Executive Licensing Panel - minutes

Centre 0294 (Craigavon Area Hospital)

Renewal Inspection Report

Change of Centre Name

Tuesday, 16 June 2020

HFEA Teleconference Meeting

Panel members	Clare Ettinghausen (Chair) Joanne Anton Kathleen Sarsfield-Watson	Director of Strategy and Corporate Affairs Head of Regulatory Policy Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

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

1.2. The panel noted that Craigavon Area Hospital has held a treatment (insemination using partner sperm) licence with the HFEA since 2007. The centre provides basic fertility services and activities involve the processing of sperm and its use in partner insemination, but not the creation, processing, use or storage of gametes or embryos.

1.3. The panel noted that there was a temporary cessation of licensed treatments at the clinic from April 2019 to August 2019. This decision was made by the Person Responsible (PR), in consultation with senior hospital management, due to the unforeseen extended sickness period of two members of the centre's staff. The situation was further compounded by the failure of a critical piece of equipment used in the processing of gametes for treatment. The decision was not taken lightly, but was considered necessary to protect the safety of patients attending the centre for licensed treatment and their gametes.

1.4. The panel noted that licensed activity recommenced once the number of staff working at the centre had returned to safe levels and the critical equipment had been appropriately repaired. Patients who were due to undertake treatment at the centre were kept fully informed of the situation.

1.5. The panel noted that, in 2019, the centre provided 89 cycles of partner intrauterine insemination. In relation to activity levels this is a small sized centre.

1.6. The panel noted that, out of the 89 cycles of partner intrauterine inseminations provided in 2019, the centre reported nine pregnancies, representing a clinical pregnancy rate of 11%, and this is in line with the national average. All the clinical pregnancies, following partner insemination, were singletons.

1.7. The panel noted that the licence application fee should be paid upon submission of the application to renew the centre's licence as stated in General Directions 0008, sections 1 and 2. This centre should have submitted the fee with the application in January 2020.

1.8. Since the inspection in February 2020, the centre's inspector has been in regular contact with the PR regarding the outstanding licence fee. The PR states that he has done everything within his powers to enable the payment to be made, but has been unsuccessful. The HFEA's Director of Compliance and Information contacted the hospital's Director of Finance, by email, on 27 May 2020, but despite this, as of the date of this Executive Licensing Panel (ELP) meeting, a response has yet to be received and the licence fee remains outstanding.

1.9. The panel noted that, on 30 March 2020, the PR informed the centre's inspector that the centre had suspended all treatment activity as per General Directions 0014 (version 1) issued on 23 March and the centre's staff had been redeployed to other areas of the hospital to assist in the hospital's Covid-19 Strategy. The PR further updated the centre's inspector on 28 May 2020, confirming that the clinic remains closed and no treatments of any type are being undertaken. The centre's staff are still deployed elsewhere in the hospital and the PR has not yet applied to the HFEA to resume treatment services as per the requirements of General Directions 0014 (version 2) issued on 11 May 2020.

1.10. An inspection was carried out at the centre on the 5 February 2020.

1.11. The panel noted that at the time of the inspection, there were no areas of practice that required improvement.

1.12. The panel noted that the centre is well led and provides a good level of patient support. The inspector commended the centre on their performance.

1.13. The panel noted that, subject to payment of the licence fee, the inspection team recommends the renewal of the centre's treatment (insemination using partner sperm) and storage licence for a period of four years, without additional conditions.

2. Decision

2.1. The panel had regard to its decision tree. It was not satisfied that the appropriate application and fee had been submitted as required by General Directions 0008.

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

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

2.4. The panel endorsed the inspectorate's recommendation, subject to receipt of the renewal fee, to renew the centre's treatment (insemination using partner sperm) and storage licence for a period of four years, without additional conditions. The renewal licence offer cannot be issued to the centre until the receipt of the outstanding fee has been confirmed, as required by General Direction 0008. Once the fee is paid, the panel agreed that if no representations or any other information is received within 28 days of the licence offer being issued, the final renewal licence should be issued.

3. Variation of Name

3.1. The panel noted that the centre's PR had also submitted an application to change the centre's name.

3.2. The panel noted that the name is presently Craigavon Area Hospital and the centre now wishes to be known as The Orchard Clinic, Craigavon Area Hospital.

3.3. The panel noted the inspectorate's recommendation to approve the variation of licence to change the centre name.

4. Decision

4.1 The panel endorsed the inspectorate's recommendation to change the centre's name to The Orchard Clinic, Craigavon Area Hospital, subject to the receipt of the outstanding renewal licence fee; an updated licence will not be issued until this has been confirmed.

5. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

22 June 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. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 5 February 2020

Purpose of inspection: Renewal of a licence to carry out Treatment (insemination using partner sperm).

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: Julie Katsaros and Sara Parlett

Date of Executive Licensing Panel: 16 June 2020

Centre name	Craigavon Area Hospital
Centre number	0294
Licence number	L/0294/4/b
Centre address	Lurgan Road, Portadown, Craigavon, BT63 5QQ, United Kingdom
Person Responsible	Dr Timothy McCormick
Licence Holder	Dr Andrew Knox
Date licence issued	1 September 2016
Licence expiry date	31 August 2020
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Craigavon Area Hospital has held a Treatment (insemination using partner sperm) licence with the HFEA since 2007. The centre provides basic fertility services.

There was a temporary cessation of licensed treatments at the clinic from April 2019 to August 2019. This decision was made by the Person Responsible (PR), in consultation with senior hospital management, due to the unforeseen extended sickness period of two members of the centre's staff. The situation was further compounded by the failure of a critical piece of equipment used in the processing of gametes for treatment. The decision was not taken lightly but was considered necessary to protect the safety of patients attending the centre for licensed treatment and their gametes.

Licensed activity recommenced once the number of staff working at the centre had returned to safe levels and the critical equipment had been appropriately repaired.

Patients who were due to undertake treatment at the centre were kept fully informed of the situation.

The centre provided 89 cycles of partner intrauterine insemination treatment in 2019. In relation to activity levels this is a small centre.

The centre's activities involve the processing of sperm and its use in partner insemination but not the creation, processing, use or storage of gametes or embryos.

This current licence has been varied to reflect a change of Licence Holder (LH) in February 2020.

Variation to Licence

The PR has requested that the centre name be changed to The Orchard Clinic, Craigavon Area Hospital.

Pregnancy outcomes

In 2019, the centre reported 89 cycles of partner insemination with nine pregnancies, this represents a clinical pregnancy rate of 11% which is in line with the national average.

Multiple births

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

In 2019, all the clinical pregnancies following partner insemination were singletons.

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;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre **has not** submitted an application fee to the HFEA in accordance with requirements.

The committee should note that the licence application fee should be paid upon submission of the application to renew the centre's licence as per General Directions 0008 sections 1 and 2. This centre should have submitted the fee with the application in January 2020.

Since the inspection in February, the centre's inspector has been in regular contact with the PR regarding the outstanding licence fee. The PR states that he has done everything within his powers to enable the payment to be made but has been unsuccessful. The HFEA's Director of Compliance and Information contacted the hospital's Director of Finance by email on 27 May, but despite this, as of 2 June 2020, a response has yet to be received and the licence fee remains outstanding.

On 30 March 2020, the PR informed the centre's inspector that the centre had suspended all treatment activity as per General Directions 0014 (version 1) issued on 23 March and the centre's staff had been redeployed to other areas of the hospital to assist in the hospital's COVID19 Strategy. The PR further updated the centre's inspector on 28 May, confirming that the clinic remains closed and no treatments of any type are being undertaken. The centre's staff are still deployed elsewhere in the hospital and the PR has not yet applied to the HFEA to resume treatment services as per the requirements of General Directions 0014 (version 2) issued on 11 May.

The ELP is asked to note that at the time of the inspection there were no areas of practice that required improvement.

Recommendation to the Executive Licensing Panel

The centre has no areas of non-compliance and their success rates are consistent with the national average and their multiple clinical pregnancy rates are below the target. The inspection team commends the centre for their performance.

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

The inspection team recommends, subject to the payment of the licence fee, the renewal of the centre's Treatment (insemination using partner sperm) licence, for a period of four years without additional conditions.

The inspection team also recommends the centre's name is changed from Craigavon Area Hospital to The Orchard Clinic, Craigavon Area Hospital.

Centre 0294 does not import or export gametes or embryos and so has not applied for an Importing Tissue Establishment (ITE) import certificate from 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 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 the patient to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.
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

The centre does not recruit donors or provide treatment with donor gametes therefore this area of practice is not applicable to this inspection.

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 laboratories conducting tests that impact on the quality and safety of gametes (relevant third parties) are suitable.

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

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

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

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

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

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre does not perform surgical procedures as part of its licensed activities therefore this area of practice is not applicable to this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The centre is providing only insemination treatments, but such treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. The single biggest risk of fertility treatment is a multiple pregnancy and birth. Thus, it is important for centres providing insemination treatments to have a multiple births minimisation strategy. The centre's procedures are compliant with HFEA requirements to have a multiple births minimisation strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

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

- document the justification for the use of the patient's gametes 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 does not distribute gametes therefore this area of practice is not applicable to this inspection.

Receipt of gametes and embryos (Guidance note 15)
The centre does not receive distributed gametes therefore this area of practice is not applicable to this inspection.

Imports and exports (Guidance note 16; General Direction 0006)
The centre does not import or export gametes therefore this area of practice is not applicable to this inspection.

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

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

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have transport and satellite treatment links therefore this area of practice is not applicable to this inspection.

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

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

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes 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. No adverse incidents have occurred at the centre since the last inspection, but discussions with centre staff demonstrated that any adverse incident would be appropriately managed. 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
Nothing identified at this inspection.

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
Staff

What the centre does well

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

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

Leadership
The centre is compliant with HFEA guidance regarding effective leadership.

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

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

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

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

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well
The centre does not perform embryo testing therefore this area of practice is not applicable to 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. No patients have provided feedback in the last 12 months, despite the efforts of staff to direct patients to the HFEA website. The PR is asked to further consider ways to promote the use of this facility and this will be followed up at the next inspection.

The centre's own feedback was reviewed, with 40 patients providing feedback over the last year. Feedback was mainly positive.

During the inspection the inspectors spoke to two patients who also provided positive feedback on their experiences.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- 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 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 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)
The centre provides basic partner treatment services only and therefore is not subject to the counselling requirements of schedule 3 of the HF&E Act 1990 (as amended).

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not offer egg or sperm sharing, therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not offer treatments involving surrogacy arrangements therefore this area of practice is not applicable to this inspection.

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.

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

Information

What the centre does well

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

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

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

What the centre does well

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

Legal parenthood (Guidance note 6)
This centre provides only basic partner treatment services under its HFEA licence. It does not provide treatment with donor gametes. Therefore, requirements related to consent to legal parenthood were not relevant at this inspection.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Consent to disclosure to researchers' requirements are not relevant to basic partner IUI services, therefore this area of practice is not applicable to this inspection.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
The centre does not create embryos therefore this area of practice is not applicable to this inspection.

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 and processing of gametes.

Storage of gametes and embryos (Guidance note 17)
The centre does not store gametes or embryos therefore this area of practice is not applicable to this inspection.

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

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre does not create or store embryos therefore this area of practice is not applicable to this inspection.

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 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 provided an annual return for IUI treatments undertaken in 2019 within the required timeframe (General Direction 0005).
What the centre could do better Nothing identified at this inspection.

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 two 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

As this centre provides partner IUI treatment only, the centre's success rates are not subject to on-going monitoring through the HFEA risk tool.

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 areas of non-compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or 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
None identified at this inspection.		The PR thanks the HFEA for its detailed inspection and for its advice following the inspection. As a unit we have identified areas for practice improvement during audit and have already initiated changes which will make the delivery of patient care more consistent and effective. We undertake to continue to monitor this process with rigorous audit.	

Major areas of non-compliance

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

- which poses an indirect risk to the safety of a patient, donor, embryo or 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
None identified at this inspection.		The PR is relieved that there are no critical or major areas of non-compliance and as a unit we undertake to maintain our compliance to the statute of the HFEA Act.	

Other areas of practice that require improvement

'Other' areas of practice that require improvement are any areas of practice which cannot be classified as either a critical or major area of non-compliance, but which indicate a departure from statutory requirements or good practice.

An 'other' area of non-compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
None identified at this inspection.		We undertake to continues to maintain the quality and safety of our service and to ensure its effective delivery.	

Reponses from the Person Responsible to this inspection report
The PR sincerely thanks the HFEA inspection team for their inspection and for their advice and help over the period leading up to and during the inspection. We are glad that our service is fully compliant and it our aim to preserve this level of compliance. Audit has shown us that minor changes are necessary to ensure the safety and efficacy of our service continues and we have undertaken to implement these changes and subject them to further audit. We look forward to working in conjunction with the HFEA to ensure that patient and client experience is maximised and the efficacy of licenced treatment is increased. We understand that Novel Coronavirus (Covid-19) has the potential to affect our service as our clinic is based within an NHS Hospital which will become a Coronavirus Centre in the event of a serious and sustained pandemic. Our unit will not be used for direct Covid-19 patient care under such circumstances, but it may become necessary to restrict our practice in the interest of public safety and to limit the potential for viral spread. We undertake to keep our inspection team and clients fully informed of any decisions taken at Trust level which may impact our service and the delivery of care.