Executive Licensing Panel Minutes

Centre 0021 (Hull IVF Unit)

Renewal Inspection Report

Variation to Change Person Responsible (PR)

Date:	6 April 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Helen Crutcher Dan Howard	Director of Strategy and Corporate Affairs Risk and Business Planning Manager Chief Information Officer
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood	Licensing Manager

Declarations of interest

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

The panel had before it:

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

1. Consideration of Application

1.1. The panel 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 Hull IVF Unit is currently located in the Hull and East Yorkshire Women's and Children's Hospital and has held a treatment and storage licence with the HFEA since 1992. Other licensed activities at the centre include the storage of gametes and embryos. The centre provides a full range of fertility services.

1.3. The panel noted that the centre is planning to move to a new purpose built facility later in the year and an application to change premises will be submitted in due course.

1.4. The panel noted that the centre has submitted an application for a change of Person Responsible (PR) and this will also be for consideration at the meeting.

1.5. The panel noted that, in the 12 months to 31 January 2021, the centre provided 432 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small sized centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers.

1.6. The panel noted that, HFEA register data, for the period November 2019 to October 2020, show the centre's success rates for IVF and ICSI are in line with the national averages.

1.7. The panel noted that, in 2020, the centre reported one cycle of partner insemination, with no pregnancy. This represents a clinical pregnancy rate which is comparable to the national average.

1.8. The panel noted that, HFEA register data, between November 2019 and October 2020, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 1%. This represents performance that is statistically lower than the 10% multiple live birth rate target for this period.

1.9. The panel noted that the centre followed professional body guidance to suspend all non-essential treatments in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services.

1.10. The panel noted that, the centre's interim inspection occurred in June 2019 and a renewal inspection was scheduled to be undertaken by June 2021. However, due to the Covid-19 pandemic, a Desk Based Assessment and Risk Based Approach (DBA/RBA), was conducted for this renewal of centre's licence. It was established that any items of concern identified could be reviewed effectively using virtual technology, rather than an on-site inspection. This process removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

1.11. The panel noted that the DBA was conducted on 11 February 2021, which included telephone conversations with key members of staff.

1.12. The panel noted that, at time of the inspection, there were two major areas of non-compliance concerning infection control/safety and suitability of premises and medicines management. There were also two 'other' non-compliances regarding information and obligations and reporting requirements. Since the virtual inspection, the PR has fully implemented the recommendation in relation to infection control/safety and suitability of premises. The PR has provided evidence that actions have been taken to address the outstanding recommendations made in the report and has committed, where required, to audit the effectiveness of those

actions within the required timescales. The proposed PR has confirmed that he 'will take responsibility for any outstanding non-compliances noted in the recent inspection reports.'

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

1.14. The panel noted that the inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

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

1.16. The panel noted that the inspection team recommends the renewal of the centre's treatment and storage licence, for a period of four years, without additional conditions, subject to the recommendations in the report being implemented in the prescribed timescales.

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

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

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 to renew the centre's treatment and storage licence for a period of four years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

3. Change of Person Responsible - Consideration of Application

3.1. The panel considered the papers, which included a completed application form, an executive summary, previous licensing minutes, a CV and confirmation of acceptance from the proposed Person Responsible (PR).

3.2. The panel noted that an application to change the PR for Hull IVF Unit has been received by the HFEA on 10 March 2021 and it is requested to be considered by the Executive Licensing Panel (ELP).

3.3. The panel noted that the proposed PR, Mr Thomas Keith Cunningham, has academic qualifications in the field of medicine and has more than two years of experience which is directly relevant to the activity to be authorised by the licence. The proposed PR has successfully completed the HFEA PR Entry Programme (T/1382/82).

3.4. The panel noted that, from the information provided, that the character, qualifications and experience of the proposed PR, Mr Thomas Keith Cunningham, are suitable to carry out a PR's duties under section 17 of the HFE Act 1990 (as amended).

3.5. The panel noted that the centre had a renewal licence inspection on 11 February 2021, where two major and two 'other' areas of non-compliance were identified. The proposed PR is aware of the non-compliances and has agreed to take responsibility for any outstanding issues.

3.6. The panel noted that all the information required under General Directions 0008 has been provided.

3.7. The panel noted that inspectorate's recommendation to vary the centre's licence to Mr Thomas Keith Cunningham, as the PR.

4. Decision

4.1. The panel agreed that it was in receipt of the appropriate documentation as required by the HFE Act 1990 (as amended) in relation to Section 16(2), which sets out the requirements with regard to the role of Licence Holder and Person Responsible.

4.2. The panel endorsed the inspectorate's recommendation and agreed to vary the licence of Hull IVF Unit (centre 0021) with immediate effect to reflect the change of Person Responsible to Mr Thomas Keith Cunningham, in accordance with Section 18A of the HFE Act 1990 (as amended).

5. Chairs signature

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

Signature

Name

Clare Ettinghausen

Date

12 April 2021

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 report provides information on the centre's application to renew its existing licence. Licensed centres usually receive a licence to operate for up to four years, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law).

The 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: 11 February 2021

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 and communications received from the centre.

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

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

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

This centre was last inspected in June 2019, therefore an on-site inspection should usually be conducted by June 2021. However, following the DBA/RBA for this clinic, it was concluded that any items of concern identified during the DBA were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site inspection. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

This inspection was therefore carried out by DBA followed by a virtual inspection, which included telephone conversations with key members of centre staff.

Inspectors: Polly Todd (lead); Grace Lyndon; Karen Conyers; Sarah Stedman (HFEA observer)

Date of Executive Licensing Panel: 6 April 2021

Centre name	Hull IVF Unit
Centre number	0021
Licence number	L/0021/14/a
Centre address	Hull and East Yorkshire Women and Children's Hospital, Hull Royal Infirmary, Anlaby Road, Hull, HU3 2JZ, United Kingdom
Person Responsible	Mr Stephen Maguiness
Licence Holder	Dr John Robinson
Date licence issued	1 October 2017
Licence expiry date	30 September 2021
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Hull IVF Unit is currently located in the Hull and East Yorkshire Women's and Children's Hospital and has held a Treatment and Storage licence with the HFEA since 1992. The centre are planning to move to a new purpose built facility later in the year and will be making an application to change premises at that time. The centre provides a full range of fertility services.

The centre provided 432 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2021. In relation to activity levels this is a small centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers.

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

The centre has also submitted an application for a change of Person Responsible (PR) which is being considered by the ELP at the same time as this report.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period November 2019 to October 2020 show the centre's success rates are in line with national averages.

In 2020, the centre reported one cycle of partner insemination with no pregnancy, which is in line with the national average.

Multiple births[2]

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

Between November 2019 and October 2020 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 1%. This represents performance that is statistically lower than 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;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including two major and two 'other' areas of non compliance.

Since the inspection, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales. The proposed PR has confirmed that he 'will take responsibility for any outstanding non-compliances noted in the recent inspection reports.'

Major areas of non compliance:

- The PR should ensure that infection prevention and control measures and fire safety practices are compliant with regulatory and best practice guidance.
- The PR should ensure compliance with medicines management regulatory requirements and professional body guidance.

'Other' areas that requires improvement:

- The PR should ensure that information provided to patients on the clinic's website is compliant with the requirements of the CoP guidance.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have two major of areas of concern.

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

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy / live birth rates are below the target at a statistically significant level.

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

The inspection team recommends the renewal of the centre's 'Treatment and Storage' licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Centre 0021 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 partially suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

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

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be 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/safety and suitability of premises (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 facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

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

Multiple births (Guidance note 7; General Direction 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. 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 note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with

HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

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

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. The centre has not yet 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. The centre is therefore compliant with General Direction 0006.

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

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

Quality management system (QMS) (Guidance note 23)
The 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 any satellite or transport arrangements, therefore this area of practice is not relevant 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 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

Infection control/ Safety and suitability of premises (Guidance Note 25)
On inspection the following issues were noted:

- there were reams of paper and boxes on the stock room floor, this means that the floor cannot be adequately cleaned;
- there was a trolley and some rubbish bags in a corridor which was a designated fire exit. The inspection team considered this to be a fire hazard and safety risk to patients and staff needing to exit the building in an emergency.

See recommendation 1.

SLC T2; DH Health Building Note 00-09: 'Infection control in the built environment' (2013); Regulatory Reform (Fire Safety) Order 2005 14(1).

Medicines management (Guidance Note 25)
There were several entries in the Controlled Drug (CD) register where:

- the carry-over from one page to another was not always recorded, signed or witnessed;
- corrections in the CD register were not made in line with regulatory requirements which require corrections of entries be made by way of a marginal note or footnote, which specifies the date on which the correction is made. In the absence of the centre having an SOP which indicates how corrections should be made in the register, the inspection team expects the Regulations to be followed.
- the amount of controlled drug supplied was not routinely witnessed.

See recommendation 2.

SLC T2; Safe use and management' Misuse of Drugs (safe Custody) Regulations 2001; Association of Anaesthetists 'Controlled drugs in perioperative care 2019: Good practice for controlled drugs administered directly by registered healthcare professionals in the theatre environment'.

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 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 **Preimplantation genetic screening (Guidance note 9);** **Embryo testing and sex selection (Guidance note 10)** The centre is not licensed to perform embryo testing therefore this area of practice was not relevant 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. Only 41 patients have provided feedback in the last 12 months, giving an average 4.5 star rating to the clinic. However, this is an improvement since the last inspection report in 2019, where no patients had provided feedback to the HFEA. The PR is encouraged to continue to promote this system of feedback. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to.

The centre's own most recent patient survey responses were also reviewed. One hundred and twenty four responses were provided to the clinic with 45% giving an overall satisfaction rating of 97%. Almost all patients providing feedback indicated that they would recommend the clinic to family and friends.

The inspection was conducted virtually, so the inspectors did not speak to any patients.

On the basis of this feedback and discussions held 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)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

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

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

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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

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

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

Information

What the centre does well

Information (Guidance note 4)
The centre's procedures for providing information to patients and / or donors are broadly 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

Information:
The website does not have a statement stating that information on success rates is of limited value in comparing centres and choosing where to seek treatment.

See recommendation 3.

CoP guidance 4.8(g).

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

What the centre does well

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

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

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

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Three 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 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 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's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

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

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)

The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities

expressly authorised by the Authority.

What the centre could do better

Use of embryos for training staff (Guidance note 22)

The information leaflet provided by the centre for the DBA was not compliant with requirements of SLC T97c as it did not inform patients that they can vary or withdraw the terms of their consent until the point the embryos are used in training (SLC T97c). A similar finding was made at the time of the renewal inspection in 2017. On further investigation by the centre, it was noted that this leaflet was one only used in the centre's waiting room (until May 2020) and is not the primary information leaflet that is sent out to patients in the 'consent pack'. Immediately after the inspection the centre's consultant Embryologist/Quality Manager undertook an incident investigation and root cause analysis and identified that the leaflet used in the waiting room had not been updated as a result of the findings of the renewal inspection in 2017, whereas the primary information document that is sent out to patients had been. In view of the immediate actions taken by the centre to investigate this issue and corrective actions identified to address the finding the inspection team does not consider a formal recommendation is necessary at this time.

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)
It is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

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

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

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
There are three outstanding historic treatments using unregistered donors which have not been reported to the HFEA, the details of these patients have been provided to the PR.

See recommendation 4.

General Direction 0005.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2019, recommendations for improvement were made in relation to one area of major non compliance and one 'other' area of non compliance.

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

On-going monitoring of centre success rates

In 2019, the centre was asked to review procedures for the provision of treatments involving fresh IVF in patients under 38 years old. The PR responded to the request, provided a report to the HFEA, and gave a commitment to keep success rates in this group of patients under review. No further success rate alerts have been issued for this group of patients.

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.			

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
1. Infection control/ safety and suitability of premises On inspection the following issues were noted: • there were reams of paper and boxes on the stock room floor, this means that the floor cannot be adequately cleaned; • there was a trolley and some rubbish bags in a corridor which was a designated fire exit. The inspection team considered this to be a fire hazard and safety	The PR should ensure that infection prevention and control measures and fire safety practices are compliant with regulatory and best practice guidance. The PR should address the issues identified in this report. The PR should confirm to the centre's inspector that the issues identified have been addressed when responding to this report.	We have checked all of the items on the notice board in the waiting area. All of them are laminated. Some of the laminations are matt finished which may have appeared not to have a wipe clean surface. If asked, we could have confirmed that this was the case during the virtual tour. There were reams of paper in the store room that have now been removed. Staff have been reminded that all stock must be stored off the floor for infection control purposes to allow washing and cleaning of	The executive acknowledges the PR's response and actions taken to address this recommendation. No further action is required.

risk to patients and staff needing to exit the building in an emergency. SLC T2. DH Health Building Note 00-09: 'Infection control in the built environment' (2013). Regulatory Reform (Fire Safety) Order 2005 14(1).		the floor. The Unit has very limited space for storage. We have had to ensure that we have adequate stock levels as a precaution for Brexit. This has caused the issue. As part of our risk assessment we will check the stock room weekly to ensure that the floor is not used for storage. We accept that the trolley was seen on the day of the inspection. If asked, we could have explained that this was being used to bring some heavy boxes of patient records from the adjacent office to the archive room where it is normally kept. The bags contained papers. It is not our usual practice to leave this trolley in the corridor and the administration staff know not to store anything in the corridor. Staff have been reminded that the trolley must be put away straight after it has been used.	
2. Medicines management There were several entries in	The PR should ensure compliance with medicines	1.As part of the IVF Unit's Medicine Management Policy,	The executive acknowledges the PR's response and review

the CD register where: • the carry-over of stock from one page to another was not always recorded, signed or witnessed; • corrections in the CD register were not made in line with regulatory requirements which require corrections of entries be made by way of a marginal note or footnote, which specifies the date on which the correction is made. In the absence of the centre having an SOP which indicates how corrections should be made in the register, the inspection team expect the Regulations to be followed. SLC T2. Safe use and management' Misuse of Drugs (safe Custody) Regulations 2001. Association of Anaesthetists 'Controlled drugs in	management regulatory requirements and professional body guidance. The PR should review medicines management practices and procedures including staff training requirements, and provide a summary report of this review, including any corrective actions taken and timescales for their implementation to the centre's inspector by 17 May 2021. Three months after this 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 review should be provided to the centre's inspector by 17 August 2021.	Nurses must read and comply with the Hull University Hospitals Trust Drugs Policy and comply with the Trust's policy regarding 'ADDITIONAL PRECAUTIONS TO BE TAKEN WHEN HANDLING and STORING CONTROLLED DRUGS'. This policy states how mistakes and corrections will be made with regards to the controlled drugs register. The Hull IVF Unit 'Medicine Management Policy' has been be ammended to incorperate this information and ensure it is more accessible / explicit. 2.An internal audit performed in the Unit in Feb 2021, picked up that carry-over stock was not always recorded and witnessed. A staff training and teaching session was subsequently performed with the nursing staff at this time. As four of the nursing staff were new this will be repeated again in April 2021. A further audit of a.Corrections in the register b.Carry over stock records	of medicines management practices. No further action is required beyond submission of an audit of medicines management practice due by 17 August 2021.

perioperative care 2019: Good practice for controlled drugs administered directly by registered healthcare professionals in the theatre environment'.		Will be carried out on 10th May 2021.	

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
3. Information: The website does not have a statement stating that information on success rates is of limited value in comparing centres and choosing where to seek treatment. CoP guidance 4.8(g).	The PR should ensure that information provided to patients on the clinic's website is compliant with the requirements of the CoP guidance. The PR should review the clinic's website with reference to the requirements in the CoP and make the necessary amendments. The PR should confirm to the centre's inspector when this has been completed. It is expected that the clinic's website is compliant with requirements by 17 August 2021.	The website was audited as part of the internal audit programme on the 09/12/2020 and whilst the link was present the comment required by GN 4.8 g was missing and this was corrected 15/12/2020, prior to the inspection. For point 4.8e we believe the site is compliant (see tab 'our success rates HFEA validated'). This data in the table is for 2017 as stated, however the date in the title text header was not updated and is incorrect, hence the confusion. The 2018 data has now been released the HFEA website, the Unit website data is due for review March 2021 and will be updated accordingly.	The executive notes the PR's response. No further action is required beyond confirmation that the website is compliant with all aspects of guidance note 4 in the CoP, due by 17 August 2021.

4. **Obligations and reporting requirements:** There are three outstanding historic treatments using unregistered donors which have not been reported to the HFEA the details of these patients have been provided to the PR. General Direction 0005.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should provide the information for the three outstanding donor treatments when responding to this report. The PR should review procedures for submitting data to the HFEA and provide a summary report of this review, with any corrective actions implemented to the centre's inspector by 17 May 2021. Three months after this review PR should audit procedures for submitting data to the HFEA to ensure that any 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 17 August 2021.	As stated at the time of the inspection, we have no record of having received the initial request for the historic treatments, which was apparently made in May 2020. As we always reply quickly to these requests, would it not have been reasonable for a follow up request to have been made sooner? It may be advantageous to have a read receipt for these types of requests. I did make the HFEA aware of problems with the HUTH e-mail system some time ago, and have asked that all communication be sent to both my e-mail addresses. All treatments are reported within the timeframes required by GD 0005 (as per audit evidence submitted prior to the inspection and our Clinic dashboard statistics- which consistently show no missing forms or outstanding errors). As an additional measure all forms for the past 10 years have been audited - 5 validation errors appeared (this would equate to an error rate	The executive acknowledges the PR's response and efforts to resolve this matter and confirms that the PR has been very proactive in addressing this recommendation. The PR is unable to progress further with implementing this recommendation without the support of the HFEA's register team. The centre's inspector will continue to liaise and support the PR in getting the matter resolved. No further action is required beyond that noted above.

		of <0.01%). Forms have been amended, if possible. There are no systematic errors or corrective actions to implement as overall compliance is already maintained. The issue raised at this inspection relates to 3 historic cases (from 2000-2003) using donors recruited at other licensed centres and imported (details submitted to HFEA). The requirement to register these donors is with the recruiting centre. The Centre has been contacted and have provided evidence that these donors were registered at the time of use and this evidence has been submitted to the HFEA for review. The HFEA registry team, have indicated that the forms need to be updated, however it is not possible to make amendments for this historic data as a system error message appears 'root element missing'. It is difficult to conduct a full investigation as the EDI system can not be	

		interrogated for this time period. EDI support have been contacted.	

Reponses from the Person Responsible to this inspection report
Obviously we are working in difficult times, and the use of a virual tour is a new experience for us all. Two issues in this report (laminating patient info, and the trolley in the corridor) might have been better addressed at the time of the tour, or in the final inspection meeting. I am disappointed that the Registry request is listed as an issue for this clinic. As stated I think it would be reasonable for the HFEA to ask for read receipts, and follow up requests if not responded to. We have received e-mail confirmation (forwarded to Neil McComb at the HFEA on 15th March) that the donors are registered with the HFEA according to their anonymised donor usage reports. So we have asked why your records don't match up with this? I also note from e-mail correspondence today that help from edisupport has been requested by the HFEA. The executive acknowledges the PR's comments, and in particular his comments about the patient information sheets in the waiting room. The executive has subsequently removed this area of non-compliance from the report.