Executive Licensing Panel - minutes

Centre 0301 (London Women's Clinic, Wales)

Renewal Inspection Report

Tuesday, 10 December 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Richard Sydee (Chair) Howard Ryan Helen Crutcher	Director of Finance and Resources Data Analyst Risk and Business Planning Manager
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 four years.

1.2. The panel noted that the London Women's Clinic, Wales is located in Cardiff and has held a licence with the HFEA since 2008. The centre provides a full range of fertility services including embryo testing and storage of gametes and embryos.

1.3. The panel noted that, in the 12 months to 31 July 2019, the centre provided 994 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 year ending 30 April, 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.

1.5. The panel noted that, in 2018, the centre provided 52 cycles of partner inseminations, with eight pregnancies. This represents a clinical pregnancy rate of 15%, which is in line with the national average.

1.6. The panel noted that, between 1 May 2018 and 30 April 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is likely to be statistically lower than the 10% multiple live birth rate target.

1.7. An inspection was carried out at the centre on the 28 and 29 August 2019.

1.8. The panel noted that at the time of the inspection, there were four major areas of non-compliance concerning witnessing, medicines management, the Quality Management System (QMS) and third party agreement (TPAs). There were also three 'other' non-compliances regarding equipment and materials, information and data submission. Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations surrounding medicines management, equipment and materials and data submission, and has committed, where required, to audit the effectiveness of those actions within the required timescales. The PR has given a commitment to fully implement the recommendations relating to witnessing, the QMS, TPAs and information.

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 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 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.

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 noted that the required summary reports, audits, and evidence, regarding the non-compliances relating to witnessing, the QMS and TPAs, had been due for receipt by 29 November 2019; the panel requested that should the inspectorate not receive a satisfactory and timely response, an update report should be presented to the Executive Licensing Panel (ELP) for consideration.

2.5. The panel congratulated the centre on its low multiple birth rates, also acknowledging the improvements made since the last renewal inspection, conducted in September 2015.

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

2.7. 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

Richard Sydee

17 December 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 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: 28 and 29 August 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: Andrew Leonard (lead), Victoria Brown, Louise Winstone and Nicola Lawrence.

Date of Executive Licensing Panel: 10 December 2019

Centre name	London Women's Clinic, Wales
Centre number	0301
Licence number	L/0301/4/a
Centre address	15 Windsor Place, Cardiff, CF10 3BY, United Kingdom
Person Responsible	Dr Hemlata Thackare
Licence Holder	Dr Kamal Ahuja
Date licence issued	1 March 2016
Licence expiry date	28 February 2020
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The London Women's Clinic, Wales is located in Cardiff and has held a licence with the HFEA since 2008.

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

The centre provided 994 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2019. In relation to activity levels this is a medium sized centre.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year ending 30 April 2019 show the centre's success rates are in line with national averages.

In 2018, the centre reported 52 cycles of partner insemination with eight pregnancies. This represents a clinical pregnancy rate of 15%, which is in line with the national average.

Multiple births[2]

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

Between 1 May 2018 and 30 April 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is likely to be statistically lower than the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), 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 her 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 four major and three 'other' areas of non compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

Major areas of non compliance:

- The PR should ensure that medicines management procedures and practice are in line with statutory and regulatory requirements.

'Other' areas of non compliance:

- The PR should ensure that equipment is used for the purposes designated in the instructions for use.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

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

Major areas of non compliance:

- The PR should ensure that all witnessing steps are documented.
- The PR should ensure that the quality management system (QMS) is effective and robust, to improve the quality and effectiveness of the service provided.
- The PR should ensure that third party agreements (TPAs) include all HFEA requirements relevant to the third party services and that those services are audited against the requirements in the TPAs at least every two years.

'Other' areas of non compliance:

- The PR should ensure that the centre's website is compliant with CoP Guidance 4.8.

Recommendation to the Executive Licensing Panel

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

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/ live birth rates meet or are below the target.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a 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.

Centre 0301 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 partially compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better

Witnessing (Guidance note 18)
Witnessed checks are carried out during egg collection and embryo transfer and these were observed during the inspection. However, some of these witnessed checks are not documented in the patient records. Similarly, when removing gametes or embryos from storage, witnessed checks of the storage location and sample identifiers against the patient records are also not documented.

SLC T71; recommendation 1.

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 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, albeit limited evidence is held by this centre for the compensation provided to donors at some donor banks abroad (see 'Third Party Agreements' below). It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

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

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

Suitable premises and suitable practices

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

Equipment and materials
Process validation
Adverse incidents

What the centre does well

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

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

The premises of the centre's satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and 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 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 accreditated by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

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

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

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

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

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

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

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

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

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

Receipt of gametes and embryos (Guidance 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, notwithstanding concerns related to the compliance of imports of donor sperm from donor banks within the EU with the terms of General Direction 0006, as discussed in 'Third Party Agreements'.

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. This 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 TCS 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 compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

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

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

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

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

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are broadly compliant with HFEA requirements. Some 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 lessons learned from incidents and continuously improve their services.

What the centre could do better

Medicines management (Guidance Note 25)

Several entries in the controlled drugs register had missing signatures in the witnessing column for “administered by” and the time of administration was not routinely recorded.

SLC T2, The Association of Anaesthetists of Great Britain & Ireland ‘Controlled Drugs in Peri-operative Care’ (2018); recommendation 2.

Quality management system (QMS) (Guidance note 23)
The following audits have not been performed within the last two years: the PGS treatment pathway and embryo testing process; informing and consenting donors; verifying the electronic records used to manage the bring forward process against storage consent records; storage consents and medical practitioner statements for samples stored for more than 10 years. Audits of TPAs against HFEA requirements and of third party services against the requirements in the TPAs have not been performed as is discussed below in ‘Third Party Agreements’.

Thirty standard operating procedures (SOPs) and several TPAs were out of date and had not been reviewed in the last two years, so were at risk of not reflecting current best practice guidelines and regulatory requirements.

SLC T33b, T36 and T111; recommendation 3.

Third party agreements (Guidance note 24)
Some TPAs do not clearly specify the HFEA requirements which the third party services have to meet. The centre has also not effectively audited the compliance of services provided by third parties, including suppliers of donor sperm, with the relevant HFEA requirements (which should be specified in TPAs). For example, evidence was not available for the compliance of compensation provided to sperm donors by donor banks, generally, and for each specific donor, nor was evidence available for the appropriate accreditation of the QMS at one donor bank. Thus, evidence was not present for the compliance of some imports of donor sperm with the requirements of General Direction 0006, under which the imports had been made. Evidence was available for the compliance of donor screening and the accreditation of the screening tests undertaken, but this has not been reviewed in an effective third party service audit. Relevant TPAs also did not clearly state the screening requirements.

General Direction 0001; General Direction 0006; SLCs T36, T69, T112 and T116; recommendation 4.

Equipment and materials (Guidance note 26)
An embryologist was observed using the lid of a culture dish to decant follicular fluid whilst looking for eggs during an egg collection. Although the dish itself is CE marked to an appropriate level, the lid is not; therefore, this medical device is being used ‘off label’ i.e. for a purpose for which it is not CE marked. Centres should use CE marked medical devices wherever possible – as should have occurred in this situation. Where a CE marked medical device is not available, a non CE marked device may be used after robust risk assessment. However, this does not apply in this case because an appropriately CE marked device is available and in stock at the centre.

SLC T23; recommendation 5.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

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, notwithstanding the need for the process to be audited (see 'QMS' above). 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 and 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. Only 51 patients have provided feedback in the last 12 months, giving an average 4.5 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 PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting the staff at the clinic.

There were several negative comments from patients who felt they did not have enough information and these were discussed with the PR. She advised the inspectors and provided evidence that this trend has been noted in the centre's own patient surveys and actions have already been taken to address it. The centre will continue to monitor patient feedback to ensure the actions taken are effective.

The centre's own most recent patient survey responses were also reviewed. The response rate was approximately 15-20% and feedback was generally positive and comparable to that provided to the HFEA.

During the inspection, the inspectors spoke to three patients who 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;
- treats patients with empathy and understanding.

What the centre could do better

Nothing identified at this inspection.

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

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

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

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

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

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and / or donors are broadly compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's website does not consistently provide live birth rates and age stratified success rates for each treatment type. In addition, success rate data on the ICSI treatment webpage is labelled as being for IVF/ICSI, and is identical to that for IVF, which led the inspection team to question the accuracy of the data presentation. The centre's webpage also includes comparative success rate data for multiple licensed centres in Wales and the south west of England. This data presents a picture which is not useful to patients because it is out of date (data is for July 2012 -June 2015), has no age stratification and groups IVF and ICSI data together as 'fresh' treatment cycles. This is concerning because it potentially mis-informs patients about the performance of other licensed fertility centres. The inspection team recognises that more contemporary data is not available on the HFEA website, but also that it soon will be. Moreover the data presentation on the website is not compliant with several aspects of CoP Guidance 4.8 (recommendation 6).

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

What the centre does well

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

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

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At that inspection in August 2017, legal parenthood consenting processes were found to be robust.

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

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing assisted reproductive techniques (ART) and those born following ART treatment.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and 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 centre's procedures for submitting information about licensed activities to the Authority are broadly 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 some evidence of problems with the timeliness of the centre's submission of data to the Register.

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
Information about partner insemination treatments in 2018 was not reported by the centre to the HFEA within the timeframe required. This information has however now been submitted to the HFEA.

General Direction 0005 and SLC T41; recommendation 7.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2017, recommendations for improvement were made in relation to one major and three 'other' areas of non compliance.

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

On-going monitoring of centre success rates

Since the last interim inspection, the centre has received three risk tool alerts during 2017 and 2018 related to performance to which the PR has responded appropriately. These include:

- Pregnancy rate per cycle for fresh IVF treatment in patients aged 38 and over
- Pregnancy rate per cycle for fresh IVF treatment in patients aged under 38 years

The centre has not received any alerts from the HFEA with regards to the success rates of treatments during 2019 and the success rates are currently in line with national averages.

Areas of practice requiring action

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

Critical 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 identified.			

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 partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Witnessing Not all witnessed checks are documented, as detailed in the main body of the report. SLC T71.	The PR should ensure that all witnessed checks are documented. The PR should review witnessing procedures and record sheets to ensure that all witnessed checks are documented. A summary report of the review, including corrective actions with timescales for implementation, should be submitted to the centre's inspector by 29 November 2019. Three months after any changes have been	Since the Inspection, we have carried out a review of the witnessing procedures and record sheets. ID checks are routinely carried out in theatre by two members of staff - embryologist and doctor prior to Egg collection and Embryo transfer. However these were not recorded. The lab record has now been amended and ID witnessing is now recorded on the lab sheets at both events. The Lab SOP has been amended to reflect this change.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided the updated laboratory record as evidence of changes implemented to record patient ID checks, following the inspection. The PR has undertaken a review of witnessing procedures and a summary report of this review due by 29 November 2019 is awaited.

	implemented, the witnessing process should be audited to ensure the documentation of witnessed checks is compliant. A summary of this audit should be provided to the centre's inspector by 29 February 2020.	Enclosed is the updated laboratory record. we will re-audit after three months. We reviewed our witnessing process and confirmed that all witnessing steps are carried as per HFEA guidance when thawing eggs or embryos. For sperm thaws, the witness step removing the sample from the dewar was not double witnessed. The sample was double witnessed before adding to any sperm prep tubes. The lab record has now been amended and the witness step is now being recorded. The change in witnessing process will be audited and a report provided to the centre's inspector by 29 February 2020	The PR has committed to perform an audit to evaluate the effectiveness of changes in this area of practice and provide a report of this audit to the centre's inspector by 29 February 2020. **Further action is required.**
2. Medicines Management Several entries had missing signatures in the witnessing column for "administered by" and the time of administration was not routinely recorded. SLC T2.	The PR should ensure that medicines management procedure and practice is in line with statutory and regulatory requirements. The PR should review practices relating to the	We have reviewed our Medicines management procedure and practice. Anaesthetists have been advised to document time of injection and dose in controlled drugs register. Theatre nurses and	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has undertaken a review of practices relating to

The Association of Anaesthetists of Great Britain & Ireland 'Controlled Drugs in Peri-operative Care' (2018).	management of medicines to ensure compliance with regulatory and statutory requirements. A summary report of this review including corrective actions with timescales for implementation, should be provided to the centre's inspector by 29 November 2019. Three months after any changes have been implemented, medicines management practices should be audited for compliance. A summary of this audit should be provided to the centre's inspector by 29 February 2020.	anaesthetists have been advised to sign for 'supplied, administered and discarded'' in the controlled drugs register for each patient. We have audited this change of practice and enclose a copy for your review. This audit has been added to the centre's yearly audit schedule	the management of medicines and implemented appropriate changes. The PR has provided the centre's inspector with the report of a compliance audit conducted two months following the implementation of corrective actions. No issues were identified. **No further action required**.
3. QMS A number of non compliances were noted by the inspection team within the QMS, as described in the main body of the report. SLC T33b, T36 and T111.	The PR should ensure that the QMS is effective, robust and compliant with HFEA requirements, so as to improve the quality and effectiveness of the service provided. The PR should review the QMS with respect to the issues identified in this report, but also more generally, to	Please see PRs response below in the "Responses from Person Responsible to this inspection report section".	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided a sample of an SOP that has been reviewed and updated. A summary report of a QMS review and reports of the

	ensure it is compliant and effective. A summary report of this review, including all corrective actions required with timescales for implementation, should be provided to the centre's inspector by 29 November 2019. This report should list all audits that need to be performed, and TPAs and SOPs which need to be reviewed and updated. It is expected that all corrective actions should be completed by 29 February 2019. The centre's inspector will select a sample of documents for review when the summary report is provided.		audits performed due by 29 November 2019 is awaited. **Further action required.**
4. Third party agreements The centre has not effectively evaluated the compliance with HFEA requirements and the terms of TPAs, of services provided by third parties generally, including suppliers of donor sperm, as detailed in the main body of the report. General Direction 0001, General Direction 0006.	The PR should ensure that TPAs include all HFEA requirements relevant to the services provided. Before third party services are engaged, the PR should evaluate their compliance with HFEA requirements as should be stated in the relevant TPAs. Evidence supporting the evaluation should be retained.	All TPAs are currently under review to confirm whether the TPA content meets HFEA requirements. It is surprising that the HFEA did not address non-compliance of the TPA when the centre applied for ITE certificate for importing donor sperm. We recently received approval of TPA with California Cryobank from the HFEA	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. Evidence of the implementation of these recommendations due by 29 November 2019 is awaited. **Further action required.**

SLC T36, T69, T112 and T116.	On-going compliance should be audited at least every two years. For individual donor sperm samples imported under General Direction 0006, specific evidence for the compliance of the donor sperm with HFEA requirements (e.g. General Direction 0001 and SLCs T52 and T53) should be collected and stored by the centre. Evidence of the implementation of these recommendations should be provided to the centre's inspector by 29 November 2019.	senior inspector. We intend to use this as a template to send it to other donor banks for whom we have been granted ITE import certificates. On-going compliance will be audited every two years. Our lab Manager has written individually to all donor banks to provide specific evidence for the compliance of donor sperm against HFEA requirements, GD 0001 and SLC T52 and T53 for every sample imported. Evidence of implementation of these recommendations will provided to the centre's Inspector by 29.11.2019	

Other areas of practice that require improvement

Other areas of practice that require 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
5. Equipment and materials A medical device is being used 'off label' i.e. for a purpose for which it is not appropriately classified. SLC T23.	The PR should ensure that medical devices are used for their designated purpose, as detailed in the instructions for use and for which the CE mark was awarded. The centre should advise the centre's inspector of the actions taken to implement this recommendation when responding to this report.	Laboratory Manager has sent an email to the team reminding them to use only CE marked equipment. The Lab manual has been amended. Any non conformances will be reported as an incident for action to be taken internally as appropriate.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. **No further action required.**
6. Information Data presentation on the centre's website is not compliant with several aspects of CoP Guidance 4.8.	The PR should ensure that the centre's website is compliant with all aspects of CoP Guidance 4.8. The PR should audit the content of the centre's website against the requirements of CoP Guidance 4.8 and should provide a report of the audit,	The contents of the centre's website are being reviewed and plans for corrective actions will be submitted to the centre's inspector by 29 November 2019.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The report of the website audit due 29 November 2019 is awaited.

	including plans for corrective actions, to the centre's inspector by 29 November 2019. Success rate data in the Choose a Fertility Clinic area of the HFEA website is currently being updated. When updated data has been published, the centre should implement the corrective actions identified in the compliance audit within three months and should advise the centre's inspector when this has been completed. It is expected that this should be by 29 February 2020.		**Further action required.**
7. Data submission Information about partner insemination treatments was not reported by the centre to the HFEA within the timeframe required. General Direction 0005 and SLC T41.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframes required by General Direction 0005. The PR should review the process by which partner insemination data is annually reported to the HFEA, to identify and address the reasons for the delayed submission.	Previous delays in data submission were due to sudden departure of admin staff. This task is now re-allocated to two staff members with senior fertility nurse and laboratory manager overseeing the timeframes required by General Directions 0005 Reminder has been set for annual reporting of Partner	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. **No further action required.**

	A summary of the findings of the review including corrective actions with timescales for implementation, should be provided to the centre's inspector by 29 November 2019.	Insemination Data to comply with GD 0005	

Responses from the Person Responsible to this inspection report
QMS - Please see my response below to QMS non-compliance noted at the Renewals Inspection. I was unable to document my response in the appropriate space in this report We have carried out audits on 1. PGS treatment pathway 2. Informing and consenting donors 3. Content of TPAs against HFEA requirements We aim to put corrective actions in place by 29.02.2020 We are in the process of auditing 1. Electronic records used to manage the bring forward process against storage consent records 2. Storage consents and medical practitioner statements for samples stored for more than 10 years 3. Audit of third party services against requirements in the TPAs. Report of the above audits will be submitted to the HFEA Inspector by 29.11.2019 SOPs - Since the Inspection, all SOPs have been reviewed and are now in date. I wish to bring to your attention that despite partial compliance of the centre's QMS to HFEA requirements, the centre consistently has received high approval ratings on the HFEA CaFC as well as the centre's own survey. This is duly confirmed also by low number of complaints received and adverse incidents as well as high success rate and low multiple pregnancy birth rate in line with national average as validated by the HFEA. I disagree that the centre does not proactively seek patient feedback. In fact, 51 patients have provided the HFEA with feedback which is significantly higher than what is published on HFEA CaFC for other clinics. Patient feedback is actively sought via every email sent and text message sent to patients after directing to HFEA survey as well as patient questionnaires. Since the Inspection at the end of August 2019, CaFC confirms that 17 more patients have provided feedback to the HFEA with patient rating of 4.5/5 based on 68 ratings. We have updated the information given to patients to enable them to consent donating their gametes/embryos for training or research. We are establishing links with centres holding research licences to enable our patients donate their gametes or embryos for reesearch.