Executive Licensing Panel Minutes

Centre 0035 (Oxford Fertility)

Renewal Inspection Report

Date:	4 May 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Yvonne Akinmodun Kathleen Sarsfield-Watson	Director of Strategy and Corporate Affairs Head of Human Resources Communications Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood Niamh Marren	Licensing Manager Regulatory Policy 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 Oxford Fertility has held a licence with the HFEA since 1992. The centre provides a full range of fertility services including gamete and embryo storage and embryo testing.

1.3. The panel noted that, in the 12 months to 31 January 2021, the centre provided 1586 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a large sized centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers.

1.4. The panel noted that, HFEA register data, for the period 1 November 2019 to 31 October 2020, show the centre's success rates for IVF and ICSI are in line with the national averages.

1.5. The panel noted that, in 2020, the centre reported 6 cycles of partner insemination, with no pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.6. The panel noted that, HFEA register data, between 1 November 2019 and 31 October 2020, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target for this period.

1.7. 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.

1.8. The panel noted that the centre reported a grade A incident to the HFEA in January 2020. This incident was investigated by the centre and a HFEA inspection team; a report of the incident investigation and inspection was presented to the Licence Committee (LC) on 7 May 2020. No regulatory sanctions were recommended or imposed and the committee acknowledged the positive and proactive way the incident had been handled. However, the committee asked that the centre's corrective actions were followed up at the licence renewal inspection to ensure they have been implemented and are effective.

1.9. 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. Following this, it was established that any items of concern identified were of relatively low risk and 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.

1.10. The panel noted that a DBA, followed by a virtual inspection, was conducted on 23 February 2021, which included videoconferencing with key members of staff.

1.11. The panel noted that, at time of the inspection, there were two major areas of non-compliance concerning medicine management and storage of gametes and embryos. There were also two 'other' non-compliances regarding the quality management system (QMS) and the website. Since the virtual inspection, the Person Responsible (PR) has implemented the recommendations surrounding the website and the QMS. The PR has given a commitment to

fully implementing the recommendations concerning medicines management and the storage of gametes and embryos.

1.12. The panel noted that, in respect of the Grade A incident reported to the HFEA in January 2020, the inspection team confirmed that the centre has learnt from this incident and implemented appropriate changes in processes to prevent recurrence.

1.13. The panel noted that the PR is encouraged to continue to use the QMS to best effect to monitor and improve their success rates and the quality of the service offered to patients. The centre is well led and provides a good level of patient support.

1.14. The panel noted that, as a result of the UK's departure from the Eurpoean Union (EU) a relicensing exercise is currently in progress. This follows approval by the Licence Committee of a variation without application on 4 March 2021. This means that new offer licences are being sent to all clinics, incorporating changes to some of the standard licence conditions. The varied licences will all come into effect on 1 July 2021, after the transition period ends on 30 June 2021.

1.15. The panel noted that this renewal is being considered during that relicensing period. However, since this renewal licence (if approved) will begin on 1 October 2021, which is after 1 July 2021, the renewal licence will simply follow on in the normal way from the centre's current active licence, which by that date will be the new, varied, licence.

1.16. The panel noted that the inspection team recommends the renewal of the centre's treatment (including embryo testing) 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.

1.17. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to section 24(4AD). Such certificates are generally synchronised to the centre's HFEA licence. The executive therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

2. Decision

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

2.2. The panel noted that the premises to be licensed are suitable for the conduct of 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 (including embryo testing) 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.

2.5. The panel endorsed the executive's recommendation to renew the centre's import certificate, in line with the centre's licence.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

10 May 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: 23 February 2021

Purpose of inspection: Renewal of a licence to carry out Treatment (including embryo testing) and Storage.

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection 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 desk based assessment followed by a virtual inspection, which included videoconferencing with key members of centre staff.

Inspectors: Louise Winstone, Lesley Brown and Grace Lyndon

Date of Executive Licensing Panel: 4 May 2021

Centre name	Oxford Fertility
Centre number	0035
Licence number	L/0035/14/b
Centre address	Institute of Reproductive Sciences, Oxford Business Park North, Oxford, Oxfordshire, OX4 2HW, United Kingdom
Person Responsible	Mr Tim Child
Licence Holder	Ms Laurel Hird
Date licence issued	01 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:

Oxford Fertility has held a licence with the HFEA since 1992.

The centre provides a full range of fertility services including gamete and embryo storage and embryo testing.

The centre provided 1586 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2021. In relation to activity levels this is a large centre.

The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers.

The centre reported a grade A incident to the HFEA in January 2020. This incident was investigated by the centre and a HFEA inspection team, and a report of the incident investigation and inspection was presented to the Licence Committee on 7 May 2020. No regulatory sanctions were recommended or imposed and the committee acknowledged the positive and proactive way the incident had been handled. However, the committee asked that the centres corrective actions were followed up at the licence renewal inspection to ensure they have been implemented and are effective.

The centre's licence was varied in July 2019 to change the Licence Holder.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 November 2019 to 31 October 2020 show the centre's success rates are in line with national averages.

In 2020, the centre reported six cycles of partner insemination with no pregnancies which is in line with the national average.

Multiple births[2]

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

Between 1 November 2019 and 31 October 2020, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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

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

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- 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 visit, the following recommendations have been fully implemented:

'Other' areas that require improvement:

- The PR should ensure that the timeframe in which screening blood samples are provided is clearly documented in the relevant SOP's.
- The PR should ensure that the centre's website is compliant with guidance.

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

Major areas of non compliance:

- The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice requirements.
- The PR should ensure that there is effective written consent in place for all gametes and embryos that are in storage.

Regarding the grade A incident reported to the HFEA in January 2020, the inspection team can confirm that the centre has taken full learning from this incident and has implemented appropriate changes in processes to prevent recurrence.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have two major areas of concern. The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy rates meet the target. The PR is encouraged to continue to use the quality management system (QMS) to best effect to monitor and improve their success rates and the quality of the service offered to patients.

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

The inspection team recommends the renewal of the centre's Treatment (including embryo testing) 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 0035 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

As a result of the UK's departure from the EU, there is currently a relicensing exercise under way. This follows approval by the Licence Committee of a variation without application on 4 March 2021. This means that new offer licences are being sent to all clinics, incorporating changes to some of the standard licence conditions. The varied licences will all come into effect on 1 July 2021, after the transition period ends on 30 June 2021.

This renewal is being considered during that relicensing period. However, since this renewal licence (if approved) will begin on 1 October 2021, which is after 1 July 2021, the renewal licence will simply follow on in the normal way from the centre's current active licence, which by that date will be the new, varied, licence.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

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

What the centre does well

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

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

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

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

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

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

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

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

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

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

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

recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)

The centre has systems in place to manage and monitor the prevention and control of infection that are 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 been allocated an ITE import certificate and imports of gametes and embryos from TCSs outside the EU/EEA have been made since the introduction of the ITE import certification scheme on 1 April 2018.

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

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

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

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

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

Equipment and materials (Guidance note 26)

The centre uses equipment and materials that are 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

Medicines management (Guidance Note 25)
The following issues were identified in the controlled drugs (CD) register:

- Some entries in the CD register were obliterated by over-writing. This is not 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;
- In the stock balance column of the CD register, the number '1' was written to look like a number '2', ('11' looked like '21'). This is misleading and gives the wrong impression of the number of ampoules that remain in the controlled drugs cupboard;
- The carry-over from one page to another was not always signed or witnessed;
- In one entry, the amount of drug supplied, administered or discarded was not documented;
- The amount of controlled drug given to the patients was not always recorded on the patient's prescription chart.

See recommendation 1.

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'.

Quality management system (QMS) (Guidance note 23)

Audits provided by the centre as part of the DBA and discussions with laboratory staff during the virtual inspection provided assurance that blood samples are provided within the timeframe specified by the Authority. However, the centre's SOP for blood borne virus testing describes that these tests can be carried out at any time in the cycle. Centre staff described that this referred to the menstrual cycle and not the treatment cycle, however this is not clear from the SOP.

See recommendation 3.

SLC T33.

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

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

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

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

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

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. 96 patients have provided feedback in the last 12 months, giving an average five star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. All patients confirmed that they had paid what they expected to.

There were two negative comments regarding the waiting area being shared with Ultrasound Direct and this was discussed with centre staff. They advised the inspectors that actions will be taken to address this matter. The inspection team urge the centre to continue to monitor patient feedback to ensure the actions taken are effective.

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

Based on this feedback and information received during 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 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 sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind;
- egg providers are fully assessed and medically suitable; and
- the benefit offered is the most suitable for the egg 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 (Guidance note 4)
The centre's website is not compliant with guidance because the live birth rate data is displayed as 'per treatment cycle started' and not 'per embryo transferred'.

See recommendation 4.

CoP Guidance 4.8.

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

What the centre does well

Consent (Guidance note 5 and 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 that inspection in April 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. Five 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 partially 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
Storage of gametes and embryos (Guidance note 17)

The centres own storage audit was reviewed as part of the DBA. This showed that four patients had extended storage past the statutory storage period of ten years but did not have a valid Medical Practitioners Statement (MPS), signed within the relevant period. This was discussed during the virtual inspection, where centre staff described that further investigations, with legal involvement are currently ongoing.

See recommendation 2.

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 Paragraph 4.

Use of embryos for training staff

What the centre does well

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

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

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are 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 HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

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

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

Section 3: Monitoring of the centre's performance

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

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

On-going monitoring of centre success rates

In 2020, the centre was asked to review procedures for the provision of ICSI treatment in all age groups. The PR responded to the request and during discussions at the time of the inspection, provided a commitment to keep success rates in this group of patients under review.

Areas of practice requiring action

This 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.			

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 partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. Medicines management The following issues were identified in the controlled drugs (CD) register: • Some entries in the CD register were obliterated by over-writing. This is not 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	The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice requirements. The PR should review practices and procedures relating to medicines management including, but not exclusively, the issues identified in this report. A summary report of this review, including any corrective actions and staff training requirements, with timescales for implementation,	We have reviewed the inspection feedback with the Lead Consultant Anaesthetist, Recovery Nurse and all trained recovery staff and have taken steps to improve the quality of record keeping within the CD Register. We will continue to monitor compliance with regulatory requirements in respect of all aspects of medicines management through regular planned audit of practices. The outcome of audits will be shared with the HFEA within	The executive acknowledges the PR's response and commitment to implementing this recommendation. The outcome of audits will be provided to the centre's inspector by 23 May 2021 and the re-audit by 23 August 2021. **Further action is required.**

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; • In the stock balance column of the CD register, the number '1' was written to look like a number '2', ('11' looked like '21'). This is misleading and gives the wrong impression of the number of ampoules that remain in the controlled drugs cupboard; • The carry-over from one page to another was not always signed or witnessed; • In one entry, the amount of drug supplied, administered or discarded was not documented; • The amount of controlled drug given to the patients was not always recorded on the	should be provided to the centre's inspector by 23 May 2021. Three months after the review the PR should audit medicines management practice and procedures to ensure that any corrective actions implemented have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 23 August 2021.	the specified timeframe of 23 May 2021. SOP 1.8: Controlled Drug Ordering, Storage, Administration And Destruction which includes detail for any corrections to the register will be updated to ensure further clarity on how corrections should be made to remain compliant. All pages of the CD Register where a carryforward entry was required contained a signature and witness, however, we accept that the witness signature in one entry was not correctly placed within the allocated space. We will also ensure staff are trained in how to correct the CD register when an entry is started then no controlled drugs used and ensure all requirements of record keeping within the CD register are compliant going forward. For clarification, the amount of controlled drug given is	

patient's prescription chart. 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'.		recorded on the patients drug chart correctly. It was found after inspection that the 'mg/mcg' text was missing from the table within the 'GP Summary' provided at discharge following OCR. This omission within the table was immediately rectified post inspection to indicate mg/mcg against each drug option. Following submission of our report to the HfEA by 23rd May 2021 we will re-audit and provide a summary report from this re-audit to the inspector by 23 August 2021 as requested.	
2. Storage of gametes and embryos The centres own audit showed that four patients had extended storage past the statutory storage period of ten years but did not have a valid Medical Practitioners Statement (MPS), signed within the relevant period. This was discussed during the virtual inspection, where	The PR should ensure that there is effective written consent in place for all gametes and embryos that are in storage. With regards to the four cases identified with a delay in the signing of the MPS form, the PR should provide the centre's inspector with a summary of any legal advice	We will provide the summary of legal advice, actions and timescales, as requested, regarding the four cases identified within our intenal audit to the inspector by 23 May 2021. A review of all procedures for extending storage consent is currently in progress and the summary of this review will be	The executive acknowledges the PR's response and commitment to implementing this recommendation. The summary of the review and legal advice obtained will be provided to the centre's inspector by 23 May 2021 and the follow up review by 23 August 2021.

centre staff described that further investigations, with legal involvement are currently ongoing. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 Paragraph 4.	obtained as well as the centre's intended actions and anticipated timescales for their implementation by 23 May 2021. The PR must review the procedures for extending storage consent and ensure they are robust and effective in ensuring written effective consent is in place for all cryopreserved gametes and embryos. The PR must provide a summary report of this review including any corrective actions taken, to the centre's inspector by 23 May 2021. Three months after the review, the PR must audit storage consent procedures to ensure that corrective actions implemented have been effective in achieving compliance. A summary report of this review should be provided to the centre's inspector by 23 August 2021.	shared with the inspector by 23 May 2021. A further review will be performed and the results shared with the inspector by 23 August 2021.	**Further action is required.**

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. Quality management system (QMS) Audits provided by the centre as part of the DBA and discussions with laboratory staff during the virtual inspection provided assurance that blood samples are provided within the timeframe specified by the Authority. However, the centre's SOP for blood borne virus testing describes that these tests can be carried out at any time in the cycle. Centre staff described that this referred to the menstrual cycle and not the treatment cycle, however this is not clear from the SOP. SLC T33.	The PR should ensure that the timeframe in which screening blood samples are provided is clearly documented in the relevant SOP's. The PR should review relevant SOP's and ensure that the timeframes in which blood samples are to be provided are clearly documented. The PR should provide the updated SOP's to the centre's inspector by 23 May 2021.	We have reviewed our SOPs and have a single SOP which details the screening for blood borne virus testing. This has been updated with the suggested revision made within the text to clarify the timing in which screening blood samples are provided. A copy of the revised SOP has been supplied with this report.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The revised SOP has been provided. **No further action is required.**

4. Website The centre's website is not compliant with guidance because the live birth rate data is displayed as 'per treatment cycle started' and not 'per embryo transferred'. CoP Guidance 4.8.	The PR should ensure that the centre's website is compliant with guidance. The PR should audit the content of the centre's website against the requirements of CoP Guidance 4.8 and should provide a report of the audit, including plans for corrective actions, to the centre's inspector by 23 May 2021.	We have reviewed our website against the requirements of CoP Guidance 4.8. A copy of the audit detailing all non-compliance and corrective actions has been supplied with this report. All corrective actions have been implemented and the website is now compliant with the guidance.	The executive acknowledges the PR's response and commitment to implementing this recommendation. **No further action is required.**

Responses from the Person Responsible to this inspection report
This was our first experience of a virtual inspection and the pre-work and data submission required beforehand made the inspection very smooth and professional. We welcome all comments from the inspection team and will work to complete all recommendations within the allocated time frame.