Executive Licensing Panel - minutes

Centre 0049 Wales Fertility Institute – Cardiff

Renewal Inspection Report

Wednesday, 1 August 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Niamh Marren Kathleen Sarsfield Watson	Director of Strategy and Corporate Affairs Regulatory Policy Manager Communications Manager
Members of the Executive	Richard Chamberlain Bernice Ash	Temporary Committee Clerk Committee Officer
Observers	Catherine Burwood	Senior Governance 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:

- 8th 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 renewal inspection report, a renewal application form, and licensing minutes from the last three years.

1.2. The panel noted that the centre has held a licence with the HFEA since 1992.

1.3. The panel noted that the Wales Fertility Institute is located in the University Hospital of Wales, Heath Park, Cardiff, CF14 4XW.

1.4. The panel noted that the centre was inspected on 22 and 23 May 2018 and the inspector's report covers the performance of the centre since the previous inspection on 12 April 2016.

1.5. The panel noted that the purpose of the inspection was to inform the renewal of a licence to carry out treatment and storage.

1.6. The panel noted that the centre reported 624 cycles of treatment in the 12 months to 31 March 2018 and in relation to its activity is a medium-sized centre.

1.7. In 2017, the centre reported 51 cycles of partner insemination with four pregnancies. This represents a clinical pregnancy rate of 8%, which is also in line with the national average.

1.8. Between January 2017 and December 2017 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represents performance that is below the 10% multiple live birth rate target.

1.9. The panel noted that at the time of the inspection there were a number of areas of practice that required improvement, including one critical, one major and five 'other' areas of non-compliance.

1.10. The panel noted that the critical area of area of non-compliance concerned storage of gametes and embryos beyond the initial 10 year storage period and noted that the inspection found one set of records where the medical practitioner's statement was completed about one month after the expiry of the initial 10 year storage period. The inspector was satisfied with the centre's response to this non-compliance and will review the summary report of the audits when they are complete.

1.11. The panel noted that the major area of non-compliance concerned medicines management where corrections in the controlled drugs register were not clearly crossed out and re-written in line with regulatory guidelines. Although there was a suitable thermometer in the drugs fridge, there was no log of minimum and maximum temperatures maintained in line with legal requirements. The panel noted that the inspector was satisfied with the centre's response on monitoring and training and will review the finalised summary report and subsequent audit report when these are complete.

1.12. The panel noted the five 'other' areas of non-compliance regarding their QMS, the third party agreement with the screening laboratory, expiry date of single-use gloves had been exceeded, disclosure of information on the HFEA Register for use in research, and record keeping and document control. From the information provided to the inspector the panel were satisfied that the issues had now been resolved.

1.13. The panel noted the inspectorate's recommendation to renew the centre's licence for treatment and storage of gametes and embryos for a further four years, without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

2. Decision

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

2.2. The panel noted that the premises to be licensed are suitable for the conduct of 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 was satisfied with the PR's response to the non-compliances reported and note his positive engagement with the inspection. The panel noted that four areas of non-compliance required no further action and that the PR was committed to resolving the remaining ones.

2.5. The panel decided to grant renewal of the licence for treatment and storage of gametes and embryos for a further four years but looked forward to any outstanding actions regarding areas of non-compliance being completed in the required timescale to the inspectorate.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

28 August 2018

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 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: 22 and 23 May 2018

Purpose of inspection: Renewal of a licence to carry out treatment and storage.

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Dr Vicki Lamb, Dr Mhairi West and Mrs Kathryn Mangold

Date of Executive Licensing Panel: 1 August 2018

Centre name	Wales Fertility Institute - Cardiff
Centre number	0049
Licence number	L/0049/16/b
Centre address	University Hospital of Wales, Heath Park, Cardiff, CF14 4XW, United Kingdom
Person Responsible	Dr Paul Knaggs
Licence Holder	Mr Hamish Laing
Date licence issued	1/10/2014
Licence expiry date	30/09/2018
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 – Cardiff has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 624 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2018. In relation to activity levels this is a medium-sized centre.

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

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period January 2017 to December 2017 show the centre's success rates are in line with national averages.

In 2017, the centre reported 51 cycles of partner insemination with four pregnancies. This represents a clinical pregnancy rate of 8%, which is also in line with the national average.

Multiple births[2]

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

Between January 2017 and December 2017 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represents performance that is below 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 Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

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

Since the inspection the PR has fully implemented the following recommendations:

'Other' areas that require improvement:

- The PR should ensure that audits are suitably recorded and that SOPs include all relevant information.
- The PR should ensure that third party agreements include all the information required.
- The PR should ensure that items are not used beyond their stated expiry date.
- The PR should ensure that records are maintained in line with the centre's SOPs and that records are recorded in a clear manner.

The PR has given a commitment to implement the following recommendations within the prescribed timescale:

Critical area of non-compliance:

- **The PR must ensure that all staff are fully conversant with the requirements of the extended storage regulations.**

Major area of non-compliance:

- The PR must ensure that medicines management practices at the centre are compliant with regulatory requirements.

'Other' areas that require improvement:

- The PR should ensure that the disclosure consent information supplied to the HFEA accurately reflects that given and recorded on disclosure consent forms.

Recommendation to the Executive Licensing Panel

The centre has one critical of area of concern and one major area of concern.

The inspection team notes that the success rates are consistent with the national average. and the team also notes the centre's multiple clinical pregnancy rates are below the target and they are congratulated on this. The PR is encouraged to continue to use the Quality Management System (QMS) to best effect to monitor and improve their success rates and the quality of the service offered to patients.

The 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 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.

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 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 CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

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

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

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

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

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

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

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

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

as fit for purpose.

Receipt of gametes and embryos (Guidance 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.

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

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

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

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any transport or satellite centres, therefore requirements related to this guidance note were not relevant at this inspection.

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

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

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better
Medicines management (Guidance Note 25)
Corrections in the controlled drugs register were not clearly crossed out and re-written in line with regulatory guidelines. Anaesthetic drugs in theatre were not locked in the controlled drugs cupboard. Although there was a suitable thermometer in the drugs fridge, there was no log of minimum and maximum temperatures maintained. (Standard Licence Condition (SLC) T2, Controlled Drugs (Supervision of Management and Use) Regulations 2013, The Misuse of Drugs Regulations, 2001; Section 20(c)) (see recommendation 2).

Quality management system (QMS) (Guidance note 23)
The mismatches recorded in the electronic witnessing system are audited every six months, but this is not in the audit schedule and the findings of the audit and any corrective actions are not documented (SLC T36) (see recommendation 3).

The SOP for adverse incidents does not include the timescales for reporting relevant incidents to the HFEA (SLC T33b) (see recommendation 3).

Third party agreements (Guidance note 24)
The third party agreement with the screening laboratory does not include how the results of the tests are relayed to the clinic (SLC T114f) (see recommendation 4).

Equipment and materials (Guidance note 26)
One of the boxes of single-use gloves used in the laboratory had an expiry date of January 2018 (SLC T2 and T23) (see recommendation 5).

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 broadly 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 does not perform preimplantation genetic screening or embryo testing and sex selection therefore requirements related to these guidance notes were not relevant at this inspection.

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

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to one patient couple who provided feedback on their experiences. A further patient has also provided feedback directly to the HFEA in the time since the last inspection. Feedback was very positive.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

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 requirements related to this guidance note were not relevant at this inspection.

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 / or 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 timeframe. The centre's audit identified two anomalies; children had been born to two couples treated with donated gametes without the required legal parenthood consent forms having been completed. The PR has informed the HFEA of the actions taken to inform the couples involved and to address these consent anomalies, which the executive considers to be supportive and appropriate.

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 responded to this communication and provided the required reassurances to the satisfaction of the Executive.

At the inspection on 12 April 2016, the centre's audit of legal parenthood was reviewed and found that it had been performed according to the method specified by the HFEA. Actions had been taken in response to the audit findings. To provide further assurance of the effectiveness of the centre's procedures, five patient records detailed on the centre's legal parenthood audit were cross referenced with the information held by the HFEA. Two of the five records where patients had used donor sperm and the treatment had resulted in a live birth, were not included on the centre's audit. In the first record the patient had been treated as a single person in 2010, resulting in a live birth. Whilst her single status should have precluded her from the legal parenthood audit, the centre had included other single patients but had omitted this patient. In the second record the patient couple had not been included in the centre's audit. The appropriate consents had been completed correctly in both records and therefore there was no issue with regard to legal parenthood. However, the absence of these patients from the centre's original audit according to the centre's audit criteria, cast some doubt on the robustness of the audit process.

Since the inspection in 2016 the PR provided evidence and assurances that a complete re-audit of legal parenthood had been performed, with four anomalies found but no live births resulting from those treatments.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)

The centre's procedures for taking consent to disclosure to researchers are broadly 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

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)

Ten sets of notes were checked and two discrepancies were found between completed patient/partner disclosure consents in patient notes and the related consent data submitted for inclusion on the register. In all the cases noted the patients had consented to disclosure of information, but it was reported to the HFEA that they had not consented (General Direction 0005) (see recommendation 6).

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
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/or embryos.

Storage of gametes and embryos (Guidance note 17)

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

What the centre could do better

Storage of gametes and embryos (Guidance note 17)

A review of four sets of records where storage had been extended beyond the initial 10 year storage period found one set of records where the medical practitioner's statement was completed approximately one month after the expiry of the initial 10 year storage period (Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009) (see recommendation 1).

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 broadly compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better
Record keeping and document control (Guidance note 31)
In the laboratory, one incubator that had been cleaned had not been recorded as ready for use in line with the centre's SOP (SLC T2 and T26) (see recommendation 7).

In some records reviewed the decision regarding freezing, not freezing or re-checking for freezing had not been completed in line with the centre's SOP (SLC T2 and T102) (see recommendation 7).

Although the inspectors were satisfied that induction and competency was appropriately performed, the records for this were complex, resulting on some occasions in the incorrect sections being completed (SLC T15) (see recommendation 7).

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2016, recommendations for improvement were made in relation to four areas of major non-compliance and one 'other' area of non-compliance.

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

On-going monitoring of centre success rates

In August 2017, the centre was asked to review procedures for the provision of IVF and ICSI treatment in patients under 38 years of age. The PR responded to the request and provided a commitment to keep success rates in this group of patients under review. Success rates for both these groups of patients are now in line with national averages.

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
1. Storage of gametes and embryos A review of four sets of records where storage had been extended beyond the initial 10 year storage period found one set of records where the medical practitioner's statement was completed approximately one month after the expiry of the initial 10 year storage period (Human Fertilisation and Embryology (Statutory Storage Period for	The PR must ensure that all staff are fully conversant with the requirements of the extended storage regulations. The PR should audit all instances where storage of gametes or embryos has been extended beyond the statutory storage period. A summary report of this audit, including corrective actions, should be provided to the	All staff attending the recent Whole Clinic Meeting (Cardiff and Neath) were reminded of the importance of completing MPS forms prior to expiry of the statutory consent period. A new system for initiating MPS completion has been drafted and briefly all requests for extension of storage will now go to an MDT 1 year prior to the end of the storage period giving enough time for any relevant investigations to be	The inspector is satisfied with this response and will review the summary report of the audits when they are complete. Further action required.

Embryos and Gametes) Regulations 2009).	centre's inspector by 23 August 2018. Six months after the implementation of any corrective actions the PR should audit the effectiveness of the corrective actions and provide a summary of the audit findings to the centre's inspector by 23 December 2018.	completed An audit has been initiated to investigate whether patients who have extended storage have completed MPS. The audits will be completed within the timescale requested.	

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
2. Medicines management Corrections in the controlled drugs register were not clearly crossed out and re-written in line with regulatory guidelines. Anaesthetic drugs in theatre were not locked in the controlled drugs cupboard. Although there was a suitable thermometer in the drugs fridge, there was no log of minimum and maximum temperatures maintained. (Standard Licence Condition (SLC) T2, Controlled Drugs (Supervision of Management and Use) Regulations 2013, The Misuse of Drugs	The PR must ensure that medicines management practices at the centre are compliant with regulatory requirements. The PR should review the causes of the non-compliances identified. A summary of the findings of this review, any corrective actions and timescales for implementation should be provided to the centre's inspector by 23 August 2018. Three months after the implementation of corrective	The issues highlighted with the register are subject to ongoing monitoring, nurse and clinical education. Currently the register is being audited on a weekly basis. The anaesthetic reversal drugs were not locked away as they may have been required for the case that was observed. Anaesthetic drugs are always locked away when theatre is not in use. A system of post theatre-list checks is currently being considered.	The inspector is satisfied with the initial proposals reported by the PR and will review the finalised summary report and subsequent audit report when these are complete. Further action required.

Regulations, 2001; Section 20(c))	actions the PR should audit the effectiveness of the corrective actions and provide a summary of the audit findings to the centre's inspector by 23 December 2018.	Audits will be conducted and reported to the HFEA within the required timescale.	

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
3. QMS The mismatches recorded in the electronic witnessing system are audited every six months, but this is not in the audit schedule and the findings of the audit and any corrective actions are not documented (SLC T36). The SOP for adverse incidents does not include the timescales for reporting relevant incidents to the HFEA (SLC T33b).	The PR should ensure that audits are suitably recorded and that SOPs include all relevant information. The PR should report to the centre's inspector what actions have been taken to ensure this occurs by 23 August 2018.	The standalone audit of mismatches has been added to the QMS audit calendar and separate reports will be prepared and reported via WFIs QM mechanisms. The SOP for adverse incidents has been amended to include reporting timescales.	From the information provided the inspector is satisfied that these issues have now been resolved. No further action.
4. Third party agreements The third party agreement with the screening laboratory does not include how the results of the tests are relayed to the clinic (SLC T114f).	The PR should ensure that third party agreements include all the information required. The PR should report to the centre's inspector what actions have been taken to ensure this	TPAs have been amended to include reporting arrangements.	From the information provided the inspector is satisfied that this issue has now been resolved. No further action.

	occurs by 23 August 2018.		
5. Equipment and materials One of the boxes of single-use gloves used in the laboratory had an expiry date of January 2018 (SLC T2 and T23).	The PR should ensure that items are not used beyond their stated expiry date. The PR should report to the centre's inspector what action has been taken to address this when responding to this report.	A single pair of gloves were found that had expired. All lab gloves have been audited and found to be in date. Staff have been reminded to check expiry dates prior to use of all consumables.	From the information provided the inspector is satisfied that this issue has now been resolved. No further action.
6. Disclosure of information, held on the HFEA Register, for use in research Ten sets of notes were checked and two discrepancies were found between completed patient/partner disclosure consents in patient notes and the related consent data submitted for inclusion on the register. In all the cases noted the patients had consented to disclosure of information, but it was reported to the HFEA that they had not consented (General Direction 0005).	The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the HFEA accurately reflects that given and recorded on disclosure consent forms. The PR should also correct the submissions that have been identified as being incorrect. Confirmation of the corrections and a summary of the findings of the review, any corrective actions and timescales for implementation should be provided to the centre's inspector by 23 August 2018. The PR should conduct an audit six months after implementing any corrective	Staff have been reminded of the importance of correct reporting of consent. Refresher training will be organised for those staff completing EDI. These consents have now been included on the audit plan. We will correct the forms once the IDs have been provided by the HFEA. Results of audits will be provided to the HFEA within the agreed timescales	The patient identification numbers have been provided to the PR and corrections have been made. The inspector will review the summary reports provided by the PR when they have been completed and submitted. Further action required.

	actions to confirm that the actions have had the desired effect. A summary of the audit should be provided to the centre's inspector by 23 December 2018.		
7. Record keeping and document control In the laboratory, one incubator that had been cleaned had not been recorded as ready for use in line with the centre's SOP (SLC T2 and T26). In some records reviewed the decision regarding freezing, not freezing or re-checking for freezing had not been completed in line with the centre's SOP (SLC T2 and T102). Although the inspectors were satisfied that induction and competency was appropriately performed, the records for this were complex, resulting on some occasions in the incorrect sections being completed (SLC T15).	The PR should ensure that records are maintained in line with the centre's SOPs and that records are recorded in a clear manner. The PR should report to the centre's inspector what actions have been taken to ensure this occurs by 23 August 2018.	The record for the particular incubator had been partially completed post cleaning. Embryologists have been reminded to fully complete cleaning records. The embryology notes have been reviewed and the tick boxes for Freeze, Not freeze and Recheck have been removed - these decisions will be recorded more fully in the embryology records Competency documents will be simplified.	The PR has provided suitable information to indicate that appropriate actions have been taken in relation to these issues. No further action.

Reponses from the Person Responsible to this inspection report
Whilst disappointing to have a critical and major non-conformance, the inspection process was fair and has highlighted areas where we can improve. We were pleased to have so many areas that demonstrated good practice and did not require improvement.