Renewal 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: 18 January 2023

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 response to UK measures to contain and mitigate the spread of Covid-19, 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.

This inspection was carried out by DBA followed by an onsite visit.

Inspectors: Polly Todd (lead), Karen Conyers, Lynne Nice (external advisor) and Sarah Charles (DBA only)

Date of Executive Licensing Panel: 2 May 2023

Centre name	Wales Fertility Institute, Neath
Centre number	0329
Licence number	L0329/3/b
Centre address	Wales Fertility Institute, Neath Neath Port Talbot Hospital Baglan Way Port Talbot

	SA12 7BX
Person Responsible	Dr Paul Knaggs
Licence Holder	Mrs Christine Morrell
Date licence issued	01 August 2019
Licence expiry date	31 July 2023
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Wales Fertility Institute, Neath has held a licence with the HFEA since 2013 and currently has a 'Treatment (including embryo testing) and Storage' licence. The centre provides a full range of fertility services including embryo testing and storage of gametes and embryos.

The centre works closely with Wales Fertility Institute Cardiff (HFEA licensed centre 0049) which enables patients to access services local to their area. The PR of centre 0329 is also PR of centre 0049. The quality management system (QMS) spans across both centres with local variations, where applicable, for standard operating procedures (SOPs).

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

- 4 March 2021- All centres variation without application (European Union (EU)) exit requirements.

Pregnancy outcomes

Whilst PRISM went live in September 2021, it is still at the embedding stage working through the validation and verification exercises required to confirm accuracy of data. Until such times as this process is complete, the activity levels and success rates of the centre are not being reported.

The centre provided their own analysis of the centre's pregnancy outcomes and success rate data including the multiple birth rate for the DBA. On discussion with staff and further review of the raw data during the inspection, it appeared that not all the data may have been analysed accurately because there appeared to be a mismatch between the raw data and the key performance indicator (KPI). For example, the clinical pregnancy rate for a practitioner was recorded as 14% but the person had only carried out five cases, therefore this percentage could not be accurate.

The inspection team noted that the centre's KPI targets were a rolling average of their own recent outcomes, and the inspection team was concerned that this may not be a valuable measure to use because any decreases in their rolling averages would then decrease the KPI target and would not be effective as a target to drive continuous improvement. The inspection team also noted that the centre had identified that their KPIs were below a 'national average', however, it was not clear what this national average figure referred to as the most recent national data is not available from the HFEA due to the ongoing data validation and verification work.

SLC T32. See recommendation 1.

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) and General Directions (GD), 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 fulfilled their duty under section 17 of the HF&E Act 1990 (as amended) with the exceptions noted in this report;
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable with the exceptions noted in this report;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

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

Since the inspection visit, 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:

'Other' areas that requires improvement:

- The PR should ensure compliance with controlled drugs (CD) regulatory requirements.
- The PR should ensure compliance with General Direction 0003 to audit the effectiveness of the centre's multiple birth minimisation strategy.

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

Major areas of non-compliance:

- The PR should ensure that the centre's success rates are accurately assessed and monitored against relevant KPIs.
- The PR should ensure the quality management system (QMS) is effective in ensuring the quality of services provided.
- The PR should ensure that consenting practices and procedures are compliant with regulatory requirements.
- The PR should ensure that legal parenthood practice and audit methodology is compliant with regulatory requirements and HFEA guidance.
- The PR should ensure compliance with statutory storage regulations.
- The PR should ensure that the information provided to patients regarding the use of their embryos in training is accurate and compliant with standard licence conditions.

- The PR should ensure that record keeping practice and procedure is compliant with standard licence conditions.

Other areas of non-compliance:

- The PR should ensure that the screening of donors is compliant with standard licence conditions and professional body guidance.

Recommendation to the Executive Licensing Panel

The inspection team has assessed the renewal of the licence in accordance with the HFEA's Compliance and Enforcement policy (effective 1 June 2021) ("C&E Policy") to evaluate the level of risk of non-compliances and/or areas of poor practice identified during this inspection. The assessment provides guidance on the actions to be taken (level 1 to 3), whether any additional conditions are indicated and the appropriate length of licence to be recommended. The recommendation below has been reached following the completion of the assessment of risk, in particular, regarding the non-compliance relating to consenting processes at the clinic, (including consent to treatment and storage and legal parenthood consenting practices), considering relevant mitigating and aggravating factors, and the role of the PR based on information available at the time of the assessment.

The centre provides a good level of patient support however significant improvement is required in order for the centre to reflect suitable practices. The centre has a QMS and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

The inspection team was particularly concerned that the PR had not known about or recognised that patients had completed the WT ('Your consent to your eggs and embryos created using your eggs being used in treatment (IVF and ICSI) or stored') consent forms incorrectly. It is expected that the PR should know whether or not staff were properly trained in consenting patients following the introduction of new consent forms and in ensuring that there is a proper process in place for checking the completion of the consent forms. In addition, we have no evidence that the patients have been contacted about the anomalies noted or that the PR has recognised the potential seriousness and impact of the non-compliances in the centre's own audit.

Additionally, some of the non-compliances identified in this report were previously identified during the inspection of centre 0049 Wales Fertility Institute, Cardiff, in July 2022 (of which this PR is also the PR) and the inspection team was concerned that learning from that inspection did not appear to have been implemented into practice at centre 0329.

Where the C&E Policy assessment may have indicated options for licence lengths, the inspection team has considered these and made the most proportionate recommendation, taking into account the specific circumstance of this centre and the inspection findings. In this case, the assessment indicated a licence length of three or four years, and the executive considered it was proportionate to recommend that the centre's 'Treatment (including embryo testing) and Storage licence' is renewed for a period of three years without additional conditions, given the concerns noted. An interim inspection should be carried out in one year at which time it is expected that the PR will be able to demonstrate

robust evidence of actions that have been taken to address the issues identified during this inspection (particularly those relating to the major areas of non-compliance) and will be able to provide assurance of how they are ensuring ongoing compliance.

Centre 0329 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.

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 broadly 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

Screening of donors (Guidance note 11)
The centre provided an audit of donor records for the DBA in which it indicated full compliance with regulatory and professional body guidance. However, the centre did not provide all the required information in this audit, such as dates of screening. Therefore, the PR was asked to complete the missing data in the audit and submit to the lead inspector following the inspection.

On inspection the inspection team reviewed one of the records previously audited by the centre and found areas of non-compliance with professional guidance, that the centre had indicated to be compliant. Furthermore, on review of the updated audit provided soon after the inspection the following non-compliances were noted:

- In all four records audited there was no documented final sign off by a clinician to confirm that the donor was suitable to donate.
- In one donor record, the clinician had identified that additional screening was required for Glucose 6 phosphate dehydrogenase, due to the donor's ethnic origin, but this was not undertaken as the clinician deemed the condition was not life threatening.
- All four egg donor records audited showed the donors were only screened using serology (not serology and NAAT testing), and the eggs, or embryos created with them, were not quarantined prior to use in treatment. This goes against professional body guidance which requires that where only serology screening is undertaken, the eggs or embryos created from them should be quarantined for six months. It is not clear if there was a risk assessment for each of these cases where the centre had deviated from professional body guidance.

The inspection team was concerned that the PR did not provide reasons (at the time of the inspection) as to why the centre had not considered or followed professional guidance for the screening of donors and whether risk assessments had been carried out and documented for these cases.

SLC T52(h)(i); SLC T53(b); CoP 11.23-11.25; UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors (2019). See recommendation 8.

What the centre does well

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

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

The premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes 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 broadly compliant with guidance.

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

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

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

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

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

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

Receipt of gametes and embryos (Guidance note 15)

The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. 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 HF&E Act 1990 (as amended) was amended on 1 April 2018 by the HF&E (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 in third countries, i.e. 'third country suppliers' (TCS). From 1 April 2018 until 31 December 2020, third countries included all countries outside of the European Union/European Economic Area (EU/EEA) or Gibraltar. The legal effects of EU exit mean that from 1 January 2021, for centres in Great Britain, third countries include all countries outside the United Kingdom, while for centres in Northern Ireland, third countries include all countries which are outside of the EU/EEA. Clinics must apply to the HFEA for an ITE import certificate to allow imports from a specified clinic in a third country (i.e. a TCS), a clinic's import 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 have not been made since the introduction of the ITE import certification scheme on 1 April 2018. No imports have been made from TCS which are not specified on the centre's ITE import certificate. The centre is therefore compliant with General Direction 0006(GB).

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 partially 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 does not have any satellite or transport agreements therefore this area of inspection was 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 of the 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)
In the audit provided by the centre for the DBA, there was a mismatch in the amount of controlled drug (CD) recorded as having been given in the patient's prescription chart, to that recorded in the CD register. The centre had not identified this from their audit.

'Dangerous Drugs; The Misuse of Drugs Regulations 2001'. See recommendation 9.

Multiple births (Guidance note 7; General Direction 0003)
The PR monitors the centre's multiple pregnancy and birth rates and was aware of a recent upward trend in these outcomes compared to previous low rates. The centre's multiple pregnancy rates from their own data for all fresh and frozen embryo transfers between January 2022 and June 2022 and provided for the DBA was 11%. The inspection team noted that centre's data for multiple pregnancy rates for all IVF, ICSI and FET cycles for all age groups provided to the HFEA for the year ending 31 May 2021 was 2% which is statistically significantly below the 10% target. This was discussed with the PR during the inspection and whilst it is acknowledged that the PR is aware of, and is

monitoring this upward trend, there was no documentation of these reviews or audit of the centre's compliance with their MBMS.

General Direction 0003 paragraph 3(b). See recommendation 10.

Quality management system (QMS) (Guidance note 23)
The following issues were noted during the DBA and onsite inspection visit:

- The findings of the centre's audit of counselling had not been analysed and no corrective actions had been documented or implemented.
- The date by which corrective actions are due, and confirmation of their completion was not documented in some audits (consent, counselling and legal parenthood).
- KPIs documented for the recording keeping audit did not include the requirements for compliance with SLC T46 and T47.
- The centre's surrogacy Standard Operating Procedure (SOP) issued 1 October 2022, details incorrect information about application for Parental Orders in that it says the intended parent must be married to each other, and it references the 2010 HFEA Parental Orders Regulations rather than the HF&E Act 2008 (Remedial) Order 2018, which states that a Parental Order can be made by a sole applicant irrespective of their marital status (this was also a non-compliance at the inspection of centre 0049 in July 2022).

Given the breadth and potential impact of key issues not being identified by audit, this non-compliance has been graded as major.

See also Legal Parenthood and Consent sections of this report.

SLC T36. See recommendation 2.

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of biological sciences 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
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 (with the exceptions noted in the legal parenthood and consent sections of this report), 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

Leadership
The inspection team are aware that some of the issues identified at this inspection were identified at the inspection of centre 0049 in July 2022 including, legal parenthood, surrogacy and QMS. It would have been expected that learning from the inspection at centre 0049, was also disseminated and implemented into practice at centre 0329, which does not appear to have been the case, given the non-compliances identified.

This raises concerns as to the PR's effectiveness in leadership however no formal recommendation has been made at this stage.

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 with the exception noted in the 'Record keeping and document control' section of this report.

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

Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10)
The inspection team noted that the centre has not carried out any treatments involving embryo testing activities since February 2017. The PR has reported that during 2022, the PR and Laboratory Manager undertook ongoing competency assessments of embryo biopsy involving a small numbers of embryos. The PR has also reported that they have previously provided training courses in embryo biopsy in the UK and Denmark.

Because of this, the inspection team were initially minded to recommend a licence for Treatment and Storage only, however the inspection team is assured that before any treatments involving embryo testing resume, the PR will ensure that relevant staff involved are suitably trained and competent, and therefore no further recommendation is considered necessary at this time.

Progress with maintaining appropriate skills and experience in this area of practice will be followed up at the next inspection.

2. The experience of patients

Patient feedback

What the centre does well

The HFEA's Choose a Fertility Clinic webpage enables patients to 'rate' their experience and provide additional feedback on their individual experience at their clinic directly to the HFEA. Only four patients have provided feedback in the last 12 months, giving an average 2.5 star rating to the clinic. The low level of feedback suggests that the clinic does not actively seek patient feedback for comparison purposes. This was discussed with the PR and Quality Manager at the inspection. The centre uses the 'Family and Friends' system of gaining patient feedback, which is generalised to meet the needs of all patients providing feedback on their experience of NHS services.

In view of the ongoing low level of patient feedback to the HFEA's 'Choose a fertility clinic' the inspection team discussed this with the PR who has confirmed his commitment to looking at ways to address this. The inspection team acknowledges that the Covid-19 pandemic impacted the centre's ability to make progress with promoting this facility with patients. In view of this no further recommendation is made at this time and this will be followed up at the next inspection.

The inspectors were not able to speak to patients about their experiences at the clinic.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- treats patients with empathy and understanding.

What the centre could do better

The inspection team urge the centre to monitor patient feedback more effectively to ensure that any actions taken are effective.

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 requirements to ensure that staff, prospective and current patients, and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

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

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

Counselling (Guidance note 3)
It is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood. The centre's counselling procedures are compliant with HFEA requirements with the exception noted in the 'QMS' section of this report.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not undertake egg or sperm sharing arrangements therefore this area of inspection was not relevant to this inspection.

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements with the exception noted in the 'QMS' section of this report. 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
It is important that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.
The centre's procedures for providing information to patients and/or donors are compliant with HFEA requirements with the exceptions noted in the 'Storage of gametes and embryos', 'QMS', 'Legal Parenthood' and 'Patient feedback' sections of this report.

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

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

What the centre does well

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

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 must give written consent 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.

The centre's procedures for collecting legal parenthood consent are partially compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.
It is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patient's identifying information to researchers, with their consent.

This area of inspection has been suspended until associated IT development work and validation processes have been successfully undertaken.

What the centre could do better

Consent (Guidance note 5; 6)
In the records reviewed on inspection, two patients had completed a WT ('Your consent to your eggs and embryos created using your eggs being used in treatment or stored') consent form effective from 1 July 2022 (when the new Storage Regulations came into effect).

In these two records, the patients had completed sections of the consent form that contradicted each other. Sections 4.1 and 4.2 of the WT are to be completed by the patient when providing consent to storage for the first time, and Sections 4.3 and 4.4 of the WT consent form are to be completed when the patient wishes to consent to an additional storage period in circumstances where they have previously given consent (in sections 4.1 and 4.2) for a period of less than 10 years. In both records reviewed the patients had completed all sections, i.e., 41., 4.2, 4.3 and 4.4. and there was no indication that this error had been identified by staff prior to treatment.

In addition, the centre provided a consent audit for the DBA. The audit identified 37 errors or omissions out of the 41 records audited (90% error rate), however, the nature of the issues identified was not detailed on the audit nor provided to the inspection team at the onsite visit. Centre staff assured the inspection team that these errors had no impact on the validity of the consent provided by the patient. Corrective actions were documented but the inspection team was unable to assess whether these actions were appropriate, or robust, in the absence of the raw data indicating the nature of the errors. Additionally, there was no record of whether any corrective actions had been implemented.

SLC T15; T59. See recommendation 3.

Legal parenthood (Guidance note 6)
The following issues were noted during the DBA and onsite inspection:

- An audit of legal parenthood consent completed by the centre identified several anomalies with legal parenthood consents including:
  - the incorrect consent form was completed by the patient i.e., the woman having treatment completed a PP consent form ('Your consent to being the legal parent') instead of the WP consent form ('Your consent to your partner being the legal parent'). The patient's partner completed the WP form, but they should have given their consent to legal parenthood on the PP form. No live birth resulted from this error therefore this is considered a near miss;
  - a PBR consent form ('Your consent to being registered as the legal parent in the event of your death') had been completed by a patient having intrauterine insemination (IUI). This form should only be completed by married couples having IVF/ICSI treatments involving the use of embryos;

- on one WP consent form an error had been corrected and initialled by the partner of the patient not the patient providing the consent;
- the inspection team did not consider that the corrective actions documented in this audit were not robust or appropriate. For example, one of the actions was to assess the competencies of the embryology team, but it is the nursing team that is responsible for obtaining legal parenthood consents with patients.

- The centre has not audited legal parenthood records inline with the audit methodology issued by the HFEA in April 2021.This was a non-compliance at the inspection of centre 0049 in June 2022.

- In one record reviewed there appeared to be conflicting information on the centre's documents regarding the couple's marital status. The registration form and centre's 'checklist' completed in June 2022 indicated *'not married'* but there was also a checklist from January 2022 and November 2022 that stated, *'civil partnership'*. This was discussed with staff who reported that the couple were not married and that the patients must have stated *'civil partnership'* on the checklist in error. However, these forms are checked by a staff member at the time of completion, and this did not appear to have been picked up or corrected at the time. The inspection team noted that the couple have correctly completed a WP ('*Your consent to your partner being the legal parent*') and PP ('*Your consent to being the legal parent*') consent form, therefore if the couple are not married there is effective consent to legal parenthood in place if required.

- The inspection team noted that in the records audited the registration form did not include a question to confirm that the patient is not married to anyone else other than the person they are seeking treatment with. However, the PR showed the inspection team an updated version of this form which includes this question and confirmed it has been in use since September 2022.

Legal parenthood non-compliances were noted at the inspection of centre 0049 in 2022.

HF&E Act 2008 Part 2; HFEA Code of Practice (CoP) 6; Clinic Focus Article April 2021. See recommendation 4.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

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

Storage of gametes and embryos (Guidance note 17)

The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of gametes or embryos not required for immediate use also means that patients may be able to undergo further fertility treatment without additional invasive procedures being performed. It is important that gametes and embryos are stored appropriately to maintain their quality and safety and that the centre only stores gametes and embryos in accordance with the consent of the gamete providers.

On 1 July 2022, amendments to the HF&E 1990 Act introduced by the Health and Care Act 2022, came into effect. In summary, these amendments introduced new statutory storage periods for gametes and embryos already in storage or to be stored for patients' own treatment (including after death or loss of mental capacity), for donation and for training

and research purposes. The amendments to the law also set out specific actions that centres must take during a 'Transitional Period' (TP) from 1 July 2022 to 30 June 2024.

The centre's processes for implementing the changes to the legislation were reviewed during this inspection. This included review of actions taken by the centre to implement the new requirements and HFEA guidance, staff training, updates to processes, information for patients, counselling services and use of new HFEA consent forms from 1 July 2022.

The centre's procedures for storing gametes and embryos are partially compliant with HFEA requirements.

The centre has not acted fully on all guidance from the HFEA in relation to the changes to the storage regulations that came into force on 1 July 2022. See also 'Consent' section of this report.

What the centre could do better

Storage of gametes and embryos (Guidance note 17)
The PR confirmed that the centre's information for patients and donors considering storage of gametes has been updated with information regarding the changes to storage regulations that came into effect on 1 July 2022. However, the update of similar information relating to storage of embryos and storage of embryos for use in training, has not yet been completed.

The PR confirmed that all patients who need to be contacted during the TP have been identified and the centre are in the process of preparing the statutory notices and consent forms to be sent out. However, the centre has not yet developed a process for contacting patients with material in storage prior to 1 July 2022 to facilitate their consent under the new regulations.

SLC T58. See recommendation 5.

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 partially 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 centre's written information for patients considering donating their embryos for use in training states *'If you have given consent for training you may change your mind at any point up until the day after embryo transfer.'* This is not compliant with T97c which states: *'that they can vary the terms of or withdraw their consent until the point the embryos are used in training'.*

SLC T97(c). See recommendation 6.

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 partially 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)
In September 2021, the HFEA launched the HFEA PRISM data submission system following which, associated IT development work was required to build functionality back into the register to produce data reports. In addition, centres went live with the new system via a deployment phase; and therefore, the information submitted by centres was received by the HFEA at varying stages (depending on which system clinics use to submit data to the HFEA).

Until the HFEA development work is complete, and all centres are fully deployed, have submitted their historic data and are submitting real time data, this area of inspection is suspended.

What the centre could do better
Record keeping and document control (Guidance note 31)
During the inspection seven sets of records were audited to assess the centre's record keeping processes. These included three couples having treatment with donor sperm or embryos created with donor sperm, and two sets of couples entering into a surrogacy arrangement which included the intended parents' (IPs), the surrogate's and their spouse's records. The following issues were noted:

- The centre had not recorded by whom, the patient/donor has been reliably identified.
- One patient record had patient identification stickers with the same name and date of birth but with two different hospital numbers.
- In two cases it was noted that there was an error in the date entered by the patient when they signed the welfare of the child assessment form, but this had not been identified by the clinician confirming the offer of treatment.
  In one of these cases the patient had corrected the error (initialled and dated 2022). However, the offer of treatment had been documented by the clinician in 2021, therefore the clinician had not identified this error. The inspection team was concerned that the patient had made a correction to the form almost a year after the assessment but there was no other information to confirm if the assessment

had been repeated or reviewed by clinic staff when the correction had been made in 2022.

- In one case a request for additional testing for HTLV was documented but there was no record of the result in the notes, or any confirmation that this had been done and reviewed.
- One set of records provided to the inspectors for review had a large amount of loose sheets not secured within the records. Not all of these loose sheets had any patient identifier on them. This was also noted in other records reviewed by the inspectors. The inspection team was concerned that if these pages become separated from the patients' record file or for example are copied for release to the patients or another healthcare provider there is no identification of who this record related to.

General Direction 0012 (1)(b); SLC T37, T46(b); SLC T47. See recommendation 7.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2021, there were no recommendations for improvement or non-compliance.

On-going monitoring of centre success rates

This area of inspection has been suspended until associated IT development work and validation processes have been successfully undertaken.

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 or practice guidance. A critical area of non-compliance requires immediate action to be taken by the PR.

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 or practice guidance;
- which indicates a failure of the PR to carry out their 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. Success rates: The centre provided their own analysis of the centre's pregnancy outcomes and success rate data including the multiple birth rate for the DBA. On discussion with staff and further review of the raw data during the inspection it appeared that not all the data may have been analysed accurately because there appeared to be a mismatch between the raw data and the key performance indicator (KPI). For example, the clinical pregnancy rate for a practitioner was recorded as 14% but the person had only	The PR should ensure that the centre's success rates are accurately assessed and monitored against relevant KPIs. The PR should provide a report with updated success rate data to the centre's inspector when responding to this report. The PR should review the centre's processes for monitoring and analysing their data to ensure that an appropriate KPI is identified to facilitate continuous improvement in outcomes for	We have looked at the most recent results and found that the error was due to a "cut and paste" error in excel which we did not pick up from the results powerpoint presentation. This has now been recitfied and the updated slide show is attached. We are in the process of validating outcomes from Oct-Dec 22 and going forward we will return to using a more comprehensive data set based on the ESHRE Vienna concensus. Rather than producing a slide show, each graph will be presented	The executive acknowledges the PR's response and commitment to implementing this recommendation. The PR has provided updated data sets of the centre's KPIs for treatments carried out between January 2022 and September 2022. A full set of KPI data is to be provided by 18 April 2023. The PR has also provided a summary of their review of processes for monitoring and analysing data. The executive notes that the PR plans to

carried out 5 cases, therefore this percentage could not be accurate. The inspection team noted that the centre's KPI targets were a rolling average of their own recent outcomes, and the inspection team was concerned that this may not be a valuable measure to use because any decreases in their rolling averages would then decrease the KPI target and would not be effective as a target to drive continuous improvement. The inspection team also noted that the centre had identified that their KPIs were below a 'national average', however, it was not clear what this national average figure referred to as the most recent national data is not available from the HFEA due to the ongoing data validation and verification work. SLC T35. CoP guidance note 23.12	patients. A summary report of the findings of the review and corrective actions identified with timescales for implementation should be provided to the centre's inspector by 18 April 2023.	against in its native excel data in the clinics regular QSI meeting. This will ensure that data is scrutinised more thoroughly and the inclusion of "static" target values will allow analysis and discussion of each indicator. Rolling averages are only used for looking at longer term trends and reference to national data (in this case the most recent data available from the HFEA website acknowledging when it was last updated). Presenting more detailed data to staff will be used as a teaching/ training opportunity to develop a wider appreciation for the complexities of IVF, especially to those who are new to the service and/ or unfamiliar to data analysis. A full set of KPIs graphs will be sent to the to the inspector by April 18th	return to using a more comprehensive data set based on the 'ESHRE Vienna consensus' (minimum performance and aspirational values across 19 indicators) and will include 'static target values' for analysis and comparison. These were not included in the information provided in response to this report. Further action required.

2. QMS: There were several issues noted with the QMS which are detailed in the main body of this report. Given the breadth and potential impact of key issues not being identified by audit, this non-compliance has been graded as major. See also Legal Parenthood and Consent. SLC T36.	The PR should ensure the quality management system is effective in ensuring the quality of services provided. The PR should conduct a robust review the QMS including, but not exclusively, the issues identified in this report and provide a summary report of the review, with corrective actions taken to the centre's inspector by 18 April 2023. Three months after the review the PR should audit the QMS to ensure that any corrective actions taken have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 18 July 2023.	The PR and senior team will conduct a review of the QMS and report back to the HFEA within the given timescale. We have already agreed that what is needed is a more "task and finish" approach to ensure that not only is information disemminated but that any required actions are detailed, timelined/ implemented and subsequent changes analysed. We also aim to more closely align the QMS with the CoP and Directions, Clinic Focus, etc and their consideration will be integral to the quality cycle of assessment, change reassment that needs to be implemented. Again this will be done on a task and finish basis with clear responsibilities and timelines	The executive acknowledges the PR's response and commitment to implementing this recommendation. The PR has committed to providing the requested summary report of their robust review of the centre's QMS by 18 April 2023 and that of an audit by 18 July 2023. Further action required.
3. Consent: In the records reviewed on inspection, two patients had completed a WT ('Your consent to your eggs and embryos created using your	The PR should ensure that consenting practices and procedures are compliant with regulatory requirements.	We have started the review of consents from July 2022 and will complete in the allotted timeframe. Patients found to have errors who have gametes or embryos in	The executive acknowledges the PR's response and commitment to implementing this recommendation.

eggs being used in treatment or stored') consent form effective from 1 July 2022 (when the new Storage Regulations came into effect). In these two records, the patients had completed sections of the consent form that contradicted each other. Sections 4.1 and 4.2 of the WT are to be completed by the patient when providing consent to storage for the first time, and Sections 4.3 and 4.4 of the WT consent form are to be completed when the patient wishes to consent to an additional storage period in circumstances where they have previously given consent (in sections 4.1 and 4.2) for a period of less than 10 years. In both records reviewed the patients had completed all sections, i.e., 41., 4.2, 4.3 and 4.4. and there was no indication that this error had been identified by staff prior to treatment. In addition, the centre provided a consent audit for DBA. The audit identified 37	The PR should review the records of patients who have given consent to storage of gametes or embryos since 1 July 2022 to determine if there are any further cases where these consent forms have been completed incorrectly. Where any anomalies or errors in consent forms are identified, the patients should be contacted, and new consents completed. When responding to this report the PR should provide an action plan on how this will be undertaken and a timeline for completion. It is expected that the review is completed by 18 April 2023, and corrective actions completed by 18 June 2023. The PR should review consenting practice and procedure at the clinic, including but not exclusively, the issues identified in this report, staff training requirements, and provide a summary report of the actions	storage will be contacted at the conclusion of the audit to explain the need to change their consents and and asked to reconsent (either in person or electronically) If errors are identified in only the storage section of consents and the patients have nothing in storage, The consents will be noted and when the patients attend for further treatment they will be fully consented again. We are initiating a series of nurse training sessions beginning on the 16th March to cover aspects where training that is felt is needed, the first will be regulation, consent and consent forms. These sessions are going to be monthly events and will cover clinical and regulatory aspects of work in IVF. Formal teaching sessions are hoped to be more beneficial to those members of the team that are relatively new to the service and will feed directly into competency assessment	The PR has provided a summary of their action plan to address the issues identified by the inspection team and has confirmed that they have started the review of records of patients who have given consent to storage of gametes or embryos since 1 July 2022. The PR has confirmed the actions that will be taken should any anomalies or errors in consents be identified. The executive notes the PR's plans to provide training to the nursing team regarding regulation, consent and consent forms beginning 16 March 2023, however, the executive would expect that following this training the PR would ensure relevant staff are competent to conduct the proposed 'virtual clinic' due to start at the end of March 2023, prior to its commencement. A summary report of the PR's review of the centre's

errors or omissions out of the 41 records audited (90% error rate), however, the nature of the issues identified was not detailed on the audit nor provided to the inspection team at the onsite visit. Centre staff assured the inspection team that these errors had no impact on the validity of the consent provided by the patient. Corrective actions were documented but the inspection team was unable to assess whether these actions were appropriate, or robust in the absence of the raw data indicating the nature of the errors. Additionally, there was no record of whether any corrective actions had been implemented. SLC T15; T59.	taken, to the centre's inspector by 18 April 2023. Three months after the review the PR should audit consent practice, procedure and staff competence to ensure any corrective actions taken have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 18 July 2023.	A new virtual clinic will also be introduced by the end of the March in an attempt to further improve compliance. At this clinic all notes of patients who are considered ready for treatment will be checked by an allocated member of the nursing team to ensure that all consents, screening and other information is in place before being passed to a treatment planning appointment. Any errors/ omissions found at this clinic will be recorded and notes sent back to appropriate department for rectification. After rectification the notes will again go to the next virtual checking clinic to be assessed again and if found to be correct passed to treatment planning. In this way we should be better able to understand patterns of error or omission and formulate more effective ways of preventative action.	consenting practices by 18 April 2023 and that of an audit by 18 July 2023 are awaited. Further action required.
4. Legal Parenthood: There were several issues noted with legal parenthood consenting processes which	The PR should ensure that legal parenthood practice and audit methodology is compliant with regulatory	The current and ongoing LP audit practice is compliant with regulatory requirements the remainder of the 2022	The executive notes the PR's response but cannot reconcile the PR's claim that *'current and ongoing LP audit practice*

are detailed in the main body of the report. HF&E Act 2008 Part 2. HFEA Code of Practice (CoP) 6. Clinic Focus Article April 2021.	requirements and HFEA guidance. The PR should review legal parenthood consenting practice and procedure at the clinic, including but not exclusively, the issues identified in this report (staff training requirements, audit CAPA), and provide a summary report to the centre's inspector by 18 April 2023. The PR should investigate why the centre has failed to implement legal parenthood consent audit methodology issued by the HFEA in April 2021 and provide a summary report when responding to this report. The PR should audit all records where treatment has been provided using donor sperm, or embryos created with donor sperm, from the last inspection on 9 February 2021 to the date of this inspection (18 January 2023) using HFEA audit methodology.	consents will be audited and the full audit data sent within the timescale. Practice was changed in 2022 to include the elements required and was ongoing at time of inspection. The lack of a fully rounded task and finish approach to our QMS, together with some considerable post covid recovery challenges has meant that adapting to and implementing change has not been managed as it should and the team are determined to change the approach to make information dissemination, change management and training more robust so we can ensure compliance	*is compliant with regulatory requirements'* given the nature of the non-compliances found at this inspection and in the audit provided for the DBA. The PR is reminded of the requirement to provide the audit (including raw data) of all records where treatment has been provided using donor sperm, or embryos created with donor sperm, from the *last* inspection on 9 February 2021 to the date of this inspection (18 January 2023) using HFEA audit methodology, *not*, as they state in their response, the 'remainder of the 2022 consents'. The executive notes that the PR considers that the lack of robustness of the centre's QMS in having a 'fully rounded' approach and covid recovery challenges have impacted on their ability to ensure compliance, and the PR's acknowledgement that *'adapting to and implementing*

	The audit report (including the raw data) should be provided to the centre's inspector by 18 July 2023.		*change has not been managed as it should'* . The executive remains concerned that the PR has reported that practice was only 'changed in 2022' (even though the HFEA issued guidance on robust legal parenthood audit methodology in April 2021). The PR has a responsibility to ensure guidance issued by the HFEA is implemented into practice. The PR is urged to consider if there are other areas of HFEA (or other professional body guidance) that may not have been implemented and take any necessary actions ensure implementation. Further action required.
5. Storage of gametes and embryos: The PR confirmed that the centre's information for patients and donors considering storage of gametes has been updated with information regarding the changes to storage	The PR should ensure compliance with statutory storage regulations. When responding to this report the PR should provide an update on progress with completing the amendments	The written information for storage of embryos has been updated (including embryos stored for training has been updated) to reflect changes in storage regulations. We are also going to relook at the information provided via the electronic consenting platform	The executive notes the PR's response. The executive acknowledges that new legislation was introduced in a short timeframe.

regulations that came into effect on 1 July 2022. However, the update of similar information relating to storage of embryos and storage of embryos for use in training has not yet been completed. The PR confirmed that all patients who need to be contacted during the TP have been identified and the centre are in the process of preparing the statutory notices and consent forms to be sent out. However, the centre has not yet developed a process for contacting patients with material in storage prior to 1 July 2022 to facilitate their consent under the new regulations. SLC T58.	to patient information to fully reflect the new storage laws. The PR should investigate why the centre has not acted on HFEA guidance to develop processes for contacting patients with gametes and embryos in storage prior to 1 July 2022 and provide a summary response when responding to this report. The PR should as a priority, develop and implement a process for contacting patients with material in storage prior to 1 July 2022. It is expected that this process will be fully implemented when responding to this report. The PR should ensure that staff are suitably trained in, and competent with, the new storage laws, and consenting processes, and should provide detail of the actions taken to ensure staff competence in this area of practice when responding to this report.	to ensure it reflects the changes to storage laws and this will be completed and this will be completed by the 18 April. Should it be decided that the information on storage is incomplete, we will contine with written information until it is changed Given the relatively short time scales in which to incorporate the new legislation we concentrated on the transitional patients first. We did however discuss what to do about the existing patients and though we didn't document this it became clear after the last PR meeting in London that we would have to write to everyone with stored sample to inform them of the change in storage laws so that they may avail themselves of the benefits that they offer. They can choose to change their consents now or wait till the end of their current storage period. Patients are being offered the option of attending the clinic in person or to update their consents	The HFEA provided a number of supportive measures for the sector. These included detailed guidance for clinics published in May 2022, drop-in sessions provided by the Director of Compliance and Information (with opportunities for Questions & Answers (Q&A)), training videos, flow charts and Frequently Asked Questions (FAQs) throughout the initial implementation stages. The HFEA was also available to respond to any queries relating to the new legislation. All of this was ongoing since May 2022. The PR event in October 2022 was not the first opportunity for the PR to seek guidance and learn that patients with samples in storage would have to be written to. The executive notes the PR has ‘concentrated on the transitional patients first’ and that patients with material in storage prior to 1 July 2022

		electronically. The process will begin with the verification of all addresses of patients to ensure information is correctly and will be followed by a mail shot. All patients will have been contacted by the end of August 2022. All staff undertaking consenting activities will have ongoing training to ensure they are fully conversant with the new storage laws and consenting process. This will include repeat screenings of the HFEAs informational videos, group discussions based on the FAQs and observation of consenting and peer assessment of completed consent forms	will 'have been contacted by end of August 2022'. The executive assumes that the PR means August 2023. The executive expects that that given the significance of the changes that have been made to the laws relating to storage of gametes or embryos the PR should as a priority, ensure processes for contacting patients with material in storage prior to 1 July 2022 are implemented in a timely manner. The PR should provide the executive with confirmation that this recommendation has been implemented as required. Further action required.
6. Use of embryos for training staff: The centre's written information for patients considering donating their embryos for use in training states *'If you have given consent for training you may change your mind at any point*	The PR should ensure that the information provided to patients regarding the use of their embryos in training is accurate and compliant with standard licence conditions. The PR should review current information provided to	The form has been changed to include the wording from T97c. The team understand that the patients may alter/ withdraw their consent at any point up until they are used in training (normally the day after embryo transfer as we do not	The executive acknowledges the PR's response and commitment to implementing this recommendation. The executive acknowledges receipt of a proposed patient information sheet (tracked changes were on the leaflet

up until the day after embryo transfer.' This is not compliant with T97c which states: *'that they can vary the terms of or withdraw their consent until the point the embryos are used in training'.* SLC T97(c).	patients relating to the use of their embryos in training, including any staff training requirements needed following the amendments, and provide a summary report of the review and a compliant patient information leaflet, to the centre's inspector by 18 April 2023.	keep frozen samples for training purposes)	provided to the executive which would indicate the document is still in draft). The PR should provide a finalised version of the leaflet by 18 April 2023. The executive notes that the document provided does not include any information relating to storage of gametes or embryos for use in training and expects that this is incorporated in other patient information sheets that the PR confirmed have been updated as a result of the changes to the storage laws effective from 1 July 2022. Further action required.
7. Record keeping and document control: There were several issues identified with the centre's record keeping practices which are detailed in the main body of this report. General Direction (GD) 0012 (1)(b).	The PR should ensure that record keeping practice and procedure is compliant with standard licence conditions. The PR should review record keeping and document control practice and procedure, including, but not exclusively the issues identified in this	We will organise a review of record keeping and return by the specified date. We will also organise training and competency assessments for all departments to ensure improvement and compliance is achieved in all areas of record keeping	The executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required.

SLC T37,T46(b) and T47.	report, and provide a summary report to the centre's inspector by 18 April 2023. Three months after the review the PR should audit record keeping practices and procedures to ensure that any corrective actions taken, have been effective in achieving and maintaining compliance. A summary report of the audit should be provided to the centre's inspector by 18 July 2023.		

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 practice guidance.

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
8. Screening of donors: On inspection the inspection team reviewed one of the records previously audited by the centre and found areas of non-compliance with professional guidance, that the centre had indicated to be compliant. Furthermore, on review of the updated audit provided soon after the inspection the following non-compliances were noted: • In all four records audited there was no documented final sign off by a clinician to confirm that the donor was suitable to donate. • In one donor the clinician had identified that additional screening was required for Glucose 6	The PR should ensure that the screening of donors is compliant with standard licence conditions and professional body guidance. The PR should provide a summary report as to why guidance issued in 2019 has not been considered or implemented into practice, when responding to this report. The PR should review donor screening practices and procedures and provide a summary report of this review including any corrective actions taken or staff training requirements, to the centre's inspector by 18 April 2023.	We have learned that a task and finish approach is really the only way to ensure that changes are made in a timely manner as although changes may be discussed this clearly does not mean that they have been implemented. Additionally we are introducing a check-step into the patient pathway to ensure that all tests that have been requested have been performed and documented and that all consents are correct. We are planning a series of teaching sessions for clinic staff and one of these will be record keeping and will cover entering information legibly, where to find specific information and clinical sign-off	The executive acknowledges the PR's response and commitment to implementing this recommendation. The PR has not provided a summary report as to why guidance issued in 2019 has not been considered or implemented into practice, when responding to this report. A summary report of the review of the centre's screening practices and procedures is due by 18 April 2023 and that of an audit by 18 July 2023 are awaited. Further action required.

phosphate dehydrogenase, due to the donor's ethnic origin, but this was not undertaken as the clinician deemed the condition was not life threatening. • All four egg donors audited were only screened using serology (not serology and NAAT testing), and the eggs, or embryos created with them, were not quarantined prior to use in treatment. This goes against professional body guidance which requires that where only serology screening is undertaken, the eggs or embryos created from them should be quarantined for six months. It is not clear if there was a risk assessment for each of these cases where the centre had deviated from professional body guidance.	Three months after the review, the PR should audit donor screening practises and procedures to ensure that corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of the audit should be provided to the centre's inspector by 18 July 2023.	WFI has recently appointed a new Lead Clinician who is very much taking this approach and we have changed the in-house donor screening process to that recommended in professional guidance and rather than utilising NAT testing we will be serology screening.	

The inspection team was concerned that the PR did not provide reasons why the centre had not considered or followed professional guidance for the screening of donors and whether risk assessments had been carried out and documented for these cases. SLC T52(h)(i); T53(b). UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors (2019). CoP 11.23 – 11.25			
9. Medicines management: In the audit provided by the centre pre-inspection, there was a mismatch in the amount of CD recorded as having been given in the patient's prescription chart, to that recorded in the CD register. The centre had not identified this from their audit. 'Dangerous Drugs; The Misuse of Drugs Regulations 2001'.	The PR should ensure compliance with CD regulatory requirements. The PR should review practices at the clinic relating to the management and governance of CDs and provide a summary report of any actions taken in relation to this non-compliance, to the centre's inspector by 18 April 2023.	The PR has spoken to the lead aneasthetist for WFI to ensure that all aneasthetists are aware that correct legible entries are made in both the CD book and patient drug chart. WFI already has an extra post-procedure check that does not take place elsewhere and the nursing team have also been reminded that only correct legible entries are acceptable when first entering information	The executive acknowledges the PR's response and commitment to implementing this recommendation. No further action beyond submission of a summary report (including raw data) of an audit of CDs cross referencing the patient prescription chart and records with the CD register to ensure compliance with regulatory requirements and ensure all

	Three months after the review, the PR should audit of CDs, cross referencing the patient prescription chart and records with the CD register to ensure compliance with regulatory requirements and ensure all CDs are accounted for. A summary report, including the audit raw data, should be provided to the centre's inspector by 18 July 2023.	and when checking at the end of a procedure.	CDs are accounted for, due by 18 July 2023.
10. Multiple births: The PR monitors the centre's multiple pregnancy and birth rates and was aware of a recent upward trend in these outcomes compared to previous low rates. The centre's multiple pregnancy rates from their own data for all fresh and frozen embryo transfers between January 2022 and June 2022 and provided for the DBA was 11%. The inspection team noted that centre's data for multiple pregnancy rates for all IVF, ICSI and FET cycles for all age groups provided to the HFEA for the year ending 31	The PR should ensure compliance with General Direction 0003 to audit the effectiveness of the centre's multiple birth minimisation strategy. The PR should provide an audit of the centre's compliance with the MBMS between June 2021 and treatments leading up to the date of the inspection where pregnancy outcomes are known. A summary report of the audit including corrective actions identified to ensure compliance with the MBMS and address the upward trend	Having reviewed the data for MPR, the upward trend only seemed to affect the first half of the 2022. Data shows that the fresh MPR was 7.7% for the full year which is still an increase over the 2021 figure. WFI was quite cautious in its stimulation approach post covid and the extremely low 2021 is most likley a result of this. We will continue to monitor the efficacy of the MBMS and have already discussed whether to include increase the age range from 36 to 37, though we need more modelling to decide what	The executive acknowledges the PR's response and commitment to implementing this recommendation. The executive confirms receipt of an audit of the MBMS which states that the centre's multiple pregnancy rate from fresh embryo transfers for 2022 was '10/125 pregnancies = 8% ('one of the multiple pregnancies was from a single embryo transfer which cannot be avoided') and was 'approximately' 5% for FETs from 2019 to 2022.

May 2021 was 2% which is statistically significantly below the 10% target. This was discussed with the PR during the inspection and whilst it is acknowledged that the PR is aware of, and is monitoring this upward trend, there was no documentation of these reviews or audit of the centre's compliance with their MBMS. General Direction 0003 paragraph 3(b).	in multiple pregnancy rates should be provided to the centre's inspector by 18 April 2023.	this could do to the overall pregnancy rate	The centre's multiple pregnancy and birth rates will be reviewed when HFEA data becomes available, and at the centre's next inspection. No further action required.

Response from the Person Responsible to this inspection report
I'd to thank the HFEA for the professional manner in which they conducted the report and for giving us the opportunity to take a pause and really think about how we offer a quality, compliant service. Post covid, the service has faced many challenges, particularly in staffing post pandemic with many new staff joining the service or returning from long absence and whilst we have tried to serve our population well, we clearly need to do more. The team are eager to rise to the challenge and change our processes and procedures to accomplish this.