered recommending the renewal of the centre's treatment (with embryo testing) and storage licence for a period of three years, rather than the usual four, and that this inspection report is considered by the Licence Committee rather than the Executive Licensing Panel. This recommendation reflects concerns about the centre's level of non-compliance and will allow a targeted interim inspection to be performed within one year of the Licence Committee decision, at which the centre's compliance generally, and with regard to the implementation of this report's recommendations, will be assessed.

The executive's recommendation for renewal of the centre's licence was conditional on the PR developing and implementing effective action plans to address all non-compliances in the centre's activities. The PR was required to attend a meeting with the HFEA executive to set out how he would address the findings on inspection. The meeting took place on 14 January 2019 and the HFEA executive was able to review the PR's plans to address the issues identified and how he proposed to guarantee the future compliance of this centre.

The executive was satisfied with the PR's action plans to address the non-compliances and considered that these demonstrated his commitment to attaining compliance and good governance, thereby mitigating risks at the centre.

The PR has provided his responses to the renewal report and was also asked to provide fortnightly updates to the centre's inspector regarding the corrective and preventative actions taken in relation to significant areas of non-compliance. The PR has submitted the first of such updates to the centre's inspector, providing further assurance of the PR's commitment to fully engage with the HFEA executive.

The executive is therefore assured that the PR will fully discharge his duties and strive to demonstrate better leadership in driving the centre to achieve and maintain compliance with regulatory requirements. The executive is assured that the PR has the support of the centre's Licence Holder, who is also the Chief Operating Officer for the Fertility Partnership group.

The executive recommends the renewal of the centre's treatment (with embryo testing) and storage licence for a period of three years, rather than the usual four, as it will be important to inspect the centre within a year to ensure all corrective actions have been taken and to review the culture of compliance at the clinic, as well as emphasising to the centre and sector the consequences of inaction when critical non compliances are uncovered. Adding a further non-compliance regarding poor leadership by the PR was not thought necessary given the engagement and commitment of the PR to ensure compliance at the centre.

The HF&E Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018 (the '2018 Regulations'), to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence, Centre 0327 has an ITE import certificate. The inspection team recommends the renewal of this 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 compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

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

Donor selection criteria and laboratory tests

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

What the centre does well

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

Payments for donors (Guidance note 13; General Direction 0001)
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. The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos.

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
Nothing identified at this inspection.

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

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

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the

quality of the services provided.

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

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

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

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

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is a multiple pregnancy. The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy.

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

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

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

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

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. It 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 centre has been allocated an ITE import certificate for a 'one-off' import of gametes from a TCS outside the EU/EEA but, at the time of the inspection, this import has not taken place. The centre has not undertaken any imports from outside the EU/EEA since the introduction of the ITE import certification scheme in April 2018. The centre is therefore compliant with General Direction 0006.

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

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

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

Third party agreements (Guidance note 24)
The centre's third party agreements, including those with third country suppliers listed on the centre's ITE import certificate, are partially compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
It is important that activities performed by transport and satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements. The centre has systems in place to manage transport and satellite activities that are partially compliant with HFEA requirements.

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 are broadly compliant with HFEA requirements.

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

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

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
The centre's cryostore room has an alarm to alert staff when the oxygen levels decrease below a safe limit. Although the alarm sounds immediately outside of the cryostore this room is located in a quiet area of the clinic, on a separate floor, and the inspection team was concerned that if a member of staff is working alone in this room no-one else would be aware of an alarm triggered by low oxygen and would not be able to assist (see recommendation 9; SLC T17).

There is no indication on some consultation or scan room doors to show when the room is in use. The room is accessed using a swipe card, but the inspection team was concerned that without knowing if the room is occupied, staff could enter when a patient is being scanned. Soon after the inspection, the PR confirmed that appropriate door signage had been installed indicating whether rooms are in use or not. No further action is required.

In one of the consultation and scan rooms, there was a privacy screen but because of the position of the bed, when a patient is being scanned there is no space to position the screen to protect the patient's privacy and dignity from anyone entering the room (see recommendation 9; CoP Guidance 25.9).

Infection control (Guidance Note 25)
The seal that closes the join between the flooring and the wall was detached from the wall along a significant length in both men's sample production rooms (see recommendation 10; SLC T17, DH Health Building Note 00-09: 'Infection control in the built environment' 2013).

Medicines management (Guidance Note 25)
On inspection the following issues were noted (see recommendation 3; SLC T2, 'Controlled Drugs in Perioperative Care' 2006, NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management', and DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' and CoP Guidance 25.23):

- The carryover of controlled drugs from one page to another is not signed or

witnessed in all cases.

- In one patient record the quantity of controlled drug administered was not recorded in the patient's anaesthetic chart. This is not in line with the centre's standard operating procedure (SOP) which states that the anaesthetic chart acts as a legal prescription.
- In the centre's audit of controlled drugs, timelines for the implementation of corrective actions were not recorded (see 'Quality management system' section below).

Quality management system (QMS) (Guidance note 23)

The following non-compliances were noted in the QMS (see recommendation 11; SLC T32, SLC T35 and SLC T36):

- The centre's quality indicator for storage is '100% compliance' however it is not clear what this refers to. The centre's audit of stored materials reviewed the accuracy of the storage logs but did not include a review of the consent expiry dates recorded in the database against those recorded in the patient's consent forms, to assess the accuracy of the electronic records. Furthermore, the issues noted in the centre's 'bring forward' system, in relation to expiry of consent to storage (see 'Consent to storage' section below) that were not identified by the centre, indicate that audits of this area of practice have been ineffective.
- The inspection team considered that the centre's quality indicator monitoring, and audit of the offer and provision of counselling are not sufficiently robust, and they have therefore failed to identify the issues noted by the inspection team (see 'Counselling' section below).
- The centre's audit of surrogacy records had identified an error in the consent to legal parenthood forms noted by the inspection team (see 'Legal parenthood' section below), but it was not clear what actions had been taken to address the finding or whether other issues found by the inspection team had also been identified by the centre.
- The inspection team noted that three different audit report formats appear to be in use. As a result, corrective and preventative actions and timescales for implementation and completion, are not documented and recorded consistently in the audit reports (e.g. controlled drugs audit, infection control audit, consent audit).

Third party agreements (Guidance note 24)

The following issues were noted with regard to the centre's third party agreements (see recommendation 4; SLC T114):

- The centre's most recent agreement with 'InVitro Genetics Ltd.', the laboratory that undertakes genetic testing, expired in April 2018 and a current version was not seen in the centre's records. The inspection team also noted that this expired document included typographical errors in the nomenclature of the ISO accreditation. The third-party does have the correct laboratory accreditation in place.
- The centre did not have an agreement with the company that removes and destroys their confidential waste. The inspection team was concerned that without any formal agreement in place, the centre was not able to provide assurance that the service supplier was aware of, and was able to comply with, HFEA requirements in relation to confidentiality.

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

The centre's agreement in relation to satellite activities carried out at Spire Hospitals was not compliant with General Direction 0010 (see recommendation 5; General Direction

0010, paragraph 2).

The centre has not evaluated the ability of their satellite services to meet the required standards (see recommendation 5; SLC T112).

Equipment and materials (Guidance note 26)
The inspection team noted that the fridge used to store drugs is subject to temperature monitoring but there is no record of the acceptable temperature parameters (see recommendation 12; SLC T24). The temperatures are not monitored out of working hours and there are no processes in place to note out-of-range values or initiate action if the temperature is not within the specified range. On the second day of inspection, centre staff informed the inspection team that the fridge was now connected to the centre's systems for monitoring critical equipment.

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

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

What the centre could do better

Person Responsible (Guidance note 1)
Given the significant issues identified in this report, the team was concerned that the PR had not ensured that activities at the centre were compliant with requirements. These concerns have since been addressed to the satisfaction of the executive, as discussed in the 'recommendation to the Licence Committee' summary section of this report.

Staff (Guidance note 2)
On inspection the following issues were noted in relation to nursing and clinical staff (see recommendation 6; SLC T12, SLC T15 and CoP Guidance 2.11):

- The inspection team was not assured that the number of clinical staff was enough for the activities undertaken at the centre. There was no evidence that clinical staffing requirements had been appropriately reviewed; staff had large amounts of time-owing and annual leave to take before the end of the centre's leave year (December 2018); there was no robust system in place to cover staff sickness and absence; there was no evidence that staff had been able to undertake continuing

professional development (CPD); and there was an unrealistic expectation for staff to undertake lead roles (e.g. infection control) without consideration of the time required to undertake these roles outside of clinical practice.
- Several staff have not had their competencies assessed since starting employment at the centre.
- A senior member of staff had joined the centre six months before the inspection. Their administrative induction had been signed off two days before the inspection, but their competence to practice has not been assessed.
- Staff have been allocated lead roles for which they have not received training (e.g. infection control). Designated leads were unaware of their role and responsibilities. For example, the PR is the lead for PREVENT and any associated investigations relating to radicalisation (according to the centre's safeguarding SOP) but he had no awareness of this, despite having acknowledged receiving and reading the SOP.
- The inspection team was not clear if staff have been made aware of the provision in the HF&E Act 1990 (as amended) that anyone who has a conscientious objection to participating in a particular activity done in the centre must not be obliged to do so.

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 partially compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
It is important to ensure that the centre's patients and staff are protected from harm where possible. The centre's procedures are broadly compliant with safeguarding guidance.

What the centre could do better

Welfare of the child (Guidance note 8)
A number of issues were noted in relation to the centre's processes for the assessment of the welfare of the child who may be born as a result of treatment services, and any other child who may be affected by the birth (see recommendation 7; HF&E Act 1990 (as amended), SLC T56):
- In one set of surrogacy records reviewed, the welfare of the child form had been signed by the patient in January 2017 but was not signed by a clinician until the day of treatment in March 2017, suggesting that this assessment was not undertaken in a considered manner and may not have been completed before the provision of treatment services.
- For one couple, the welfare of the child assessment forms had been completed by the patients after treatment services had been provided.
- It is not clear if the welfare of the child assessment is being conducted in line with the centre's SOP (assessment of domestic violence; sexual exploitation etc) because there was no documentation of these considerations in the records.

- Staff could not provide evidence of the assessment of their competence to undertake welfare of the child assessment. Furthermore, during discussions around surrogacy practices, staff reported it was not routine practice to undertake welfare of the child assessments for the husbands or partners of surrogates. This is contrary to HFEA guidance that centres should assess all those involved in surrogacy arrangements before providing treatment, in line with the welfare of the child assessment processes. Despite these discussions, the inspection team noted that a welfare of the child assessment had been undertaken for the husband of a surrogate in one record reviewed.

Safeguarding (Guidance Note 25)
The centre's safeguarding SOP is very comprehensive outlining, for example, PREVENT (radicalisation), female genital mutilation (FGM) and sexual exploitation. However designated safeguarding leads are unaware of their responsibilities, even though they had provided confirmation of having read the SOP (see recommendation 13; CoP Guidance 25.33(a) and 25.35). Furthermore, some staff were not aware that they had completed safeguarding training, yet their training records indicated that such training had been provided to them. Given these findings the inspection team was concerned that there could be a risk that effective safeguarding processes are not in place at the centre.

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, and
- 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 and 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

During the inspection visit the inspectors spoke to one patient who provided positive feedback on their experience at the centre.

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. The centre has a rating of 4.5 out of 5 on the HFEA website, based on 66 responses. Of these, 30 patients provided additional free text comments. Feedback was mainly positive complimenting staff at the clinic, though 12 individuals provided negative comments on their experience. Themes and trends noted in this feedback were discussed with the PR and centre staff and were similar to those identified in the centre's own patient surveys.

The centre's most recent survey of patient feedback of 93 responses received between June and September 2018 were reviewed on inspection and included both positive and negative feedback. The centre's quality manager explained that the survey responses were reviewed and discussed at management meetings and actions were taken to address any issues identified.

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are broadly 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 asnoted in the section 'Staff' above.

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

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

- care is taken when selecting egg and/or sperm providers donating for benefits in kind
- egg and/or sperm providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg or sperm provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
It is important to protect the surrogate and any children born as a result of the treatment. The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements, with the exception of the concerns discussed in the 'Legal parenthood' section below.

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

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, with the exception of the concerns discussed in the 'Safety and suitability of premises and facilities' section above.

What the centre could do better

Counselling (Guidance note 3)
The inspection team was assured that the centre's counsellor is suitably accredited and the counselling services available to patients are compliant with HFEA requirements. However, the following issues were noted (see recommendation 8; HF&E Act 1990 (as amended), Schedule 3, paragraph 3(1)(a)):

- In two out of three egg donor records audited, the counselling appointment had taken place after the completion of their consent to donate their eggs. The inspection team was concerned that the egg donors did not have a suitable opportunity to receive counselling before giving their consent to donate their eggs.
- The inspection team noted that there is no consistent process in place to document that patients have been offered a suitable opportunity to receive counselling. If patients had not had an appointment with the centre's counsellor, it was not possible to confirm from the patient records that a patient had been offered a suitable opportunity to receive proper counselling and had declined that offer.
- The centre's quality indicator (and related audit) for counselling is '100% of patients aware of counselling service'. The inspection team did not consider that this was an appropriate quality indicator to ensure compliance with Schedule 3 of

the HF&E Act 1990 (as amended), which requires that persons giving consent are 'given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps'.

Information

What the centre does well

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

What the centre could do better

Information (Guidance note 4; Chair's Letter CH (11)02)
The centre's website is not compliant with guidance as it does not provide live birth rates, nor does it provide a like-for-like comparison to national outcomes (see recommendation 14, CoP 4.12).

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

What the centre does well

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

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.

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 that inspection in November 2016, legal parenthood consenting processes were found to be compliant with requirements.

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. 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. A further four sets of records of surrogates and couples involved in commissioning surrogacy arrangements were also reviewed on inspection. 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 HFEA Register is a rich source of information about treatment using assisted reproductive technologies (ART). It can be used by researchers and linked to other health registers to improve knowledge about the health of patients who have undergone ART and those born as a result of it. The HFEA is permitted to disclose non-identifying information to researchers but can only provide patient identifying information with the consent of the patient. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA, so that the HFEA holds an accurate record of patients' consent and only releases patient identifying information to researchers with a patient's consent.

The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

What the centre could do better

Legal parenthood (Guidance note 6)
During the audit of four surrogacy cases where treatments resulted in a live birth to a surrogate who was neither married nor in a civil partnership, the following issues were noted in the relevant consent to legal parenthood forms (see recommendation 1; Human Fertilisation and Embryology Act 2008):

- In one surrogate's record there was a SWP ('Your consent (as a surrogate) nominating an intended parent to be the legal parent) form but no corresponding SPP ('Your consent to being the legal parent in surrogacy') form.
- In one surrogate's record there was a SPP ('Your consent to being the legal parent in surrogacy') form, but no corresponding SWP ('Your consent (as a surrogate) nominating an intended parent to be the legal parent) form. This case had been identified in the centre's audit of surrogacy records, but it was not clear what actions had been taken to address the finding (see 'Quality management system' section above).
- In another record the SWP consent form contained both first names of the commissioning couple (male and female). Only one intended parent can be nominated as the second legal parent.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Two discrepancies were found between completed patient/partner disclosure consents in 10 patient files audited and the related consent data submitted for inclusion on the register (see recommendation 15; Chair's Letter (10)05 and General Direction 0005). Therefore, the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure to researchers. The inspection team noted that in one case the discrepancy could pose a risk that the HFEA may inadvertently release patient identifying information to researchers against the patient's wishes. The other error was not one that could pose such a risk.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

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

Storage of gametes and embryos (Guidance note 17)

The 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 additional invasive procedures being performed. It is important that the gametes and embryos are stored appropriately to maintain their quality and safety and that the centre only stores gametes and embryos in accordance with the consent of the gamete providers.

The centre's procedures for storing gametes and embryos are not compliant with HFEA requirements.

What the centre could do better

Storage of gametes and embryos (Guidance note 17)

In early 2017, 944 samples of cryopreserved gametes and embryos were imported to centre 0327 from centre 0078 (Wolfson Fertility Centre - Hammersmith Hospital), due to the transfer of IVF services at centre 0078 from IVF Hammersmith Ltd to Imperial College Healthcare Trust. This transfer of samples was arranged between the previous PRs of centres 0327 and 0078 and was undertaken in a relatively short time period. Since that time, the executive has received updates from the previous and current PRs at centre

0327, regarding the actions taken to ensure the compliance of the storage of the gametes and embryos and to inform the gamete providers of the presence of their stored samples at centre 0327. The previous PR of centre 0327 was aware that there were a number of issues in relation to the accuracy and completeness of the storage consent records associated with these samples. In May 2018, she provided assurance to the centre's inspector that the 'last' two remaining issues in relation to consent to storage had been resolved. However, just prior to this inspection, the current PR of centre 0327 advised the centre's inspector that there were several stored samples for which the gamete provider's consent to storage was either missing or incomplete. During the inspection, these issues were discussed in detail with the PR, the quality manager and the member of staff responsible for managing the centre's 'bring forward' system.

The inspection team requested a report of the centre's audit of the cryopreserved samples to establish exactly what consenting anomalies had been identified, and how many samples were being stored without effective consent to storage. Such an audit report was not provided, so the inspection team could not clarify these issues. The inspection team concluded that the centre had not undertaken a sufficiently detailed and systematic audit of the cryopreserved samples and associated records of consent to establish exactly what storage consents are present and how many samples are without effective storage consent (see recommendation 2; SLC T36).

Without the clear information provided by such an audit, it is not clear how the PR can seek appropriate legal advice in relation to the ongoing storage of samples for which there may not be effective consent to storage from the gamete providers. Furthermore, the inspection team was not assured that the PR was fully aware of the requirements of the regulations in relation to consent to storage: The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991; The Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996; and The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 (see recommendation 2; SLC T12). This lack of awareness was exemplified when the inspection team reviewed the records of three sets of stored embryos received from centre 0078, where consent to storage had been extended beyond the initial period of consent. The PR considered that these embryos were stored with effective consent, however, the following issues were noted (see recommendation 2; SLC T79, SLC T80, SLC T81 and SLC T82):

- A couple had stored two sets of embryos in February and August 2008. The consent forms which should have been in place at the time of treatment and storage were not in the records, these being the 'Women's consent to treatment and storage form (IVF and ICSI)' (WT) and 'Men's consent to treatment and storage form (IVF and ICSI)' (MT). New WT and MT forms had been completed by the gamete providers in 2018, which stated consent to ten years storage. A further form 'Consent to extending the storage of your embryos beyond 10 years' (ES) was also seen in the records, extending storage consent to 20 years in total. This was accompanied by a completed 'HFEA medical practitioners statement' (MPS) form. The inspection team noted that all consent forms (WT, MT, ES and MPS) had been completed after February 2018, which is beyond the end of the ten-year statutory storage period for the first set of embryos. Although consent forms were now present in the records, there was no information as to whether legal advice had been sought in relation to this case. The inspection team's concerns are that these embryos had been in storage without any evidence of the gamete providers' consent to storage, and that the requirements for permitting storage beyond ten years had not been met, because the MPS form was completed after the end of the first ten-year storage

period.

- A set of embryos stored on 15 July 2008 was accompanied by MT and WT forms completed at centre 0078 in 2014, allowing ten years storage. Again, the original consent forms were not present in the records and there was no information as to why MT and WT forms were completed in 2014. An ES form was completed on 29 June 2018 to allow for extension of the storage period to 20 years. A MPS form had been completed on 23 July 2018, after the end of the ten-year storage period. Again, there was no information as to whether legal advice had been sought, as the requirements for permitting storage beyond ten years had not been met because the MPS form was completed after the end of the first ten-year storage period.
- A set of embryos stored in December 2013 had been created with donated eggs. The male gamete provider's consent to embryo storage for ten years was in the records, however, a WT form was also present recording a storage consent from the woman who intended to be treated with the embryos. As these embryos were created with donated eggs, the completion of the WT form was not appropriate, and a WD form ('Your consent to donating your eggs') was required to record the gamete provider's consent to the use and storage of her eggs and embryos created with them. On further review an appropriately completed WD form was located. The inspection team was not assured that staff fully understood consent requirements since the egg recipient had been asked to complete a WT form.

The inspection team noted that staff at centre 0327 had already reviewed these records and had asked the patients to complete further consent forms in 2018 but had not recognised or documented the consenting anomalies identified by the inspector. As a result, no legal advice had been sought to provide assurance that effective storage consent was in place or that an extension of storage beyond ten years was in accordance with relevant regulations. The inspection team is not assured that centre staff fully understand the relevant consent regulations (see recommendation 2; The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991; The Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996; and The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009).

Shortly after the inspection, the PR provided a summary report listing the number of samples where there was incomplete or missing consent to storage from the gamete providers. According to this report the centre does not have records to confirm effective consent to storage for 17 sets of gametes (sperm and eggs), 12 sets of embryos and another set of gametes in storage prior to 1991, when the initial HFEA storage regulations came into force. However, the inspection team is not assured that this list accurately represents the extent of the storage consent anomalies, given the concerns regarding lack of understanding of the regulations as described above.

'Bring forward' system

Following a review of the centre's 'bring forward' system, the inspection team noted that there were five sets of sperm and six sets of embryos in storage beyond the date of expiry of consent to storage recorded in the 'bring forward' system (see recommendation 2; SLC T79, SLC T80, SLC T81, SLC T82 and Chief Executive's letter CE(16)02). A sample of these were reviewed on inspection and the following were noted:

- The expiry date for a stored sperm sample was recorded as 2004, however, on further review of the records of consent, the inspector noted that the sperm had been stored in 1994 and that the man was eligible for an extended storage period until age 55 years. This patient had two sets of gametes in storage and two dates of

expiry of consent to storage recorded in the 'bring forward' system however neither of these dates were correct. Centre staff were not able to explain why the consent expiry date of 2004 was in the system, and why this had not been identified as incorrect despite regular review of the 'bring forward' system. The inspector noted that a MPS form was present in the records although the regulations in place at the time the samples were stored do not require it. Its presence demonstrates a lack of understanding of the regulatory requirements.

- The expiry date for a sperm sample stored in 2003 was recorded as 2013 in the 'bring forward' system. On looking at the scanned records of consent, there was a 'Your consent to the storage of your eggs or sperm' (GS) form and a MT form consenting to 55 years storage, but no MPS form. This latter form should have been completed to comply with the 2009 regulations permitting storage for 55 years. There was no evidence legal advice had been sought in relation to this case to ensure compliance with the requirements for permitting storage beyond ten years.
- The inspector was informed that there were three sets of embryos in storage for which the consent to storage had expired. Centre staff said they had discussed these cases and agreed that the embryos should be removed from storage. However, these decisions, taken up to a month before the inspection date, had not been acted upon and were not documented in the patient records, for reasons which remained unclear.

The inspection team noted that all of the cases described above involve gametes and embryos which were originally stored at centre 0078 but which are now the responsibility of centre 0327. The inspection team was not assured that staff had an understanding of the importance of accurately recording dates in the 'bring forward' system database and information in a patient's records relating to stored material, such as decisions relating to the discard of stored samples (see recommendation 2; SLC T79, SLC T80, SLC T81, SLC T82 and Chief Executive's letter CE(16)02).

The centre's storage audit does not include a comparison of the consent expiry dates recorded in the 'bring forward' database and in the patient's consent forms, thereby reviewing the accuracy of the electronic records (see recommendation 2; SLC T36). The inspection team considers that there is a risk that an inaccuracy in the electronic records (which are the primary source of information for the 'bring forward' system) could lead to gametes or embryos being stored outside the terms of the gamete provider's consent, as has been determined to be the case for the samples and records reviewed by the inspection team.

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)
Good medical records are essential for the continuity of patient care. The centre's procedures for keeping records are broadly compliant with HFEA requirements to ensure that accurate medical records are maintained.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information, about licensed activities to the Authority are broadly compliant with HFEA requirements.

What the centre could do better

Record keeping and document control (Guidance note 31)
The inspection team noted that a number of documents were past their review date (see recommendation 16; SLC T34). The centre's quality manager was aware of this and had plans in place to address it, however due to the number of documents out of date the inspection team considered that further action was needed to address this issue.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The following issues were noted in relation to the centre's reporting requirements (see recommendation 17, SLC T41 and General Direction 0005):

- The donor insemination (DI) data provided by the clinic for our audit was incomplete (i.e. it recorded significantly less DI treatments during the sample period than recorded on the register as having taken place at the clinic).
- 3% (4/135) of the IVF and 24% (5/21) of the DI treatments reviewed post inspection had not been reported to the HFEA in accordance with General Direction 0005.
- 91% (119/131) of the IVF but only 31% (5/16) of the DI treatments reported had been reported to the HFEA within the 10 working days period required by General Direction 0005.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2016, no recommendations for improvement were made.

On-going monitoring of centre success rates

In August 2018 the centre was asked to review procedures for frozen embryo transfer (FET) in patients aged more than 40 years. The PR responded to the request and during discussions at the time of the inspection, provided a commitment to keep success rates in this group of patients under review.

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 in surrogacy A number of issues related to consent to legal parenthood in surrogacy were noted by the inspection team. These are described in the body of the report. Human Fertilisation and Embryology Act 2008.	The PR should ensure that proper consent to legal parenthood is obtained. The PR should provide a summary of immediate actions to be taken to ensure that proper consent to legal parenthood is obtained for all patients when responding to this report.	A full audit of all surrogacy cases since 2016 will be undertaken by 31st January 2019. This will then be reviewed by the PR and Grp Head of Quality to ensure that any remedial actions are appropiate and implemented. A summary report of the review findings, including remedial actions taken will be sent to our inspector by 5	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. In addition, the PR has provided the requested fortnightly update on this issue to the centre's inspector. The PR has confirmed that no new surrogacy patients are

	The PR should review the centre's processes for taking consent to legal parenthood, in particular for surrogates and couples commissioning a surrogacy arrangement to consider why the issues identified during the inspection arose. A summary report of the findings of the review including corrective actions and timescales for implementation should be provided to the centre's inspector by 5 March 2019. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 5 June 2019.	March 2019. No new surrogacy patients are being accepted at Boston Place until the unified TFP surrogacy programme has been launched. Our TFP Lawyer will provide direct training to the team on all areas of legal parenthood and surrogacy on 22nd Jan 2019, for which staff attendance records will be available. There are also current plans, at HR Group-level, to review and refresh staff competency reviews as part of their annual performance review/appraisal process. We are aiming to launch the on-line consenting programme by end of March. The on-line programme provides patients with informative videos of the treatment they are expected to consent to, clearly explains the processes and also ensures the patients understand what they are consenting to, before they have the opportunity to	currently being accepted at the centre. The PR has also confirmed that staff training was provided on 22 January 2019, that assessment of competencies has been undertaken for relevant staff, and that a full audit of surrogacy cases has been completed. A summary of the findings of this audit and the requested review of the centre's processes for taking consent to legal parenthood due by 5 March 2019 is awaited. An audit to evaluate the effectiveness of changes in this area of practice due by 5 June 2019 is awaited. **Further action is required**.

		attend a nurse consultation in the clinic. A summary report of the review of the effectiveness of the changes introduced will be sent to our inspector by 5 June 2019.	
2. Consent to storage A number of non-compliances in relation to the storage of cryopreserved samples were noted on inspection, as discussed in detail in the body of the report. These are related to: the apparent storage of gametes and embryos without consent; inadequate audit of records related to stored material; inadequate understanding amongst relevant staff of the regulations and requirements governing statutory storage periods and their extension; inadequate actions to address non-conformances in the storage records; inadequate records of storage consent and of decisions related to the discard of material at the end of storage.	The PR should ensure that there is effective written consent in place for all stored gametes and embryos. The PR should undertake a systematic and detailed audit of the storage consent forms in place for all stored samples received from centre 0078, to clarify what anomalies or issues there are in relation to the consent to storage of all these samples. This audit should also review the accuracy of the records (e.g. storage consent expiry dates) held within the centre's database which is used to manage the 'bring forward' system. The PR should ensure that relevant staff are provided with	A new audit has been designed to fully audit all stored samples and their relevant consents. The audit is designed to check all items from the original clinic records through to the computerised version in Boston Place. Full training on what to check and the importance of each of the points will be provided and signed-off prior to commencing. We plan to use support form our sister clinics to provide the resources to ensure this can be completed accurately and thoroughly within a reasonable time period. The "standard" bring-forward system is being refined with input from our Group, and use	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. In addition, the PR has provided the requested fortnightly update on this issue to the centre's inspector. The PR has confirmed that a new methodology for the audit of stored samples has been designed and approved, and that full training has been provided to the staff who are performing the audit. The findings of this audit of storage consent forms in place for all stored samples received from centre 0078 to clarify what anomalies or issues there are in relation to the consent to storage of all these samples

The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009. SLCs T12, SLCT36, SLC T79, SLC T80, SLC T81 and SLC T82. Chief Executive's letter CE(16)02.	training in the regulations and requirements governing gamete and embryo statutory storage periods and their extension, prior to undertaking this audit. This should ensure that all anomalies in storage consent are correctly identified by the audit, but also that the bring forward system and extension of storage consent are, in future, carried out in a compliant manner. When responding to this report the PR should provide the centre's inspector with a plan, with timelines, by which this staff training, and the storage consent audit will be completed. To allow a robust audit to be undertaken, it is expected that all actions will be completed by 5 March 2019 rather than immediately. A summary report of the audit, including corrective and preventative actions and timelines for their implementation, should be provided to the centre's inspector by 5 March 2019.	of the Patient Portal should help to simplify the process for the clinic and also help patients. The Cryo-storage Administrator (reporting to the Patient Support Manager) will be responsible for ensuring that letters regarding storage are sent out in a timely manner, and that every effort is made to contact patients in advance. The Lab Manager will be responsible for ensuring the tank contents and the records are compliant, and discards are undertaken in a timely manner. Destruction records will be monitored to ensure they are being done within reasonable timeframes to ensure that storage remains lawful. The timeline will be: - training provided to auditors from 17th January - audit will begin from 18th January and will be completed by 5th March.	due by 5 March 2019 is awaited. The PR has also confirmed that the cryo-storage administrator has been re-trained on his responsibilities relating to the 'bring forward' system and that processes to manage the timely discard of material at the end of storage have been implemented. The findings of the PR's review of both the centre's 'bring forward' system and the centre's procedures for auditing cryopreserved materials, to determine why they did not prevent the significant non-compliances detailed in this inspection report due by 5 March 2019 is awaited. An audit to evaluate the effectiveness of changes in this area of practice due by 5 June 2019 is awaited. **Further action is required**.

	The PR should ensure that once a stored sample has been identified as requiring discard, this action is undertaken in a timely manner. A summary of changes made to implement this recommendation should be provided to the centre's inspector by 5 March 2019. The PR is reminded of HFEA guidance in relation to the timely disposal of cryopreserved material (see Chair's letter CH(03)03). The PR should review both the centre's 'bring forward' system and the centre's procedures for auditing cryopreserved materials, to determine why they did not prevent the significant non-compliances detailed in this inspection report. Summary reports of the findings of both reviews, including corrective actions with timescales for their implementation, should be provided to the centre's inspector by 5 March 2019. The PR should audit the		

	effectiveness of changes introduced in this area of practice within three months of their introduction. A summary report of the findings of the audit should be provided to the centre's inspector by 5 June 2019.		

Major area of non-compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
3. Medicines management A number of issues with medicines management practices and the centre's audit of controlled drugs were noted by the inspection team. These are described in the body of the report. SLC T2. 'Controlled Drugs in Perioperative Care' 2006. NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'	The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice guidance. The PR should review medicines management practice including, but not exclusively, the issues identified in this report. This review should also include staff training requirements. A summary report of the findings of the review including corrective actions and timescales for implementation	Since 9th January the Theatre Lead is responsible for ensuring that any page changes are correctly noted and the requirement has been added to the Daily Theatre Task Checklist. Anaesthetists will continue to be reminded of the need to record all use of controlled drugs in the patient record and the Theatre Lead is now required to check this is completed after every case. This item is on the Daily Theatre Checklist and is also a	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided a summary of the findings of his review of medicines management practices including corrective actions and timescales for implementation. An audit to evaluate the effectiveness of changes in this area of practice due by 5

DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' CoP Guidance 25.23	should be provided to the centre's inspector by 5 March 2019. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 5 June 2019.	required field in the patient management database. The Nurse Manager has reviewed the relevant SOP and has made the changes as listed above. The centre's QM has created an audit plan for 2019, for the follow-up and timelines for corrective actions. Audit compliance, and remedial actions will be reviewed as a standing agenda item at the clinic's monthy Quality Meeting, which is attended by the PR and Group Head of Quality. A summary report of the above will be sent to our inspector by 5 June 2019.	June 2019 is awaited. **Further action is required**.
4. Third party agreements The following issues were noted with regard to the centre's third party agreements: • The centre's most recent agreement with 'InVitro Genetics Ltd.' the laboratory that undertakes genetic	The PR should ensure written agreements with all third parties who provide goods or services that influence the quality and safety of gametes and embryos are compliant with requirements. The PR should provide an	The genetic testing TPA is in place and compliant with regul atory requirements. Due to the company ownership changing they have had some name changes, but a compliant and correct TPA was in place. A current customer agreement	The executive acknowledges the PR's response. The executive notes that a third party agreement with the genetic testing laboratory was in place at the time of the inspection but had not been provided to the inspectors

testing, expired in April 2018, and a current version was not seen in the centre's records. Typographical errors in the expired document had not been identified by centre staff. • The centre did not have an up-to-date agreement on file with the company that removes and destroys their confidential waste. SLC T114.	updated third party agreement with the service provider identified and confirm this has been completed when responding to the report. The PR should establish an agreement with the company that removes and destroys their confidential waste and confirm the actions taken to address this when responding to the report.	for confidential waste is in place. We have been receiving weekly certificates of destruction each time confidential waste is removed from the premises. However, we have further enhanced the wording in our agreement in relation to waste security and confidentiality in particular, which is the provider's specialist area, and are awaiting a signed response from the provider.	therefore this was noted as a non-compliance. This has now been provided. The PR has confirmed that an agreement with the company that removes and destroys their confidential waste is now in place. **No further action is required.**
5. Satellite agreements The centre's agreement in relation to satellite activities carried out at Spire Hospitals was not compliant with General Direction 0010. The centre has not evaluated the ability of their satellite services to meet the required standards. General Direction 0010 paragraph 2 and SLC T112.	The PR should ensure that written agreements with satellite services are compliant with requirements and that the satellite activities are audited against the specifications detailed in the satellite agreements. The finalised written agreement for the satellite service should be provided to the centre's inspector when responding to this report.	An updated Satellite Agreement has been provided to Spire Hospitals, who have been very attentive and plan to return the final copy by 18/01/19. The final agreement will be provided to the HFEA as soon as it is available. The satellite audit will be undertaken in February 2019, the report will be provided to the inspector on completion, within the required timescale.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The finalised written agreement for the satellite services undertaken at Spire Hospitals has been provided. The audit of satellite activities due by 5 March 2019 is awaited.

	The PR should undertake an audit of all the centre's satellite activities to assess compliance with General Direction 0010. A summary report of this audit should be provided to the centre's inspector by 5 March 2019.		**Further action is required.**
6. Staff The inspection team had a number of concerns in relation to nursing and clinical staffing, as described in the body of the report. HF&E Act 1990 (as amended), SLC T12, SLC T15 and CoP Guidance 2.11	The PR should ensure that staff are available in sufficient number and are suitably trained and assessed as competent to undertake their roles. The PR should review the centre's process for staff induction, assessment of competency and re-assessment of competencies. The review should include, but not be limited to, consideration of the issues identified by the inspection team. A summary report of the findings of the review including corrective actions and timescales for implementation should be provided to the centre's inspector by 5 March 2019.	We review our staffing levels on a regular basis and compare the requirements and staff levels with the 9 other clinics in our Group to ensure that they are appropriate. Being part of a Group also provides the protection of providing each other with staff cover during any sickness or jury service requirements. Boston Place also has 3 nurses available and trained on a bank nurse schedule, which we feel is sufficient. Some additional training is being provided to reinforce the training that has already been provided. We have provided evidence of the induction training we provide, and hope	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided a summary of the findings of his review and the plans in place to ensure that staff are available in sufficient number and are suitably trained and assessed as competent to undertake their roles. The PR should provide the centre's inspector with updates on progress with implementing these actions which are expected to be completed by 5 June 2019. **Further action is required.**

	It is expected that any corrective actions identified will have been implemented by 5 June 2019 and the PR should provide confirmation of this to the centre's inspector by 5 June 2019.	it reassures the inspectors that a full and robust induction is followed. The General Manager will work with the group HR team to ensure that the annual appraisal process includes re-assessment of competencies.	
7. Welfare of the child A number of issues related to the welfare of the child assessments were noted by the inspection team and are described in the body of the report. These related to ensuring that such an assessment is completed prior to provision of treatment services and that competencies of staff undertaking these activities has been evaluated. HF&E Act 1990 (as amended), SLC T56 and CoP Guidance 14.1.	The PR should ensure that a woman is not provided with treatment services unless account has been taken of the welfare of the child. The PR should provide a summary of immediate actions to be taken to address the issues identified during the inspection when responding to this report. The PR should review welfare of the child practices and processes including, but not limited to, the issues identified in this report. A summary report of the findings of the review including corrective actions and timescales for implementation should be	All staff will be provided with WoC training from our TFP Lawyer on 22nd January 2019. A new process will be used: WoC (& CD) consent forms will be completed prior to initial consultation, allowing for doctors to review the paperwork at the initial consultation. A nursing Post-consenting Checklist will ensure that all the consent forms have been signed and countersigned correctly prior to issuing a prescription. This will ensure that all assessments are completed prior to the provision of treatment. The new SOP which details	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. In addition, the PR has provided the requested fortnightly update on this issue to the centre's inspector. The PR has provided a summary of the immediate actions taken to address the issues identified during the inspection including training in welfare of the child assessments completed on 22 January 2019. The PR has also confirmed that all relevant staff are aware of the new processes in place for reviewing and checking these

	provided to the centre's inspector by 5 March 2019. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 5 June 2019.	the new process will be provided to the inspector by 5th March 2019.	assessments prior to provision of treatment. The findings of the PR's review of welfare of the child practices and processes including, but not limited to, the issues identified in this report, due by 5 March 2019 is awaited. An audit to evaluate the effectiveness of changes in this area of practice due by 5 June 2019 is awaited. **Further action is required**.
8. Counselling A number of issues related to the offer and provision of counselling, and the auditing of this critical activity were noted by the inspection team. These are described in the body of the report. HF&E Act 1990 (as amended), Schedule 3, paragraph 3(1)(a), SLC T35 and SLC T36.	The PR should ensure that patients and donors are provided with a suitable opportunity to receive proper counselling and that this offer is documented. The PR should provide a summary of immediate actions to be taken to address the issues identified during the inspection when responding to this report. The PR should review the	Regarding proof of offering of counselling: A tick box has been added to the patient management system to record the clinician offer and recommendation for counselling (at intial consultation). A Checklist has been introduced for the patients to complete and sign to ensure that they know and understand the importance of the counselling that is offered/provided.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. In addition, the PR has provided the requested fortnightly update on this issue to the centre's inspector. The PR has provided a summary of the immediate actions taken to address the issues identified during the inspection including the

	centre's practices for offering patients and donors a suitable opportunity to receive counselling and what actions are to be taken to address the issues identified during the inspection. A summary report of the findings of the review including corrective actions and timescales for implementation should be provided to the centre's inspector by 5 March 2019. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 5 June 2019.	Regarding the timing of implications counselling: The SOP has been re-written to insist that counselling should be offered and delivered prior to patients consenting to treatment. An audit of patients using donor gametes during the last 12 months will be undertaken to check the timing of counselling appointments. The report and corrective actions will be provided to the inspector by 5th March 2019. This audit will be repeated after 2 months of its implementation, to measure the effectiveness and compliance of the changes made. The updated report will be provided to the inspector by 5th June 2019.	implementation of additional record keeping and checking processes. The findings of the PR's review of centre's practices for offering patients and donors a suitable opportunity to receive counselling including, but not limited to, the issues identified in this report, due by 5 March 2019 is awaited. The PR reports that an audit of the records of patients who have used donor gametes is underway and an update will be provided to the centre's inspector on 15 February 2019. Following further discussion, the PR has confirmed that this audit will also include gamete donors. A summary report of the findings of the audit should be provided to the centre's inspector by 5 March 2019. An audit to evaluate the effectiveness of changes in this area of practice due by 5 June 2019 is awaited.

			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
9. Safety and suitability of premises and facilities The centre's cryostore room has an alarm to alert staff when the oxygen levels decrease below a safe limit. Although this alarm sounds immediately outside of the cryostore this room is located in a quiet area of the clinic, on a separate floor, and the inspection team was concerned that if a member of staff is working alone in this room no-one else would be aware of an alarm triggered by low oxygen and would not be able to assist. In one of the consultation and scan rooms, there was a privacy screen, but because of the position of the bed, when a	The PR should ensure that the centre's facilities are suitable for patients and staff. The PR should ensure that the cryostore is sufficiently alarmed so that any potential risks to staff working in this area are minimised. The PR should provide a summary of the actions taken to address this finding when responding to the report. The PR should review the usage of the consulting room discussed during the inspection to consider what actions can be taken to ensure that the patients privacy and dignity are maintained at all	The SOP states that entry is not permitted into the Cryostore room when working alone to remove any risk. However a quote has been approved to add an alarm repeater into the main admin office and its installation is now being organised. The privacy screen will be replaced by a curtain rail attached to the ceiling rails, which will reduce the floor space requirements. We would like to reinforce that in addition to the door entry system requiring a staff pass to enter the room, there is also a manual lock on the door	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided a summary of actions taken to minimise the risks to staff using the cryostore and to ensure that the patients privacy and dignity are maintained. The executive is assured that these actions will be completed by 5 March 2019. **No further action is required.**

patient is being scanned there is no space to position the screen to protect the patient's privacy and dignity from anyone entering the room. SLC T17 and CoP 25.9.	times. A summary of the actions to be taken should be provided to the centre's inspector by 5 March 2019.	which is used when a patient is being scanned so that it is not possible for anyone to enter the room during a scan. Immediately after the inspections we also provided photographic evidence to the inspector of "vacant/engaged" signs that have been put onto each door. We will update the inspector when the other changes are made, this will be before 5th March.	
10. Infection control The seal that closes the join between the flooring and the wall was detached from the wall along a significant length in both men's sample production rooms. SLC T17 and DH Health Building Note 00- 09: 'Infection control in the built environment' 2013.	The PR should ensure that all clinical areas of the centre meet the requirements of infection prevention and control regulations. The PR should ensure repairs to the faulty seal are carried out and provide confirmation that this has been completed when responding to this report.	The flooring issue was fixed in the week of the inspection. Photos showing the repairs have been provided to the inspector with this report. The remaining clinic areas have been checked for this issue. There will be weekly "environment checks" by each department.	The executive acknowledges the PR's response. The PR has confirmed that the flooring has been repaired. **No further action is required.**
11. QMS A number of issues related to	The PR should ensure that the	The entire audit process is	The executive acknowledges

the centre's QMS were noted and are described in the body of the report. These related to the centre's quality indicators, a lack of robustness of some audits of critical activities, and inconsistent recording of audit findings and corrective and preventative actions taken in response to issues identified. SLC T32, SLC T35 and SLC T36.	centre's QMS and auditing processes are effective in identifying and implementing appropriate corrective actions in response to audit findings. The PR should ensure that the all quality indicators are reviewed so that they are appropriate to the relevant critical activity and that suitable audits of compliance with regulatory requirements can be performed. A revised list of quality indicators should be provided to the centre's inspector by 5 March 2019. The PR should review the centre's auditing methodology to ensure that all audits evaluate compliance with the regulatory requirements, the centre's approved protocols and quality indicators, that findings are recorded consistently, and that any corrective and preventative actions identified are documented and fully implemented. A summary report of the review including corrective actions and the	currently under revision across the Group. The audit schedule is being made much more robust; mandatory audits of each of the licensed activities and processes will be scheduled more frequently e.g. biannually. As part of this review Group audit and action plan templates will be rolled out for all clinics to use in 2019. The clinic's 2019 audit plan has already been drafted, and is due for approval at the Quality Meeting due to be held 24th January, 2019. Audit is also a standing agenda item at this meeting. Implementation and progress with the plan will be followed up by the Group Head of Quality. TFP have already implemented regular (monthly/bi-monthly) QM meetings, with a standing agenda which includes follow up of quality items e.g. incidents, audits etc, and all clinics also hold regular	the PR's response and his commitment to fully implementing this recommendation. The PR has provided a summary of the review of the QMS that is taking place as part of a wider project reviewing the system across the entire across the 'The Fertility Partnership' group. A further update on progress with these changes together with a revised list of quality indicators due by 5 March 2019 is awaited. **Further action is required.**

	timescale for implementation of corrective actions should be provided to the centre's inspector by 5 March 2019.	meetings, where these quality matters are discussed as standing agenda items. The group audit reporting and action plan templates will form part of the revised audit process which all TFP clinics will follow this year.	
12. Equipment The inspection team noted that the fridge used to store drugs is subject to temperature monitoring but there is no record of the acceptable temperature parameters. The temperatures are not monitored out of working hours and there are no processes in place to note out-of-range values or initiate action if the temperature is not within the specified range. On the second day of inspection, centre staff informed the inspection team that the fridge was now connected to the centre's systems for monitoring critical equipment. SLC T24.	The PR should ensure that all critical equipment is subject to ongoing monitoring. The drugs fridge has now been connected to the centre's equipment monitoring systems. The PR should review the centre's processes for recording and monitoring the temperature of the drugs fridge to ensure that acceptable ranges are established, and staff are aware of the actions to be taken if any out-of-range values are noted. The PR should confirm that this recommendation has been implemented by 5 March 2019.	As noted the fridge is now not only monitored out of hours, but is also has a "dial-out" alarm system. The SOP will be updated to detail the required actions if there are issues with the fridge temperature. This will be completed by 5th March.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Confirmation that the relevant SOP has been updated by 5 March 2019 is awaited. **Further action is required.**

13. Safeguarding The inspection team was concerned that there could be a risk that effective safeguarding processes are not in place at the centre for the reasons set out in the body of the report. CoP Guidance 25.33(a) and 25.35. This non-compliance has been graded as 'other' because although the inspection team considers there is a risk that robust safeguarding practices are not in place, there is no evidence that there has been a failure in these processes.	The PR should ensure that appropriate safeguarding processes are in place. The PR should ensure that staff are fully aware of their roles and responsibilities in relation to safeguarding practices and should provide a summary of immediate actions to be taken to address the issues identified during the inspection when responding to this report. The PR should review the centre's processes for implementing safeguarding practices including staff training in this area to address the issues identified during the inspection. A summary report of the findings of the review including corrective actions and timescales for implementation should be provided to the centre's inspector by 5 March 2019.	We can confirm that Safeguarding training has been completed but the course has a different name and we believe the differing terminology has caused some confusion. However to be certain, we are providing additional training and checking that all staff are aware of the required actions if they have any concerns. A summary of the training outcomes will be provided to the inspector by 5th March.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. In addition, the PR has provided the requested fortnightly update on this issue to the centre's inspector. The PR has provided a summary of his review of the centre's processes in this area of practice and that additional 'Safeguarding' training is due to take place on 4 March 2019. **No further action is required.**
14. Website The centre's website is not compliant with guidance as it	The PR should take appropriate action to ensure	The website has been corrected to include live birth	The executive acknowledges the PR's response.

does not provide live birth rates, nor does it provide a like-for-like comparison to national outcomes. CoP 4.12.	that the centre's website is compliant with requirements. The PR should ensure that the centre's website is compliant with requirements when responding to this report.	data (compared to national average) as well as the pregnancy rates.	The centre's website 'success rate' information has been updated. **No further action is required.**
15. Disclosure of information, held on the HFEA Register, for use in research Two discrepancies were found between completed patient/partner disclosure consents in 10 patient files audited and the related consent data submitted for inclusion on the register. Therefore, the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure to researchers. The inspection team noted that in one case the discrepancy could pose a risk that the HFEA may inadvertently release patient identifying information to researchers against the patient's wishes. The other error was not one	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register. The PR should confirm that the incorrect submissions identified have been corrected when responding to this report. The PR should review the centre's systems and processes to ensure that going forward, the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent	The clinic will audit 20% of the cycles from 2018. Any inaccuracies identified will be corrected and if more than 5% of cases have issues then the remaining 80% of cases will be audited. In addition to historical audit, we will conduct a weekly audit of submissions (2 cases per week) to ensure that live data entry is correct. If any discrepancies are noted, then all cases that week will be checked. This audit will run until 100% compliance is noted for 6 weeks in a row, then we will revert to the annual audit. These audit reports will be	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. In addition, the PR has provided the requested fortnightly update on this issue to the centre's inspector. The PR has confirmed that the incorrect submissions identified have been corrected. The executive notes that an audit of 20% of treatments from 2018 has been completed and errors of 5.88% were noted and corrected. As a result, all remaining cycles from 2018 are now being

that could pose such a risk. Chair's Letter (10)05 and General Direction 0005. *NB. The Centre's designated HFEA form returnee has been provided with the relevant patient and partner numbers so that the incorrect data can be reviewed and corrected.*	forms. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 5 March 2019. The PR should audit the effectiveness of changes introduced in this area of practice within six months. A summary report of the findings of the audit should be provided to the centre's inspector by 5 September 2019.	provided in the timescales requested.	audited. In addition, the PR reports that a weekly audit of records was completed and subsequently all records for January 2019 were checked (73 cases). A total of 17 errors were noted and these are being corrected. The PR has confirmed that this weekly audit will continue until 100% compliance for 6 consecutive weeks is noted. Given the number of discrepancies identified, the PR should ensure that a thorough review of the centre's systems and processes for recording and submitting patient and partner disclosure of consent information to the Authority is undertaken to establish why there are so many errors. It is expected that this review will include a root cause analysis. A summary of the findings of the review due by 5 March 2019 is awaited. An audit to evaluate the effectiveness of changes in this area of practice due by 5

			September 2019 is awaited. **Further action is required**.
16. Document control The inspection team noted that a number of documents were past their review date. The centre's quality manager was aware of this and had plans in place to address it, however due to the number of documents out of date the inspection team considered that further action was needed to address this issue. SLC T34.	The PR should ensure that the centre's document control procedures are effective. The PR should review the documents that are past their review date and provide an action plan with a timescale by which the documents can be reviewed when responding to this report. It is expected that all documents will be up to date by 5 May 2019.	The Group Head of Quality will work with the clinic Quality Manager to ensure that there is a schedule in place to ensure that all out of date documents are reviewed and that the future process ensures timely review.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Confirmation that all documents are up to date by 5 May 2019 is awaited. **Further action is required.**
17. Obligations and reporting requirements The DI data provided by the clinic for our audit was incomplete (i.e. it recorded significantly less DI treatments during the sample period than recorded on the register as having taken place at the clinic). 3% (4/135) of the IVF and 24%	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should review the systems and processes used for licensed treatment data submission to identify and	Weekly review of submissions started by 14th January. Updated SOP to ensure that DI forms are submitted by the embryologist that thaws the straw (on the day of the thaw). We will have an automatic weekly report from the patient database to ensure that all	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. In addition, the PR has provided the requested fortnightly update on this issue to the centre's inspector.

(5/21) of the DI treatments reviewed post inspection had not been reported to the HFEA in accordance with General Direction 0005. 91% (119/131) of the IVF but only 31% (5/16) of the DI treatments reported had been reported to the HFEA within the 10 working days period required by General Direction 0005. General Direction 0005 and SLC T41. *NB. The Centre's designated HFEA form returnee has been provided with the relevant patient and partner numbers so that the incorrect data can be reviewed and corrected.*	address the reasons for non-reporting and delayed submissions. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 5 March 2019. The PR should audit the effectiveness of changes introduced in this area of practice within six months. A summary report of the findings of the audit should be provided to the centre's inspector by 5 September 2019.	required reports are submitted and the timescales are being met. The follow-up audit and report will be sent to the inspector by 5th September 2019.	The PR has provided a summary of the findings of his review into this area of practice, and the corrective actions in place to address the issues identified which includes weekly checks of submitted data. An audit to evaluate the effectiveness of changes in this area of practice due by 5 September 2019 is awaited. **Further action is required**.

Reponses from the Person Responsible to this inspection report
While I am dissapointed with the issues identified in this report I am confident that the actions planned, and those already taken will ensure our centre is fully compliant with HFEA regulations and we will continue to keep all these areas under review to ensure the safety of our patients and provide the highest quality of care.