Executive Licensing Panel - minutes

Centre 0329 (Wales Fertility Institute - Neath)

Renewal Inspection Report

Tuesday, 21 May 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Howard Ryan Yvonne Akinmodun	Director of Strategy and Corporate Affairs Report Developer Head of Human Resources
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

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

1.2. The panel noted that the Wales Fertility Institute - Neath has held a licence with the HFEA since 2013 and provides a full range of fertility services. Other licensed activities at the centre include the storage of gametes and embryos and embryo testing.

1.3. The panel noted that, in the 12 months to 31 December 2018, the centre provided 592 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium sized centre.

1.4. The panel noted that, HFEA register data, for the period 1 December 2017 to 30 November 2018, show the centre's pregnancy outcomes for IVF and ICSI success rates, in terms of clinical pregnancy outcomes, are in line with the national averages with the following exception:

- The clinical pregnancy rate for frozen embryo transfers (FET) in women under 40 years old are lower than average at a statistically significant level.

1.5. The panel noted that, in 2018, the centre provided 25 cycles of partner inseminations, with nine pregnancies, and this is in line with the national average.

1.6. The panel noted that, between 1 December 2017 and 30 November 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 5%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.7. An inspection was carried out at the centre on the 19 and 20 February 2019.

1.8. The panel noted that at the time of the inspection, there was one major area of non-compliance concerning treatment success rates, alongside three 'other' areas of non-compliance regarding multiple births, traceability and obligations and reporting requirements. Since the inspection visit, the Person Responsible (PR) has fully implemented the recommendations concerning multiple births, traceability and obligations and reporting requirements and, where required and by the dates specified, will provide an update or summary of audits conducted to ensure that corrective actions taken are effective. The PR has given a commitment to fully implement the recommendation regarding the major non-compliance on treatment success rates.

1.9. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a Quality Management System (QMS) and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients. The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

1.10. The panel noted that, the inspection team recommended 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 the report being implemented within the prescribes timescales.

1.11. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018; these certificates are generally synchronised to the centre's HFEA licence. The inspection team 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 the licensed activities.

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

2.4. The panel particularly noted the centre's treatment success rate for FET in women under 40 years old, requesting a progress update on this specific area, by the close of 2020.

2.5. 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.

2.6. The panel endorsed the inspectorate's recommendation to renew the centre's ITE 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

28 May 2019

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The 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: 19 and 20 February 2019.

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 visit and communications received from the centre.

Inspectors: Julie Katsaros, Polly Todd, Sara Parlett, Nicola Lawrence (observing) and Sandrine Oakes (observing).

Date of Executive Licensing Panel: 21 May 2019.

Centre name	Wales Fertility Institute - Neath
Centre number	0329
Licence number	L0329-2-c
Centre address	Neath Port Talbot Hospital, Baglan Way, Port Talbot, SA12 7BX, United Kingdom
Person Responsible	Dr Paul Knaggs
Licence Holder	Mrs Christine Morrell
Date licence issued	1 August 2015
Licence expiry date	31 July 2019
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 provides a full range of fertility services.

The centre provided 592 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2018. In relation to activity levels this is a medium centre.

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

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

- A change of Licence Holder (LH) on 3 October 2018.
- A change of Person Responsible (PR) on 9 September 2016.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 December 2017 to 30 November 2018 show the centre's success rates are in line with national averages with the following exception:

- The clinical pregnancy rate for frozen embryo transfers (FET) in women under 40 years old are lower than average at a statistically significant level (see Section 3: Monitoring of the centre's performance and recommendation 1).

In 2018, the centre reported 25 cycles of partner insemination with nine pregnancies, which reflects a success rate in line with the national average.

Multiple births[2]

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

Between 1 December 2017 and 30 November 2018 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 5%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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

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

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

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

Since the inspection visit, the PR has fully implemented the following actions:

'Other' areas that require improvement:

- The PR should ensure that in cases where multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer, a clear explanation of the reasons for transferring more than one embryo is made in the summary log and the patient's notes.
- The PR should ensure that all relevant data about anything coming into contact with gametes or embryos is traceable.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

Where required and by the dates specified the PR will provide an update or summary of audits conducted to ensure that corrective actions taken are effective.

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

Major area of non-compliance:

- The PR should seek to improve the clinical pregnancy rates for women under 40 years old undergoing FET cycles.

Recommendation to the Executive Licensing Panel

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

The inspection team notes the success rates for FET cycles in women under 40 years old are below the national average and their multiple clinical pregnancy/live birth rates meet the target.

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

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

The centre 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 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 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 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 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 broadly 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 note15)

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

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are 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. No imports have been made from TCSs which are not specified on the centre's ITE import certificate. The centre is therefore compliant with General Direction 0006.

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

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

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

Third party agreements (Guidance note 24)
The centre's third party agreements, 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 transport or satellite arrangements and therefore this area of practice 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 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

Multiple births (Guidance note 7; General Direction 0003)
The centre keeps a summary log of cases in which multiple embryos have been transferred, but it was not clear in the log entries which cases met the criteria for single embryo transfer (eSET) as set out in their multiple births minimisation strategy. A clear explanation of the reasons for transferring more than one embryo in a case where eSET criteria was met was not recorded appropriately in either the log or in the one set of notes audited on inspection (recommendation 2, General Direction 0003).

Traceability (Guidance note 19)
An audit of ten batches of consumables in the laboratory was performed. One of the ten batches had not been recorded accurately as being in use on the centre's traceability database. This one consumable had been brought across from their sister clinic (centre 0049), because they were running low on stock.

The inspection team reviewed the centre's traceability procedures and considered that this one error does not demonstrate a systemic failing and therefore considers it appropriate for it to be graded as an 'other' non-compliance (recommendation 3, SLC T99b).

Staff engaged in licensed activity

Person Responsible (PR)
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 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.

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. Six patients have provided feedback in the last year, giving an average five star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. The inspection team discussed with the PR ways in which patients could be encouraged to use this valuable resource and were informed that the centre is about launch a new website where patients will have access via a direct link to the HFEA website, so that they can leave feedback. This will be followed up at the next inspection.

The centre's most recent patient survey responses were also reviewed. Of a total of twelve patients, all expressed satisfaction with their treatment which is comparable to the feedback on 'Choose a Fertility Clinic' .

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

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

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

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

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not perform egg or sperm sharing, therefore this area of practice was not inspected.

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

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

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

What the centre does well

Consent (Guidance note 5;6)
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.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required time frame. The audit showed that no couples were affected by legal parenthood consent anomalies.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR at the time, responded to this communication and provided the required reassurances to the satisfaction of the Executive.

During an interim inspection in January 2017, a set of patient records where the couple were neither married nor in a civil partnership and therefore consent to legal parenthood was required were reviewed. It was found that the patient had put their date of birth in the date of signing section of the declaration page. The legal parenthood consents in these records had recently been audited by the centre but the audit had failed to identify this anomaly.

Following that inspection, the PR was asked to conduct a full re-audit of all records since the granting of the centre's initial licence in 2013, where patients have been treated with donated gametes or embryos (not married or in a civil partnership), to ensure that the correct legal parenthood consents were in place. A further three consenting anomalies in records that had been previously audited were found. No pregnancies resulted from these treatments and the PR implemented new processes to assure a more robust system for completion of consents and auditing purposes.

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. Four 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 17)

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 embryos.

Storage of gametes and embryos (Guidance note 17)

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

What the centre could do better

Nothing identified at this inspection.

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

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
5% (1/20) of the donor insemination (DI) treatments reviewed had not been reported to the HFEA in accordance with General Direction 0005.

87% (102/117) of the IVF and 89% (17/19) of the DI treatments reviewed had been reported to the HFEA outside the period required by General Direction 0005.

These findings indicate that the centre's procedures for submitting information about licensed activities to the Authority, are broadly compliant with HFEA requirements (recommendation 4, General Direction 0005 and SLC T41).

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2017, recommendations for improvement were made in relation to two areas of major non-compliance.

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

On-going monitoring of centre success rates

Since the last renewal inspection in January 2017, the centre has received six risk tool alerts related to performance. These included:

- Pregnancy rate per cycle - fresh ICSI only, patient eggs, patient age <38 years;
- Pregnancy rate per cycle – fresh IVF only, patient eggs, patient age <38 years;
- Pregnancy rate per cycle – FETs, patient eggs, patient age <40 years.

The PR responded to the majority of these alert emails but due to technical issues at the HFEA did not receive an alert in November 2018. During discussions on inspection, the PR provided a commitment to keep success rates under review. Whilst the PR initially suspected that some of the alerts were due to missing early outcomes, a review after the inspection of the centre's data, indicated that success rates for FETs in those under 40 years of age between 1 December 2017 and 30 November 2018, were significantly below the national average, despite there being very few unreported early outcomes. Therefore a recommendation has been made for further actions (recommendation 1, SLC T2).

Areas of practice requiring action

The section sets out matters which the Inspection Team considers may constitute areas of non-compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, General Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non-compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
none			

Major area of non-compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. **Treatment success rates:** The centre's clinical pregnancy rate for FET in women under 40 years old, is lower than the national average at a statistically significant level. SLC T2	The PR should seek to improve the clinical pregnancy rate for women under 40 years old undergoing FET cycles. The PR should conduct a review of clinical and laboratory practices and procedures that could have an impact on the success rates for FET in patients under 40 years old. A report of the review with proposed corrective actions, with timescales for implementation, should be provided to the centre's inspector by 19 May 2019.	I acknowledge that the FET results are below the HFEAs national average per cycle started figures. A review of clinical and lab processes will be undertaken together with an evaluation of the MBMP. Additionally the PR will ask the HFEA to provide national data based on per embryo transfer results as that is a more meaningful statistic by which to measure laboratory and clinical outcomes whilst accounting for the transfer of muliple embryos.	The executive acknowledges the PR's response and commitment to improve the centre's success rates. Further action is required.

	The PR should thereafter continue to monitor success rates generally and for FET in the <40 years age group and should take further actions if problems recur. The centre's inspector will also continue to monitor success rates via the monitoring system.	The report will be sent to the HFEA before 19th May 2019	

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non-compliance, but which indicates a departure from statutory requirements or good practice.

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Multiple births: The centre keeps a summary log of cases in which multiple embryos have been transferred, but it was not clear which cases met the criteria for elective single embryo transfer set out in the multiple births minimisation strategy. A clear explanation of the reasons for transferring more than one embryo in a case where eSET criteria were met, was not recorded appropriately in either the log or in a set of notes audited on inspection. General Direction 0003.	The PR should ensure that: • the log of multiple embryo transfers includes information about whether a case meets elective single embryo transfer criteria; • in cases where multiple embryos have been transferred to a patient who meets the criteria for elective single embryo transfer, a clear explanation of the reasons for transferring more than one embryo is documented in the summary log and the patient's notes. The PR should confirm the actions taken to address this non-compliance when responding to this report.	The current recording system has been changed to incorporate a separate column in the treatment spreadsheet to enable clinicians to enter the reasons for a double embryo transfer in eSET eligible patients. Clinicians have been reminded to type a clear rationale at the time of embryo transfer. The audti will be provided to the HFEA following change of practise within the agreed timescale	The executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required beyond submission of an audit report due 19 August 2019.

	Within three months of the implementation of the change in practice, the PR should conduct an audit to ensure that the corrective actions have been effective in achieving and maintaining compliance. A summary report of this audit should be submitted to the centre's inspector by 19 August 2019.		
3. Traceability: One of ten batches of consumables audited had not been recorded accurately as being in use on the centre's traceability database. SLC T99b.	The PR should ensure that all relevant data relating to anything coming into contact with gametes or embryos is traceable. The PR should review the centre's traceability processes to ensure they are compliant with regulatory requirements. A summary report of this review, including corrective actions taken, should be provided to the centre's inspector by 19 May 2019. Within three months of the implementation of corrective actions, the PR should assess the impact of those actions in a second audit. A summary	The traceability system operated at WFI is generally reliable with the outstanding record being caused due to an extraordinary transfer of consumables between labs. WFI operate a quarterly audit of all lab consumables, which would normally highlight any anomalies. This frequency will be increased to montly to monitor compliance. If after 3 months of no anomalies being reported, audits will revert to quaterly. The HFEA will be provided with the next 3 months audit	The executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required beyond submission of an audit report due 19 August 2019.

	report of the findings of the audit should be provided to the centre's inspector by 19 August 2019.		
4.Obligations and reporting requirements: 5% (1/20) of the DI treatments reviewed had not been reported to the HFEA in accordance with General Direction 0005. 87% (102/117) of the IVF and 89% (17/19) of the DI treatments reviewed had been reported to the HFEA outside the period required by General Direction 0005. General Direction 0005 and SLC T41.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should review the systems and processes used to submit licensed treatment data to the register, to identify and address the reasons for delayed data submission. A summary of the findings of the review including corrective actions with timescales for implementation, should be provided to the centre's inspector by 19 May 2019. The PR should audit the effectiveness of the actions taken within six months. A summary report of the audit findings should be provided to the centre's inspector by 19 August 2019.	All DI treatments are now entered on EDI at the time of treatment. Between December 2017 and November 2018 the centres EDI system was largely unavailable and it was only with significant input from both the HFEA and NHS IT teams that this issue was resolved in July 2018. It was agreed with the HFEA that a 4 month period would be agreed to ensure the backlog of data could be submitted. These problems may have contributed to the reported late submission of data. Currently data submission now forms part of the quarterly data quality audit and audits will be submitted in line with required timescale. Additionally WFI is pursuing the implementation of the Meditex clinic management	The executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required beyond submission of an audit report due 19 August 2019.

		software system in order to optimise data collection analysis and submission	

Reponses from the Person Responsible to this inspection report
I very much appreciated the HFEA inspection in Neath. It was conducted in a friendly, productive manner and the staff that intereacted with the HFEA found the inspectors to be approachable and open. As always, we take the HFEAs visits to not only be about inspection but also shared learning. We feel that we have a very valuable relationship with the HFEA and hope that this continues in future.