Licence Committee - minutes

Centre 0015 (Sussex Downs Fertility Centre)
Renewal Licence

Thursday, 5 March 2020

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle	Committee Secretary
Legal Adviser	Eve Piffaretti	Blake Morgan 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:

- Renewal inspection report
- Renewal application form
- Previous licensing minutes:

    - 2020-01-08 Licensing Officer Record of Consideration - variation of Licence Holder
    - 2019-09-03 Executive Licensing Panel Minutes - variation of premises
    - 2018-04-25 Executive Licensing Panel Minutes - interim
    - 2016-08-12 Executive Licensing Panel Minutes - variation of Licence Holder
    - 2016-05-20 Executive Licensing Panel Minutes - renewal

1. Background

1.1. The Sussex Downs Fertility Centre, centre 0015 is located at the BMI Esperance Hospital in Eastbourne. The centre has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services. The centre has a satellite arrangement with BMI Goring Hall Hospital, Sussex.

Current Licence

1.2. The centre's current licence was granted for a period of four years from 1 July 2016 and is due to expire on 30 June 2020. During this time the centre's licence has been varied to reflect a change of Licence Holder (LH) in 2016 and 2020, and a variation of premises in 2019.

1.3. On 31 May 2019, the Person Responsible (PR) informed the HFEA that the BMI Esperance Hospital was ceasing services at the hospital and withdrawing from the site, and that there was an imminent change in ownership of the centre. The new owner, the Hospital Fertility Group (HFG), planned to relocate the centre to new premises within a few months. In order to continue their activities, the centre decided to rent the premises from BMI until their relocation. As part of the prelude to this move, and due to the decommissioning of some areas of the BMI Esperance hospital, several areas (where non-licensed activities took place) were required to be relocated to rooms on the ground floor. In August 2019, the PR applied to vary the centre's licence to incorporate these additional areas and rooms into the centre's licensed premises. Ownership was transferred to HFG on 1 October 2019.

1.4. A renewal inspection was conducted at the centre in November 2019 and the report of this inspection has been submitted to the Licence Committee for consideration.

2. Consideration of application

Renewal Inspection

Application

2.1. The committee was satisfied that the application was submitted in the form required and contained all the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid.

Inspection Process

2.2. The committee noted that in the 12 months to 31 August 2019, the centre provided 428 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

2.3. The committee noted that for IVF and ICSI, HFEA-held register data for the period 1 September 2018 to 31 August 2019 showed the centre's success rates were in line with national averages with the following exception:

- success rates following ICSI treatment in women under 38 years old were higher than average at a statistically significant level.

2.4. The committee noted that in 2018, the centre reported 22 cycles of partner insemination with five pregnancies, which is in line with the national average.

2.5. The committee noted that between 1 September 2018 and 31 August 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 4%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

2.6. The committee noted that the renewal inspection took place on 5 and 6 November 2019. 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, seven major and four other areas of non-compliance identified:

Critical areas of non-compliance:

- 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 effective consent is in place for all stored gametes and embryos.

Major areas of non-compliance:

- The PR should ensure that the centre's laboratory which undertakes diagnostic semen analysis is suitably accredited or provide evidence to support a status equivalent to accreditation.
- The PR should ensure compliance with infection control regulations.
- The PR should ensure compliance with controlled drugs (CD) management, supervision and use regulations and practice guidance.
- The PR should ensure that CE marked medical devices are used where possible and must ensure that equipment or materials affecting critical processing are subject to appropriate monitoring to ensure that the critical parameters are maintained within acceptable limits at all times.
- The PR should ensure that patients freezing sperm samples prior to starting oncology treatments are given a suitable opportunity to receive proper counselling and that this offer is documented.
- The PR should ensure that practice relating to surrogacy treatments is compliant with regulatory requirements, Department of Health and Social Care (DHSC) practice guidance and Code of Practice (CoP) guidance.
- The PR should ensure that legal parenthood consenting practice and procedures and auditing are robust and compliant with CoP requirements and guidance.

Other areas that require improvement:

- The PR should ensure that import of donor gametes is compliant with General Direction 0001 and General Direction 0006.
- The PR should ensure that the quality management system (QMS) is effective and fit for purpose.
- The PR should ensure that documented procedures for managing information are established ensuring accurate recording of information.
- The PR should ensure that all licensed activity is reported to the HFEA within the timeframe required by General Direction 0005.

2.7. The committee noted that since the inspection visit, the PR has fully implemented the recommendations to address the critical and major areas of non-compliance. Where required, and by the dates specified, the PR will provide an update or summary of audits conducted to ensure that corrective action taken is effective. The PR has committed to fully implementing the other areas of non-compliance.

2.8. The committee noted that significant improvement is required in order for the centre to reflect suitable practices. The PR should ensure that the QMS is effective and fit for purpose and is encouraged to monitor the quality of service provided to patients.

Management Review Meeting on 18 December 2019

2.9. On 18 December 2019, the Executive held a management review meeting in accordance with section 3.1 of the HFEA Compliance and Enforcement Policy due to the nature and extent of the non-compliances identified at the renewal inspection, to evaluate the findings and to consider a proportionate course of action.

2.10. The Executive found that the issues identified on inspection were significant and posed direct and indirect risks to patients, and immediate action and assurance was required from the PR. The Executive was particularly concerned with the critical areas of non-compliance in relation to welfare of the child and storage of gametes and embryos.

2.11. It was agreed that whilst formal action was not required at this stage, the PR would be required to attend a meeting with the HFEA, including the Chief Inspector, Director of Compliance and the centre's Inspector to discuss the findings of the renewal inspection, implementation of the recommendations and to establish a formal plan of action to address the key risks.

Meeting with the PR on 21 January 2020

2.12. As agreed at the management review meeting held on 18 December 2019, a meeting took place on 21 January 2020 and the PR provided the HFEA Executive with sufficient assurances of his engagement with the HFEA and a robust plan to implement the recommendations within the prescribed timescales.

Recommendations

Licence

2.13. The committee noted that the Executive recommends the renewal of the centre's treatment and storage licence for a period of three years (rather than the standard four years) without additional conditions, subject to the recommendations made in the renewal inspection report being implemented within the prescribed timescales.

Inspection

2.14. The committee noted that the Executive also recommends that an interim inspection is conducted within 12 months of the licence coming into force to ensure that compliance with the recommendations has been achieved and maintained.

Importing Tissue Establishment (ITE) import certificate

2.15. The committee noted that centre 0015 has not been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence.

3. Decision

3.1. The committee had regard to its decision tree, the HFEA Compliance and Enforcement Policy and HFEA Guidance on Licensing.

Administrative Requirements

Supporting Information under General Direction 0008

Application

3.2. The committee was satisfied that the application was submitted in the form required and contained all the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid.

Proposed Person Responsible (PR) – Mr David Chui

3.3. The committee was satisfied that the proposed PR possesses the required qualifications and experience and that the character of the proposed PR is such as is required for supervision of the licensed activities. It was further satisfied that the proposed PR will discharge his duties under section 17 of the HF&E Act 1990 (as amended).

Proposed Licence Holder (LH) – Dr Charlotte Hall

3.4. The committee was satisfied that the proposed LH is suitable.

Activities

3.5. The committee was satisfied with the suitability of the activities applied for.

Premises – BMI The Esperance Hospital, Hartington Place, Eastbourne, East Sussex, BN21 3BG

3.6. The committee was satisfied that the premises and facilities are suitable for the conduct of the licensed activity applied for.

3.7. The committee was satisfied that the third-party premises are also suitable.

Licence

3.8. The committee had regard to the HFEA Guidance on licensing and considered the duration of licence it should offer.

3.9. The committee noted the scale of the non-compliances with statutory requirements identified and that they were wide-ranging. The committee was concerned about the impact of these non-compliances on the quality of service provided and the potential detrimental effect on patients. However, the committee noted that since these non-compliances were identified, the PR has provided the Executive with a robust plan to ensure compliance by implementing the recommendations within the prescribed timescales.

3.10. Carefully weighing all factors in the balance, the committee agreed that a three year treatment and storage licence, with no additional conditions was appropriate.

3.11. The committee noted that this licence offer will become final and come into effect on 1 July 2020 unless the PR chooses to make representations regarding the proposed decision, or submit any other information within 28 days.

Inspection

3.12. The committee endorsed the Executive's recommendation to conduct an interim inspection within 12 months of the renewal licence coming into force.

3.13. The committee had serious concerns about the culture of this centre and expects all recommendations to be fully implemented within the prescribed timescales. The committee agreed that the PR should ensure that the QMS is fit for purpose and auditing is robust, ensuring that issues are identified and corrected in a timely manner. The PR should be proactive and demonstrate good leadership to achieve compliance.

3.14. Given the significant number of non-compliances, the committee also expects to see a change in culture towards continuous learning, improving and maintaining good practice, acting at all times in the best interest of patients.

Importing Tissue Establishment (ITE) import certificate

3.15. The committee noted that there was no application or recommendation for an Importing Tissue Establishment (ITE) import certificate for this centre.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

20 March 2020

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: 5 and 6 November 2019

Purpose of inspection: Renewal of a licence to carry out treatment and storage

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

Inspectors: Sandrine Oakes (lead), Polly Todd and Karen Conyers

Date of Licence Committee: 5 March 2020

Centre name	Sussex Downs Fertility Centre
Centre number	0015
Licence number	L/0015/17/c
Centre address	BMI The Esperance Hospital, Hartington Place, Eastbourne, East Sussex, BN21 3BG, United Kingdom
Person Responsible	Mr David Chui
Licence Holder	Dr Charlotte Hall
Date licence issued	1 July 2016
Licence expiry date	30 June 2020
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Sussex Downs Fertility Centre is located at the BMI Esperance Hospital in Eastbourne, has held a Treatment and Storage licence with the HFEA since 1992 and provides a full range of fertility services for NHS and private patients. Other licensed activities at the centre include storage of gametes and embryos. The centre has a satellite arrangement with BMI Goring Hall Hospital, Sussex.

This current licence has been varied to reflect the following changes:

- 8 January 2020 – change of Licence Holder
- 3 September 2019 - change of premises
- 12 August 2016 - change of Licence Holder

The centre provided 428 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2019. In relation to activity levels this is a small centre.

On 31 May 2019, the Person Responsible (PR) informed the HFEA that the BMI Esperance Hospital was ceasing their services at the hospital, was withdrawing from the site and that there was an imminent change in ownership of the centre. The new owner (the Hospital Fertility Group (HFG)) planned to relocate the centre to new premises in a few months' time. In order to continue their activities, the centre decided to lease the premises from BMI until their relocation. As part of the prelude to this move, and due to the decommissioning of some areas of the BMI Esperance hospital, several areas (where non-licensed activities took place) were required to be relocated to rooms on the ground floor. On 7 August 2019, the PR applied to vary the centre's licence to incorporate these additional areas and rooms into the centre's licensed premises.

The transfer of ownership to HFG occurred on 1 October 2019.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 September 2018 to 31 August 2019 show the centre's success rates are in line with national averages with the following exception:

- success rates following ICSI treatment in women under 38 years old are higher than average at a statistically significant level.

In 2018, the centre reported 22 cycles of partner insemination with five pregnancies, which is in line with the national average.

Multiple births[2]

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

Between 1 September 2018 and 31 August 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 4%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable 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, seven major and four 'other' areas of non-compliance which have resulted in the following recommendations.

Since the inspection visit, the following recommendations have been fully implemented. Where required and by the dates specified the PR will provide an update or summary of audits conducted to ensure the corrective actions taken are effective:

Critical areas of non-compliance

- **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 effective consent is in place for all stored gametes and embryos.**

Major areas of non-compliance:

- The PR should ensure that the centre's laboratory which undertakes diagnostic semen analysis is suitably accredited or provide evidence to support a status equivalent to accreditation.
- The PR should ensure compliance with infection control regulations.
- The PR should ensure compliance with controlled drugs (CD) management, supervision and use regulations and practice guidance.
- The PR should ensure that CE marked medical devices are used where possible and must ensure that equipment or materials affecting critical processing are subject to appropriate monitoring to ensure that the critical parameters are maintained within acceptable limits at all times.
- The PR should ensure that patients freezing sperm samples prior to starting oncology treatments are given a suitable opportunity to receive proper counselling and that this offer is documented.
- The PR should ensure that practice relating to surrogacy treatments is compliant with regulatory requirements, Department of Health and Social Care (DHSC) practice guidance and Code of Practice (CoP) guidance.

- The PR should ensure that legal parenthood consenting practice and procedures and auditing are robust and compliant with CoP requirements and guidance.

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

'Other' areas that require improvement:

- The PR should ensure that import of donor gametes is compliant with General Direction 0001 and General Direction 0006.
- The PR should ensure that the quality management system (QMS) is effective and fit for purpose.
- The PR should ensure that documented procedures for managing information are established ensuring accurate recording of information.
- The PR should ensure that all licensed activity is reported to the HFEA within the timeframe required by General Direction 0005.

Recommendation to the Licence Committee

The centre has two critical, seven major and four 'other' areas of non-compliance.

The inspection team notes that the centre's success rates are consistent with the national average, with those following ICSI treatment in women under 38 years old being higher than average at a statistically significant level, and their multiple clinical pregnancy/live birth rates meet the target. The PR is encouraged to continue to use the QMS to monitor the quality of the service provided to patients.

The centre provides a good level of patient support.

Due to the extent and nature of the non-compliances in this report, and in accordance with section 3.1 of the HFEA's Compliance and Enforcement Policy, a management review meeting was held on 18 December 2019, to evaluate the findings of this renewal inspection report and to consider a proportionate course of action.

The management review meeting found that the issues identified on inspection were significant and posed direct and indirect risks to patients, and immediate action and assurance was required from the PR. Of particular concern were the critical non-compliances in relation to 'Welfare of the child' and 'Storage of gametes and embryos'.

It was agreed that, whilst formal action was not required at this stage, the PR would be provided a copy of the draft inspection report and be required to attend a meeting with the centre's inspector, Chief Inspector and Director of Compliance to discuss the report, implementation of the recommendations and establishment of a formal plan of actions to address the key risks. This meeting took place on 21 January 2020 and the PR provided sufficient assurances of his engagement with the HFEA and a robust plan to implement the recommendations made in this report, within the prescribed timescales, which is also reflected in the PR's response to this report.

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

The inspection team recommends the renewal of the centre's Treatment and Storage licence for a period of three years (rather than the usual four) without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales. In addition, it is recommended that an interim inspection be

conducted within 12 months of this licence coming in to force to ensure that compliance with the recommendations has been achieved and maintained.

Centre 0015 has not been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

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

What the centre does well

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

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

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

and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

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

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

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

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

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

Laboratory accreditation (Guidance note 25)
It is important to assure the quality of the services provided by laboratories. 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 partially 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.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are partially 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 a particular subset of women having IVF treatment. 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 centre's procedures are compliant with the HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

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

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

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

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;

- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

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

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

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

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

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

Third party agreements (Guidance note 24)
The centre's third-party agreements are compliant with HFEA requirements with the exception noted in the 'Imports and Exports' section of this report.

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

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements. Most 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 partially compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

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

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

What the centre could do better

Laboratory accreditation (Guidance note 25)
The centre undertakes diagnostic semen analysis; however, the laboratory is not accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard and was not able to provide evidence to support a status equivalent to accreditation (SLC T21). The centre undertakes semen analysis using a procedure which is not endorsed by the professional guidelines (World Health Organization (WHO) laboratory manual for the examination and processing of human semen; fifth edition (2010)) and the inspection team was not clear if this had been evaluated in the centre's process validation for diagnostic semen analysis. In addition, the centre participates in an external quality assurance (QA) scheme and had identified that this parameter was one where they had not met the required standards.

Recommendation 3.

Infection control (Guidance Note 25)
Three of five clinical waste bins were unlocked outside of a secure compound. Two of these bins contained clinical waste in them (Department of Health (DH) Building note 00-09, Infection control in the built environment (2013) sections 3.162; 3.163).

Recommendation 4.

Medicines management (Guidance Note 25)
In several entries in the CD register the units of the quantity of drug given were not recorded. In addition, the ampoule drug strength (i.e. microgram per millilitre) was not recorded at the top of each page of the CD register (Misuse of Drugs Regulations 2001; regulation 19(a) and 20(a); NICE Guideline [NG46] (April 2016) 'Controlled drugs safe

use and management' section 1.7.4; Association of Anaesthetists 'Controlled drugs in peri-operative care' (2019)).

Recommendation 5.

Imports and exports (Guidance note 16; General Direction 0006)
The centre imports donor sperm from two sperm banks in Europe. In order to establish whether donors have been compensated in accordance with HFEA requirements, the centre has obtained statements from the sperm banks as evidence of compliance. However, the inspection team noted that these statements were provided in 2012 and 2016 and no further confirmation has been sought (General Direction 0001).

Furthermore, the centre has not audited compliance with the requirements of General Direction 0006 for any imports or exports undertaken within the last two years (General Direction 0006).

Recommendation 10.

Quality management system (QMS) (Guidance note 23)
On inspection, the following issues were identified.

- The centre has not established quality indicators (QI) for the submission of data to the HFEA (SLC T35).
- There is no standard operating procedure (SOP) in place describing the use of the nitrogen gas generator (SLC T33b).

Recommendation 11.

See also the 'Welfare of the child', 'Surrogacy', 'Legal parenthood' and 'Storage of gametes and embryos' sections in this report.

Equipment and materials (Guidance note 26)
The centre very occasionally uses a product to activate oocytes prior to ICSI treatment. This product is CE marked as an 'in vitro diagnostic' device but is being used as a medical device which is 'off label' i.e. for a purpose for which it was not appropriately classified. Where a centre is using a product as a medical device for which there is no CE marked alternative available, it is expected that a robust risk assessment and validation has been undertaken prior to use of this product and that appropriate information is provided to patients regarding the use of a non-CE marked product as a medical device (such as any possible risks associated with the use of this item) prior to use in treatment. The centre has not risk assessed or validated the use of this product. The centre has a patient information sheet and consent for the use of this product, but it does not explain that the product is being used 'off label' (SLCs T24, T28, T30, T72 and CoP 26.5).

The temperature of the centre's heated stages used for vitrification are monitored by heat sensitive stickers. The inspection team was concerned that this method is not accurate enough to provide assurance that the procedures are being undertaken at the specified temperature (SLC T24).

Recommendation 6.

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
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.

Leadership
At the time of the inspection, it was considered that the centre was only partially compliant with HFEA guidance regarding effective leadership.

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

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff in sufficient number, to carry out the licensed activities and associated services with the exceptions noted in the 'Welfare of the child', Counselling' and 'Legal parenthood' sections in this report. 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

Leadership
Given the nature and number of non-compliant findings at this inspection, the inspection team had some concerns regarding the efficacy of the leadership at the centre. However, given the actions already taken with regards to recommendations made within this report, and the commitment shown by the PR on meeting with senior members of the Compliance team, the executive is satisfied that the PR is now demonstrating effective leadership. Therefore, no recommendation in this regard will be made at this time. Ongoing progress with the implementation of remaining recommendations and the centre's performance will be monitored.

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 the child who may be born as a result of that treatment and of any other child who may be affected by that birth are not compliant with HFEA requirements.
Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better

Welfare of the child (Guidance note 8)
On inspection, the following significant issues were identified.

- In one record, patient (A)'s partner (B) had declared a previous history of psychosis. The inspection team was concerned that psychosis is a significant mental illness, and that there was no record that the impact of this had been explored with (B) prior to treatment; nor that any considerations were made as to any impact on the family or any child resulting from the treatment. In addition, (B) had expressed a desire to have a child at the later date and there was no record that her previous mental illness had been considered and/or explored with her in the event of a future pregnancy (SLC T56; CoP 8.2, 8.3).
- The welfare of the child SOP does not detail the requirement to repeat a welfare of the child assessment in the event of a change of medical/social/surgical history or if the patient presents with a new partner (CoP 8.5).
- There has been no competency assessment completed for the practitioners who conduct welfare of the child assessments (SLC T12).
- In one record, the date of birth had been recorded as the date of signing on the welfare of the child form; and in the same form, the clinician had signed both forms (male and female patients) on 24 July 2019, but the female patient had signed her form on 27 July 2019.
- In another record, the welfare of the child form had been signed by the clinician but the section to be completed by the clinician was blank (SLC T56; CoP 8.2).

Recommendation 1.

Also see the 'Surrogacy' section in this report.

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)
This centre does not undertake embryo testing and therefore requirements related to these procedures were not relevant at this inspection.

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

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only 28 patients provided feedback in the last 12 months, giving an average five-star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it is important that every patient knows about the rating system. The inspection team discussed this with the PR. Following the change of ownership to HFG, the PR advised the inspectors that actions have already been taken to address this matter. The inspection team was reassured that the PR will take appropriate actions to remedy the low feedback rate to the HFEA website.

The website also gives the ability for patients to comment on the cost of treatment, and most patients confirmed that they had paid what they expected to. Several patients also provided individual comments to the HFEA complimenting the professional service and respect for dignity at the clinic.

The centre's own most recent patient survey responses (January-June 2019) were reviewed. The survey measured patients' satisfaction with regards to the centre's services. Of 121 responses, 98% were positive.

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Patient support
Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

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

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

Patient support (Guidance note 3)
New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

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

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 and sperm sharing arrangements (Guidance note 12; General Direction 0001)
This centre does not undertake egg or sperm sharing arrangements and therefore requirements related to these procedures were not relevant at this inspection.

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 partially compliant with HFEA requirements.

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

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

What the centre could do better

Counselling (Guidance note 3)
Prior to giving consent all patients and donors are offered an opportunity to have counselling, with the exception of male patients freezing samples prior to starting oncology treatment. On discussion, staff explained that these patients are initially seen by the laboratory staff who provide information and obtain the man's consent to storage of his sperm. Whilst the inspection team acknowledges that the period of time between first seeing these patients and storing their gametes is usually very short, it is expected that these patients are given a suitable opportunity to receive proper counselling about the implications of being provided with these services. Furthermore, the inspection team was concerned that the competency of the laboratory staff who take consent from

patients has not been assessed appropriately since they do not ensure that an offer of counselling has been made to patients prior to taking consent (the Human Fertilisation & Embryology (HF&E) Act 1990 (as amended) Schedule 3 and SLC T12).

Recommendation 7.

Surrogacy (Guidance note 14)
On inspection, the following issues were identified.

- The surrogacy SOP lacks mention of completing a welfare of the child assessment and does not make reference to the relevant DHSC guidance documents (SLC T56; CoP 8.9, 31.9 and DHSC 'Care in Surrogacy' (2018) and 'The Surrogacy Pathway' (2018)).
- In the record reviewed, the welfare of the child assessment had not been completed for the husband of the surrogate (CoP 14.1).
- In the same record, the husband, who was supportive of the surrogacy, had completed a LC ('Lack of consent') form. The inspection team was concerned as to why this form had been completed since this form should only be used in circumstances where the surrogate can evidence facts about why the husband does not consent to being a legal parent of any child born as a result of her treatment. In addition, the section of the consent form that requires the evidence to be provided was left blank (CoP Interpretation of mandatory requirements 6l).

Recommendation 8.

Information

What the centre does well

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

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

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

What the centre does well

Consent (Guidance note 5;6)
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 partially compliant with HFEA requirements as noted in the 'Counselling', 'Surrogacy', 'Legal parenthood', 'Storage of gametes and embryos' and 'Record keeping' sections of this report.

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. The centre did have some cases where anomalies in consent to legal parenthood were identified.

Following a renewal inspection in 2016, all affected patients were informed of the anomalies in writing and offered an appointment at the centre. Despite several attempts to contact them, two couples did not respond to communications from the centre. The PR assured the executive at that time that he was committed to providing necessary support to the patients concerned, and to act in accordance with HFEA guidance should any of the patients contact the centre team and wish to pursue a declaration of parenthood through the courts.

The centre's inspector and Chief Inspector visited the centre in 2017 and were satisfied that the team had taken appropriate action with regards to the patients affected by anomalies in their consent to legal parenthood, and that the processes in place for ensuring effective consent were satisfactory.

At the interim inspection in 2018, centre staff confirmed that to date, none of the couples previously contacted have sought a declaration of parenthood through the courts. The inspection team concluded that, while the processes used to collect legal parenthood consent at this centre were compliant with HFEA requirements, the audit of legal parenthood processes required improvement in that it did not include any description of the scope or methodology used. Centre staff later confirmed that the audit methodology was compliant with CE(14)01.

At this inspection, and 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 the most recent legal parenthood consenting audits. Nine sets of records, where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required, were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are partially compliant with HFEA requirements.

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

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their

consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

What the centre could do better

Legal parenthood (Guidance note 6)

On inspection, the following issues were identified.

- The inspection team did not consider the centre's processes for recording marital or civil partnership status were robust in that, when a patient presents for treatment as a 'single' person, or with a new partner, despite staff giving assurance that marital or civil partnership status is reviewed at consultation, the centre does not record whether they asked if the patient was married or in a civil partnership to someone or to someone other than the person with whom they present for treatment (CoP 6.21 and 6.25); in addition, staff did not consistently use the same document to record the patient's marital or civil partnership status and the wording used between the documents was sometimes inconsistent (in one record, the patient was referred as 'wife' and in another document they were referred as 'partner'), which may lead staff to complete the incorrect consent forms (CoP 31.11a).
- In one record, a couple had initially completed the WP ('Your consent to your partner being the legal parent') and PP ('your consent to being the legal parent') forms in 2017. Subsequently, the couple got married and had treatment in 2018; whilst the inspection team acknowledges that the posthumous wishes on the PP form may still be valid, it was not clear from the records whether the validity of the consents had been reviewed and/or the couple had been offered an opportunity to complete a PBR ('Your consent to being registered as the legal parent in the event of your death') form, which has been in use since April 2017 (CoP 6.7 and 'Consent forms: A Guide for Clinic Staff', HFEA (2019)).
- The legal parenthood SOP has not been updated to reflect the use of the PBR form (CoP 31.9). Furthermore, the PBR form is not currently audited as part of the legal parenthood audit (SLC T36). Despite staff providing assurance to the inspection team that the PBR consent form is used when applicable, the centre conducted an audit after the inspection, which found that four relevant records did not have the PBR form. The centre has offered assurance that the relevant patients will be given the opportunity to complete a PBR form and this will be addressed by 31 January 2020 ('Consent forms: A Guide for Clinic Staff', HFEA (2019)).
- In four records, the NHS/CHI/HCN/passport numbers for either the patient, their partner or both were not recorded on the WP and/or PP forms (CoP 31.11a).
- No competency assessment has been completed for the practitioners who conduct the legal parenthood consultation (SLC T12).

Recommendation 9.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

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

Storage of gametes and embryos (Guidance note 17)

The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety.

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)

On inspection, the following significant issues were identified.

- The centre audited all cryopreserved samples between December 2017 and March 2018. The audit identified: '…there are 29 patients where they have either incorrect/incomplete HFEA consent forms and are either deceased or lost to contact or patients who are lost to contact with no in-house consent to freeze (financial contract)…'. The inspection team is significantly concerned that the PR has not taken any actions to seek legal advice on these audit findings from over a year ago,

thereby ensuring that there is effective consent for all samples in storage at the centre.
- The audit did not document any corrective or preventative actions (CAPAs) to address these anomalies (SLC T36).
- During the inspection, the team was informed that there are now approximately 40 cases where the centre is considering whether there is effective consent to storage of gametes and embryos.
- In one record audited during the inspection, the inspectors considered that the requirements for extending storage had not been satisfied. The centre staff who had also reviewed these records previously considered that the requirements for extending storage had been met. However, based on the information reviewed, the inspection team did not consider that the centre had interpreted the relevant regulatory requirements correctly. Therefore, the PR was advised to seek legal advice on this case and did so soon after the inspection. The PR informed the centre's inspector that the patients no longer wished to store these samples and they have therefore been allowed to perish.

The HF&E (Statutory Storage Period) Regulations 1991; The HF&E (Statutory Storage Period for Embryos) Regulations 1996; The HF&E (Statutory Storage Period for Embryos and Gametes) Regulations 2009; SLC T79.

In addition, the following process issues were identified.
- The expiry date for consent to storage recorded in the centre's bring forward system does not include consideration of the date on which the most recent medical practitioner statement (MPS) has been completed.
- The centre has not undertaken an audit of the accuracy of the data in the database used for the centre's bring forward system.

SLC T36.

Recommendation 2.

Use of embryos for training staff

What the centre does well

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

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

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

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

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

The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Record keeping and document control (Guidance note 31)
On inspection, the following issues were identified.

- In one record, the patient identity (ID) form had been completed and signed by both patients and a member of centre staff, but there was no photographic evidence on the document, which does not follow the clinic process.
- In the same record, there was an amendment on the WT ('Women's consent to treatment and storage form (IVF and ICSI)') form that had not been initialed or signed by the patient.
- In another record, the consent to disclosure form had been dated by the male patient with his year of birth, not the year of signing; yet, the centre's 'notes audit checklist' had been ticked to say the consents had been checked and were correct.
- In two records, the Ebola and Zika enquiry form had not been countersigned by staff as directed to do so.

Each patient file has a 'notes audit checklist' where centre staff record when they have reviewed the consent forms. However, the inspection team was concerned that none of the checklists in the records audited had noted the anomalies identified at this inspection (CoP 31.11a).

Recommendation 12.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
At the time of inspection there were a small number of outstanding donor issues that require resolution (General Direction 0005).

Recommendation 13.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2018, recommendations for improvement were made in relation to one area of major non-compliance and four 'other' areas of non-compliance.

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

However, the inspection team noted that a similar CE marking recommendation in relation to another product in use at the centre was made at the 2018 inspection.

In addition, the inspection team is concerned that the centre does not seem to have incorporated learning from previous anomalies, recommendations made at previous inspections and guidance provided by the HFEA in relation to their legal parenthood processes.

On-going monitoring of centre success rates

Since the last inspection, the centre has not received any risk-based alerts relating to treatment success rates.

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. Welfare of the child There are several issues related to the welfare of the child assessment. These are described in the body of the report. SLCs T12 and T56. CoP 8.2, 8.3 and 8.5.	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 conduct a root cause analysis into the circumstances which led to patients (A) and (B) being offered treatment without patient (B)'s previous medical condition being fully investigated. This analysis	The PR has conducted a root cause analysis regarding patients A and B. Please see attached documentation. Please also see attached document - supplementary submissions to the draft report (General Response to draft HFEA report).	The executive notes the PR's response and commitment to implementing this recommendation. The PR provided suitable assurances during the meeting and has been proactive in implementing this recommendation. The PR has provided a copy of the root cause analysis, which indicates that the centre

	should include corrective and preventive actions with timescales for implementation. A copy of the root cause analysis should be provided to the centre's inspector when responding to this report. The PR should review the process for conducting welfare of the child assessments including, but not exclusively, the issues identified in this report. A summary report of this review and a compliant SOP should be provided to the centre's inspector by 6 February 2020. The PR should ensure that no practitioner undertakes welfare of the child assessments until they have been assessed as competent to do so. The PR should ensure that competency assessments are completed for all practitioners who conduct welfare of the child assessments. The PR should provide confirmation of completed assessments to the	The PR has conducted a full review of the WOC policy (please see attached). WOC assessment with regard to surrogacy is addressed in point 8 of this document (Surrogacy). A WOC competency form has been created and all relevant pracititioners have been assessed by a member of the senior clinical team prior to any further WOC patient assessments being carried out. See copy of attached completed competencies of both practitioners who perform theses assessments at SDFC.	had assessed patient A and their partner B before providing treatment; following that assessment, it was decided that there was no potential impact on the family or any child resulting from the treatment. This was further confirmed by the counsellor who met with patients A and B. Following the findings at this inspection, the PR has confirmed that the process for conducting and recording the welfare of the child assessments has been reviewed and a revised SOP has been provided. The PR has provided evidence of competency of the two practitioners undertaking the welfare of the child assessments. No further action required.

	centre's inspector when responding to this report.		
2. Storage of gametes and embryos There are several issues related to storage of gametes and embryos practice, procedures and auditing. These are described in the body of the report. The HF&E (Statutory Storage Period) Regulations 1991. The HF&E (Statutory Storage Period for Embryos) Regulations 1996. The HF&E (Statutory Storage Period for Embryos and Gametes) Regulations 2009. SLCs T36 and 79.	The PR should ensure that effective consent is in place for all stored gametes and embryos**.** Since the inspection, the PR has confirmed that legal advice had been sought for two cases. The PR should provide an update to the centre's inspector when responding to this report. To ensure the correct audit methodology is used, the PR should seek an external audit of all samples in storage that are beyond the statutory storage period, by a specialised auditor expert in this field, to ensure that all requirements for effective consent to storage have been met. If any anomalies are found, the PR should seek immediate legal advice from a specialist expert. The PR should review the database used in the centre's bring forward system to	Legal Advice has been sought from [redacted] regarding the storage of the 2 embryo storage patients stored before 2009. Their response is attached. The centre will act upon the advice provided in this review. A full review of the 44 sperm storage patients that remain in storage with consent period beyond the statutory period has been conducted at the SDFC. Please see attached. An external review of these findings has been arranged [redacted] A full review of the storage spreadsheets for both embryos and sperm has been conducted to ensure that all patients stored beyond the statutory storage period have an expiry date commensurate	The executive notes the PR's response and commitment to implementing this recommendation The PR provided suitable assurances during the meeting and has been proactive in implementing this recommendation. The PR has provided an update on the cases being reviewed by their legal team. The PR has provided a summary report of an internal audit which has been conducted since the inspection. The PR has also confirmed that an external audit of all the samples in storage that are beyond the statutory storage period has been organised. The PR has confirmed that a review of the database used in the centre's bring forward system has been undertaken.

	ensure that it includes the date on which the most recent MPS has been completed. When responding to this report, the PR should provide the centre's inspector with a plan of actions, with timelines, by which this audit and review will be completed. The PR should confirm that this recommendation has been implemented and a summary report of the audit should be provided to the centre's inspector by 6 May 2020.	with their MPS. The relevant SOP has been updated to reflect this change. See attached policy ACULab019. Please find attached the Action Plan with timescales for completion of theses audits and reviews. A summary report of the full audit will be provided by 6th May 2020.	The PR has provided a plan of actions with timescale. Further action required.

Major area of non-compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
3. Laboratory accreditation The centre undertakes diagnostic semen analysis; however, the laboratory is not accredited by UKAS or another accreditation body recognised as accrediting to an equivalent standard and was not able to provide evidence to support a status equivalent to accreditation. The centre undertakes semen analysis using a procedure which is not endorsed by the professional guidelines and the inspection team was not clear if this had been	The PR should ensure that the centre's laboratory which undertakes diagnostic semen analysis is suitably accredited or provide evidence to support a status equivalent to accreditation. The PR should review the centre's process validation for diagnostic semen analysis to ensure that it fully complies with professional guidelines. A plan of actions with timescale for implementation of this recommendation	Please see attached report for review of actions and timescales towards completion of laboratory accrediation. Please also see document with reference to summary review of the draft report. The centre's process validation for diagnostic semen analys will be updated following completion of the action points detailed above. Further to discussion with our external quality auditor (Dr Cathy Passingham, Passingham Associates) and	The executive notes the PR's response and commitment to implementing this recommendation. The PR provided suitable assurances during the meeting and has been proactive in implementing this recommendation. The PR has provided a plan of actions with timescale to implement this non-conformance. Due to the discussed timescales, the executive will

evaluated in the centre's process validation for diagnostic semen analysis. The centre participates in an external quality assurance scheme and had identified that this parameter was one where they had not met the required standards. SLC T21. WHO laboratory manual for the examination and processing of human semen; fifth edition (2010).	should be provided by the PR when responding to the report. The PR should provide evidence to support a status equivalent to accreditation for the centre's laboratory undertaking diagnostic semen analysis to the centre's inspector by 6 February 2020. The PR should provide an update on the centre's most recent performance in external QA when responding to this report. It is expected that the centre will meet the required standard in the external QA scheme by 6 May 2020.	another local IVF clinic who provide diagnostic semen analysis that this process is likely to take at least 12-18 months to complete. Therefore the deadline of 6th February 2020 is an unrealistic deadline for achievement of accrediation. Following our meeting with the HFEA on 21 January 2020 we understand this date will be amended. Please document on laboratory accreditation for update on most recent UK NEQAS results. Please refer to action plan with regard to action points and timescales for achievement of external QA standard by 6 May 2020.	continue to monitor the centre's implementation of this recommendation within the required timescales. Further action required.
4. Infection control Three of five clinical waste bins were unlocked outside of a secure compound. Two of these bins contained clinical waste in them. DH Health Building note 00-09, Infection control in the built environment (2013) sections 3.162 and 3.163.	The PR should ensure compliance with infection control regulations. The PR should ensure that clinical waste awaiting collection is kept in a locked receptacle at all times. The PR should inform the centre's inspector of the actions	A full review of the Clinical Waste Management policy is being undertaken with SRCL (SDFC Clinical Waste disposal contractor) to ensure that all clinical waste is stored and removed in line with contract and waste regulations.	The executive notes the PR's response and commitment to implementing this recommendation. The PR has provided assurances that this non-compliance has been addressed, a new process has been implemented and a

	taken to address this non-compliance by the 6 February 2020.	The Centre has also appointed an infection control nurse who will work closely with the team to ensure all areas are managed and monitored in line with the clinic's policies. As part of the policy a sign off sheet will be implimented to ensure compliance with the policy.	revised SOP has been provided. No further action required.
5. Medicines management In several entries in the controlled drugs register the units of the quantity of drug given were not recorded. In addition, the ampoule drug strength (i.e. microgram per millilitre) is not recorded at the top of each page of the CD register. Misuse of Drugs Regulations 2001, regulations 19(a) and 20(a). NICE Guideline [NG46] (April 2016) 'Controlled drugs; safe use and management' section 1.7.4.	The PR should ensure compliance with controlled drugs management, supervision and use regulations and practice guidance. The PR should review practice including, but not exclusively, the non-compliances found at this inspection and ensure compliance with regulations and best practice guidance. A summary report of this review with corrective actions taken, should be provided to the centre's inspector by 6 February 2020.	The inspectors' finding that ampoule drug strength is not recorded (i.e. at the top of each page) is incorrect. It was highlighted during the inspection that the volume of the ampoule was not recorded at the top of the page. This was rectified immediately following the inspection. Please see attached photograph of the CD book. The controlled drugs licence holder has reviewed the controlled drugs register and policies. All staff who are working with controlled drugs have completed all the relevant training. The centre also had a home office	The executive notes the PR's response and commitment to implementing this recommendation. The executive acknowledges that the centre acted on the inspector's findings on the day of the inspection with regards to the ampoule drug strength by adding the ampoule size on each page of the CD register. The executive acknowledges the receipt of the copy of the Home Office summary and notes that it details the topics which were discussed and the information/documentation that were reviewed during

Association of Anaesthetists 'Controlled drugs in peri-operative care' (2019).	Three months after the review the PR should audit medicines management practice to ensure that corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 6 May 2020.	compliance visit in Nov 2019 where all records, processes and policies were checked and compliant. All drugs clearly had the strength and doses recorded on each page.	their inspection. The executive notes the PR response and would like to clarify that this inspection report is based on the findings identified during this inspection and cannot comment on findings from other Regulators. The executive acknowledges the receipt of the CD register photographic evidence. However, the executive noted further non-compliances which have been discussed with the PR. The PR has provided a summary report of his review with corrective actions taken. Further action is required.
6. Equipment and materials A. The centre very occasionally uses a product to activate oocytes prior to ICSI treatment which is CE marked as an 'in vitro diagnostic' device but is being used as a medical device, which is 'off label'. The centre has a patient	With regards to point A, the PR should ensure that CE marked medical devices are used where possible. If the PR considers that there is no CE marked medical device available, or no other process using CE marked medical devices can be used	The risk assessment, patient information and details of process validation regarding the use of calcium ionophore due by 6 February 2020 are attached to this document.	The executive notes the PR's response and commitment to implementing this recommendation. With regards to point A, the PR has provided a risk assessment and an amended 'Information & Consent to use' informing patients that the

information sheet and consent for the use of this product, but it does not explain that the product is being used 'off label'. SLCs T24, T28, T30, T72. CoP 26.5. A similar issue in relation to another product in use at the centre was noted at the time of the last inspection in 2018. B. The temperature of the centre's heated stages used for vitrification are monitored by heat sensitive stickers. The inspection team was concerned that this method is not accurate enough to provide assurance that the procedures are being undertaken at the specified temperature. SLC T24.	to activate oocytes prior for ICSI, then he should ensure that a robust risk assessment and validation has been undertaken prior to use of this product, and that patients are informed that a product that is not appropriately classified as a CE marked medical device is to be used. A copy of the risk assessment and validation for the use of this product in treatment, and revised patient information and consent form should be provided to the centre's inspector by 6 February 2020. When responding to this report, the PR should confirm that no other products are in use as a medical device which is 'off label' i.e. for a purpose for which it was not appropriately classified. With regards to point B, the PR must ensure that equipment or materials affecting critical processing are subject to appropriate monitoring to ensure that the critical parameters are	Please find attached a review of the centre's use of non-CE marked products.	product that is not appropriately classified as a CE marked medical device is to be used. The executive notes that the centre has since decided to no longer offer the use of Calcium Ionophore to its patients. No further action required. The executive notes the actions taken in addressing point B. The PR has provided a summary report of their findings of their review of the equipment monitoring and validation. No further action required.

	maintained within acceptable limits at all times. The PR should review the validation and monitoring of all critical equipment, not only those identified by the inspection team, to ensure that critical parameters are within acceptable limits at all times. This review should include consideration of the external monitoring, including but not limited to the measurement of temperature against a traceable standard such as a thermocouple. A summary report of the findings of this review, including timescales for implementation of corrective actions identified should be provided to the centre's inspector by 6 February 2020.	A full review of all external monitoring of critical equipment carried out in the laboratory will be completed by 6 February 2020 with accompanying review of any findings/corrective actions. A thermometer that " allows the user to accurately measure the temperature of heated stages and inside media droplets, incubators and refrigerators" has been purchased from Origio (RI) and is due to arrive on at the end of January 2020.	
7. Counselling Patients freezing sperm samples prior to starting oncology treatments are not given a suitable opportunity to receive proper counselling about the implications of being provided with these services. The inspection team is also	The PR should ensure that patients freezing sperm samples prior to starting oncology treatments are given a suitable opportunity to receive proper counselling and that this offer is documented.	The policy for oncology sperm freezing has now been updated to ensure counselling is offered at the time of booking oncology patients in for sperm freezing appointments. The referral form issued to oncology nurses has also been updated	The executive notes the PR's response and commitment to implementing this recommendation. The PR has confirmed that the process for offering counselling to patients freezing sperm sample prior

concerned that the competency of the laboratory staff who take consent from patients has not been assessed appropriately since they do not ensure that an offer of counselling has been made to patients prior to taking consent. HF&E Act 1990 (as amended) Schedule 3. SLC T12.	The PR should review the centre's processes for offering counselling to male patients freezing sperm prior to starting oncology treatments. A summary report of this review should be provided to the centre's inspector by 6 February 2020. The PR should contact all male patients who froze sperm samples prior to undertaking their oncology treatment and offer them a suitable opportunity to receive proper counselling. Once the offer of counselling has been made, the PR should consider whether re-consenting these patients is required. An update on the implementation of this recommendation with timelines should be provided to the centre's inspector by 6 February 2020. It is expected that this non-compliance will be addressed by 6 May 2020.	to include this. Please see attached updated policy ACULab013 and SDFC 349. A review of this process will provided by 6 February 2020. A list has been complied of all oncology sperm storage patients cryopreserved at the SDFC since the service resumed in 2015; 27 patients were identified. Prior to writing to these patients, the GP or referring consultant has been contacted to ensure patients are alive and appropriate to contact. All appropriate patients have already been sent an offer of counselling. A spreadsheet with timescales has been put in place regarding contact of these patients. Attached also is the letter and reply slip that has been issued to all appropriate patients. An update on this action will be provided by 6 Febrary 2020	to starting oncology treatments has been reviewed and staff will offer all relevant patients a suitable opportunity to receive proper counselling prior to being provided with services. The PR has provided a copy of the letter being sent to all male patients who froze sperm samples prior to undertaking their oncology treatment and offer them a suitable opportunity to receive proper counselling. The PR has provided a plan of actions with timescale to address this non-compliance. Further action required.

		with full and final report by 6 May 2020.	
8. Surrogacy There were several issues related to surrogacy. These are described in the body of the report. SLC T56. CoP 6, 8.9, 14.1 and 31.9. DHSC guidance documents: 'Care in Surrogacy' (2018) and 'The Surrogacy Pathway' (2018).	The PR should ensure that practice relating to surrogacy treatments is compliant with regulatory requirements, DHSC practice guidance and CoP guidance. The PR should review surrogacy practices in line with regulatory requirements, DHSC practice guidance and CoP guidance, including, but not exclusively, the issues identified at this inspection and ensure compliance. A summary report of this review and a compliant SOP should be provided to the centre's inspector by 6 February 2020. Three months after the review, the PR should audit practice to ensure corrective actions implemented have been effective in achieving and maintaining compliance. The inspection team recognises that the centre does not do many surrogacy treatments so if there are no surrogacy	A full review of the surrogacy policy and associated paperwork is being carried out. Please find attached the updated policy. A summary review of this process will be compiled and issued by 6 February 2020. A further review will be implimented either 3 months following this review or after the next surrogacy case to take place at SDFC.	The executive notes the PR's response and commitment to implementing this recommendation. The PR has confirmed that the process related to surrogacy practices has been reviewed, is in line with regulatory requirements, SHSC practice guidance and CoP guidance and a revised SOP has been provided. No further action required beyond the submission to the centre's inspector of a summary report of a review after a surrogacy treatment has taken place.

	treatments in the next three months, the PR should review surrogacy practice when a treatment has taken place and provide a summary report of this review to the centre's inspector after treatment has taken place.		
9. Legal parenthood There were several issues related to the legal parenthood consenting practice and procedures and auditing. These are described in the body of the report. SLCs T12 and T36. CoP 6.7, 6.21, 6.25, 31.9, 31.11a. 'Consent forms: A Guide for Clinic Staff', HFEA (2019).	The PR should ensure that legal parenthood consenting practice and procedures and auditing are robust and compliant with CoP requirements and guidance. Taking into consideration but not limited to the findings of this report, the PR should review practices and procedures and auditing relating to legal parenthood. A summary report of this review and a compliant SOP should be provided to the centre's inspector by 6 February 2020. Three months after the review, the PR should conduct an audit of legal parenthood consents and procedures. A summary report of this audit should be submitted to the	A full review of the policy and practices with regard to Legal Parenthood has taken place. Legal parenthood audit is now an ongoing process rather than an end of year assessment. The audit is populated as soon as the patient indicates intention to start treatment with either donor sperm or donated embryos. This is double-checked against the key performance indicator reporting sheet at the time of treatment. We have adopted the audit methodology provded at the inspection in November 2019 to ensure PBR is also noted. In addition to this a retrospective audit of	The executive notes the PR's response and commitment to implementing this recommendation. The executive acknowledges receipt of the legal parenthood audit provided by the centre after the inspection. The PR has provided a summary report of his review of the legal parenthood practices and a revised SOP. Further action required.

	centre’s inspector by 6 May 2020.	PBR requirement on relevant patients with stored embryos has also been conducted and forms sent to patients where needed. A summary review and updated SOP will be provided by 6 February 2020. A further audit will be carried out 6 May 2020.	

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
10. Imports and exports The centre imports donor sperm from two sperm banks in Europe. The centre has obtained statements from these sperm banks confirming that the donors are compensated in accordance with HFEA requirements. However, the inspection team noted that these statements were provided in 2012 and 2016 and no further confirmation has been sought. Furthermore, the centre has not audited compliance with the requirements of General Direction 0006 for any imports and exports undertaken within the last two years.	The PR should ensure that import of donor gametes is compliant with General Direction 0001 and General Direction 0006. The PR should audit compliance with the requirements of General Direction 0006 for any imports and exports undertaken within the last two years. A summary report of this audit should be provided to the centre's inspector by 6 May 2020.	An assessment of those sperm donors imported to the SDFC over the last 2 years from sperm banks within the EU (Cryos and ESB) has been compiled. The appropriate centres have been contacted to ascertain compliance to General Directions 006. A summary report will be provided by 6 May 2020.	The executive notes the PR's response and commitment to implementing this recommendation. Further action required.

General Direction 0001 and General Direction 0006.			
11. QMS On inspection, the following issues were identified: • the centre has not established QI for the submission of data to the HFEA; • there is no SOP in place describing the use of the nitrogen gas generator. SLCs T33b and T35.	The PR should ensure that the quality management system is effective and fit for purpose. The PR should establish QI for the submission of data to the HFEA and confirm they are being implemented to the centre's inspector by 6 May 2020. The PR should provide a SOP describing the use of the nitrogen gas generator to the centre's inspector by 6 May 2020.	The centre has established QI for the submission of data to the HFEA and this has been added to our annual audit schedule. A copy of this audit will be provided by 6 May 2020. An SOP will be provided on the use of the nitrogen generator by 6 May 2020.	The executive notes the PR's response and commitment to implementing this recommendation. Further action required.
12. Record keeping There were several issues related to record keeping. These are described in the body of the report. CoP 31.11a.	The PR should ensure that documented procedures are established ensuring accurate recording of information. The PR should review record keeping practices, including, but not exclusively, the issues noted in this report; the PR should in particular review the consents 'audit notes checklist' quality assurance process.	The notes audit sheet has now been reviewed and expanded to encorporate all HFEA and in house forms. Please see attached (SDFC 125). All members of staff will receive training in audit practice and competency	The executive notes the PR's response and commitment to implementing this recommendation. The PR has provided several notes checklists related to their quality assurance process. Further action required.

	A summary report of the actions taken with timelines for implementation of any corrective actions should be provided by the centre's inspector by 6 May 2020. Three months after the review, the PR should audit records to ensure that corrective actions taken have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 6 August 2020.	assesment will be completed. A summary report of timelines for implimentation of any corrective actions will be provided by 6 May 2020. A review of this audit practice will be provided by 6 August 2020.	
13. Obligations and reporting requirements At the time of inspection there were a small number of outstanding donor issues that require resolution. General Direction 0005.	The PR should ensure that all licensed activity is reported to the HFEA within the timeframe required by General Direction 0005. The PR should contact the HFEA's register team to ensure historic donor issues are resolved thereby ensuring the HFEA can always supply accurate information to a donor-conceived person and their parents.	At the time of the inspection there were no noted outstanding donor issues. The current issues raised concerning treatment at the SDFC during 1992-2002 were not raised until 31st December 2019, therefore after the inspection and should not be included in the report. Neverthless the centre has already resolved 6 of the 13 issues raised and have now received support from the QA officer on how to resolve the	The executive notes the PR's response and commitment to implementing this recommendation. Further action required.

	An update of the actions taken with timelines to address this non-conformance should be provided to the centre's inspector by 6 May 2020.	remaining 7. An update will be provided by 6 May 2020.	

Reponses from the Person Responsible to this inspection report
At The Sussex Downs Fertility Centre we pride ourselves on the level of attention and care we provide our patients, we have a very experienced team who all take pride in the service we provide. I have reviewed all the points that were made at the inspection and in this report, there are some ares that we have sought expert advice and guidance on and we will continue to work with James Lawford Davies (Hill Dickinson LLP) to ensure we understand and apply the regulation guidelines to our practice. We are committed to the improvement of our services and the team, we are also seeking a centre that we can work closely with to benchmark the standards and independently audit the SOP's and our standards of care. We will continue to ensure that we are up to date with the training and attend relevant meetings and read the regular updates. The centre will work closely together and review all cases at weekly MDT clinical review meetings. We will ensure that all areas of the centre will be reviewed and managed closely as a team. We will continue to focus on our success rates and low multiple birth rates. Our focus is to ensure that we are delivering excellent patient care in a safe and effective environment. I would like to request the inspectors to review the suggested inspection renewal term and some of the grading of the points raised in this report.