Licence Committee - minutes

Centre 0316 (Centre for Reproduction and Gynaecology Wales (CRGW)

Treatment and Storage Renewal Licence Application

Thursday, 2 May 2019

HFEA, Medway meeting room, 10 Spring Gardens, London, SW1A 2BU

Committee Members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Gudrun Moore Jonathan Herring Ruth Wilde	
Members of the Executive	Moya Berry Dee Knoyle Amanda Evans Jennifer Rogerson	Committee Secretary Committee Secretary (Observer) Research Manager (Induction) Research Manager (Induction))
Legal Adviser	Sarah Ellson	Fieldfisher - LLP
Specialist Adviser		
Observers		

Declarations of interest:

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

The committee had before it:

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

The following papers were considered by the committee:

Papers enclosed:

- Cover Sheet
- Renewal inspection report with Person Responsible response
- Licence renewal application
- Previous Licensing minutes from the last three years
  - 12 July 2018 - Report of an investigation into a serious incident and a targeted interim inspection report
  - 15 July 2016 - Executive update
  - 5 May 2016 - Executive update; consent to legal parenthood audit
  - 17 March 2016 - Renewal inspection report

1. Background

1.1. The Centre for Reproduction & Gynaecology Wales (CRGW), centre 0316, has held a treatment and storage licence with the HFEA since July 2010 and provides a full range of fertility services.

Previous Licence

1.2. The centre's previous licence was granted on 10 December 2012 for a period of four years.

Current Licence

1.3. The centre's current licence was granted on 9 July 2016 for a period of three years (rather than the usual four) and is due to expire on the 8 July 2019. The reason the centre only received a three-year renewal was that several serious non-compliances were identified at the inspection (one critical, three major and ten other areas of non-compliance). The renewal inspection report highlighted as a concern, the centre's multiple pregnancy rate (26% at the interim inspection in 2014 and 27% at the renewal inspection in 2016) and a number of other wide-ranging issues.

1.4. The committee noted that in December 2017 an investigation was conducted by the Executive into a serious incident, which identified several areas of practice that fell short of expected standards. The committee also noted in March 2018, a planned targeted interim inspection was carried out. Four critical, six major and two other non-compliances were noted.

1.5. Following the findings from both these visits, the Executive concluded that it would be appropriate and proportionate for the Licensing Committee to consider the centre's renewal application. The Licence Committee agreed that the centre's licence should continue, but on the basis that close monitoring was undertaken (July-December 2018) by the inspectorate team and that the PR undertook to make the recommended improvements.

1.6. The centre has no additional conditions.

2. Consideration of application

Renewal Inspection

Application

2.1. The committee noted that the centre has submitted an application for the renewal of the treatment and storage licence.

2.2. The committee noted that the application contains the supporting information required by General Direction 0008 and that the appropriate fee has been paid.

Inspection Process

2.3. The centre provided 886 cycles of treatment (excluding partner intrauterine insemination) in the 12 months prior to 30 November 2018. In relation to activity levels this is a medium sized centre.

2.4. The committee noted that in 2018, the centre reported 137 cycles of partner insemination with 26 pregnancies. This represents a clinical pregnancy rate of 19.5% which is in line with the national average.

2.5. The committee noted that between 1 November 2017 to 31 October 2018 the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 8%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

2.6. The committee noted that the renewal inspection took place on 5 and 6 February 2019. The renewal inspection report covers the performance of the centre since the last inspection, the findings from the renewal inspection visit and communications received from the centre.

2.7. The committee noted that at the time of the renewal inspection there were no areas of practice that required improvement.

2.8. The committee noted the support given to the centre by the Executive and recognised the considerable improvements in practice and leadership that had been made over the course of the monitoring visits and at this inspection, particularly in relation to record keeping, the Quality Management System (QMS), clinical practice and protocols.

2.9. The committee noted that the Executive recommends the renewal of the centre's treatment and storage licence for a period of four years without any additional conditions.

3. Decision

3.1. The committee had regard to its decision tree, the HFEA Compliance and Enforcement Policy and HFEA Guidance on licensing.

Administrative Requirements

3.2. Supporting Information under General Direction 0008

Application

3.3. The committee was satisfied that the application was submitted in the form required and contained all the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid.

Proposed Person responsible (PR) – Mr. Lyndon Miles

3.4. The committee was satisfied that the proposed PR possesses the required qualifications and experience and that the character of the proposed PR is such as is required for supervision of the licensed activities. It was further satisfied that the proposed PR will discharge his duties under section 17 of the HF&E Act 1990 (as amended).

Proposed Licence Holder (LH) – Dr. Amanda O'Leary

3.5. The committee was satisfied that the proposed LH is suitable.

Activities

3.6. The committee was satisfied with the suitability of the activities applied for.

Premises – Ely Meadows, Rhodfa Marics, Llantrisant, CF72 8XL

3.7. The committee was satisfied that the premises and facilities are suitable for the conduct of the licensed activity applied for.

Licence

3.8. The committee commended the level of engagement and progress made by the PR and considered the duration of licence it should offer with reference to the 'Guidance on licensing'. The committee recognised the work the PR has undertaken to embed changes and act upon the recommendations set out in the last renewal report and agreed that a four-year licence was appropriate. The committee expected the centre to continue its sustained improvement.

3.9. No additional conditions were applied.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

30 May 2019

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Licence Committee (LC) 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: 5 and 6 February 2019

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: Polly Todd (Lead), Mhairi West, Julie Katsaros and Sandrine Oakes (HFEA observer)

Date of Licence Committee: 2 May 2019

Centre name	Centre for Reproduction & Gynaecology Wales (CRGW)
Centre number	0316
Licence number	L/0316/3/a
Centre address	Ely Meadows, Rhodfa Marics, Llantrisant, CF72 8XL,
Person Responsible	Mr Lyndon Miles
Licence Holder	Dr Amanda O'Leary
Date licence issued	09 July 2016
Licence expiry date	08 July 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Centre for Reproduction & Gynaecology Wales (CRGW) has held a licence with the HFEA since July 2010 and provides a full range of fertility services.

The centre is registered with Health Inspectorate Wales (HIW) which did a joint inspection with the HFEA at the centre's last renewal inspection in January 2016.

The centre provided 886 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 November 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.

Following the renewal inspection in 2016 a Licence Committee issued a three-year licence (rather than the usual four) because they had concerns about the following issues;

- the number and seriousness of non-compliances found at the renewal inspection (one critical; three major and ten other areas of non-compliance);
- the centre's multiple pregnancy rate (26% at the interim inspection in 2014 and 27% at the renewal inspection in 2016);
- the centre had not completed a full audit of legal parenthood consent;
- no-one at the centre, including the person providing conscious sedation, was trained in life support to a higher than basic level;
- intralipids continued to be prescribed by the centre off-label in cases of patient request, despite concerns being raised by the Royal College of Obstetricians and Gynaecologists over a lack of evidence of safety and efficacy.

In October 2017 the HFEA received a letter from West Hampshire CCG about the death of a baby born to a surrogate woman. CRGW had provided treatment services to the surrogate woman and intended parents. An investigation visit was conducted (21 December 2017) to review the centre's practices relating to this case and found that several areas of practice fell short of expected professional and regulatory standards.

In March 2018 a planned targeted interim inspection was carried out. Four critical, six major and two 'other' non-compliances were noted. Due to the findings of both these visits the Executive initially considered a recommendation to revoke the centre's licence. However, following consideration of submissions from the Person Responsible (PR) and his legal advisers, undertaking to make the improvements recommended by the inspectors, the Executive was satisfied that the centre's licence should continue with a period of close monitoring for a specific period of time.

The Licence Committee noted that the centre would seek licence renewal early in 2019 and the close monitoring by the Executive would reveal whether the centre had become fully compliant with all recommendations and was fit to have its licence renewed. The Licence Committee therefore agreed with the Executive's recommendation to continue the centre's licence on the basis that the 'closest possible monitoring' was undertaken.

This period of close monitoring of the centre took place between July and December 2018 in the form of a workshop and a number of site visits. This has allowed the Executive to assess the PR's ability to fulfil his duty under section 17 of the HF&E Act 1990 (as amended) and his progress towards achieving compliance.

The Executive concluded that it would be appropriate and proportionate for the LC to consider the centre's renewal licence application. It is, however, expected that future inspection reports will be considered by an Executive Licence Panel (ELP) unless the Executive has any significant concerns about the centre's compliance.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 November 2017 to 31 October 2018 show the centre's success rates are in line with national averages.

In 2018, the centre reported 137 cycles of partner insemination with 26 pregnancies. This represents a clinical pregnancy rate of 19.5%, which is in line with the national average.

Multiple births[2]

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

Between 1 November 2017 to 31 October 2018 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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

Summary for licensing decision

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

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

The Licence Committee is asked to note that at the time of the inspection there were no areas of practice that required improvement.

The inspection team draws the committee's attention to the PR's response at the end of this report and the Executive response.

This centre has been under considerable scrutiny in the past few months. Following the targeted interim inspection and the investigation into a serious incident, the PR made a commitment to implement all of the recommendations. Considerable improvements in practice and in the leadership of the centre have been noted over the course of the monitoring visits and at this inspection, particularly in relation to record keeping; the quality management system (QMS); clinical practice and protocols, for which the PR and his team are to be commended.

The Executive would expect that the PR can build on current achievements to ensure that compliance and quality standards are maintained.

Recommendation to the Licence Committee

The centre has no critical or major of areas of non compliance.

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/ live birth rates meet the target. The PR is encouraged to continue to use the QMS to best effect to monitor and improve their success rates so as to improve the quality of the service offered to patients.

The inspection team recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions.

Centre 0316 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

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

What the centre does well

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

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

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

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

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

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

Suitable premises and suitable practices

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

What the centre does well

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

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

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

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

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre has not prescribed intralipid therapy since the targeted interim inspection in March 2018, 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.

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. The centre has been allocated an ITE import certificate and imports of gametes and embryos from third country suppliers (TCS) outside the EU/EEA have been made since the introduction of the ITE import certification scheme on 1 April 2018. 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 compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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

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

Equipment and materials (Guidance note 26)

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

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

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

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

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

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

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

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre does not undertake preimplantation genetic screening or embryo testing and sex selection, therefore these areas of practice were not relevant to 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

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 10 patients have provided feedback in the last 12 months, giving an average four star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work, it is important that every patient knows about the rating system. This was discussed with the PR during the inspection. He confirms that the centre has started to encourage patients to provide feedback about their experience at the clinic to the HFEA within the last month. Posters are now displayed in the clinic and there is a link to the HFEA website on the bottom of every email that is sent to patients from the centre.

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.

The centre's own most recent patient survey responses were also reviewed. All 32 respondents that provided feedback to the centre for the month ending 31 January 2019 rated the clinic's service as 'very good' or 'excellent'.

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

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

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

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

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

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

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

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements with the exception noted below. 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

Surrogacy
Following the targeted interim inspection in March 2018, the centre took the decision to not undertake any further surrogacy treatments until staff had received additional training from clinical and legal experts in this area of practice. They have carried out surrogacy treatment on those patients they had already committed to treat or who were already undergoing a course of surrogacy treatment.

On inspection, the centre's 'Surrogacy counselling SOP' was reviewed and it was noted that it states that *'surrogate and if married, her partner will be legal parents unless they sign the Surrogacy Withdrawing your Consent (SWC) consent form'.*

The SWC consent form should only to be completed by unmarried surrogates.

As the centre are not undertaking surrogacy treatments; have addressed the statement in their SOP and have committed to undertake additional training, no recommendation is made at this time subject to the training being completed.

Information

What the centre does well

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

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

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

What the centre does well

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

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

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. 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 Executive.

At the inspection in January 2016, legal parenthood consenting processes were not found to be robust, in that there was difficulty determining the marital status of the patients. The PR was requested to submit a further audit which he did to the satisfaction of the Executive. The audit showed that there were four couples affected by legal parenthood consent anomalies. The legal parenthood status of all four couples has now been resolved by the courts.

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. Six sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

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

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

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and 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 does not use embryos for training staff therefore the requirements of this guidance note are not relevant to this inspection.

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 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 Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2018, recommendations for improvement were made in relation to four areas of critical non compliance, six areas of major non compliance and two 'other' areas 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 January 2019 the centre was asked to review procedures for the provision of fresh, stimulated IVF only treatments in patients aged 38+ years. The Executive understand however that risk tool emails have sometimes not been communicated due to a technical issue. This was discussed at the inspection, where the PR confirmed he did not receive the risk tool alert but did provide a commitment to keep success rates in this group of patients under review.

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. None		See PR comments at end of report	

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. None		See PR comments at end of report	

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. None		See PR comments at end of report	

Reponses from the Person Responsible to this inspection report

In regards to the 2016 Health Inspectorate Wales (HIW) inspection renewal referenced on page 3, CRGW has been more recently inspected by HIW on 5th December 2018. The HFEA were invited to be present at this inspection by HIW but informed HIW that they were too busy to attend. At our HFEA inspection on the 5th February I gave a copy of our December inspection report to the inspectors. The report was embargoed until January 31st 2019 so wasn't accessible online but wasn't by definition still embargoed. Since HFEA inspectors were offered to attend the HIW inspection but chose not to, have seen a copy of the most recent inspection report, could access a copy of the report directly from HIW before CRGW and since the full report is accessible via the HIW website currently I feel that the current (flawless) HIW report should be reflected in this HFEA report and likewise to the licence committee. http://hiw.org.uk/docs/hiw/inspectionreports/060319crgwen.pdf.

Between July and December 2018 we were very appreciative that you undertook the 3 site visits but we would wish you to clarify that these were frequent but not 'monthly' as stated on page 3 which wrongly insinuates we needed a frequent level of monitoring to assess progress with our compliance. CRGW welcomed the visits in pursuit of continual improvement as has always been our ethos. These HFEA visits ensured our paperwork, policies and practices conform with licensed standards.
We don't feel the comment about the case of the baby who sadly died due to poor obstetric care at a hospital 120 miles away , which remains beyond the control of CRGW gives a balanced commentary, as mentioned in this report , as this was acknowledged by the HFEA's own Director of Compliance infront of our legal representative in London in 2018. We are further concerned that the patient who is still under our care is going to have their confidentiality breached by the HFEA as couples known to them who are unaware that their treatment was carried out at CRGW are likely to be alerted to it.

In regards to page the 13 statement regarding the SWC form, we have taken advise and plan to currently continue to get married couples to sign SWC as per legal recommendation via CRGH Francesca Stein at CRGH (lead Nurse for surrogacy by surrogacy UK). CRGH complete SWC on the surrogates partner even if they are married or in a civil partnership as advised by their surrogacy lawyer. Even though the partner cannot legally withdraw his consent, completing SWC shows intent and makes it easier for a parental order to be obtained if there were to be a breakdown in the relationship. CRGH do this routinely to support patients with their parental orders.
We remain focussed to get this as water tight as possible but if we should not complete the SWC then it would be helpful to all clinics in the sector if there was a sentence on the SWC consent form by the HFEA to this effect as there are equivalently on the SPP ,SWP, PP and WP consent forms. This omission from the HFEA consent form does not help clinics with the process.

On page 19 in regards to the statement that as PR I did not receive a recent HFEA risk tool alert, the inspectors informed me at the inspection that "a lot of PR's had not been getting such alerts so were not surprised that I had not received that one". I have since the inspection failed to receive a further alert. As such I feel the statement on page 19 should reflect that point as readers of the line could interpret otherwise. If I had received the alert I would have responded to it contemporaneously (as I always do) and it would not be on the report so I don't think it should be mentioned at all. If it needs to be mentioned then the inadequacies of the HFEA IT department should naturally also be referenced.

Executive response to PR's comments:

Paragraph one:
This report is accurate in its commentary that the HFEA did a joint inspection with HIW in 2016.
The Executive cannot reconcile the PR's claim that the HFEA *'chose not to'* attend the inspection with HIW in December 2018. The HFEA and HIW liaised in 2018 regarding undertaking a joint inspection visit but were unable to secure a date that was suitable to both inspection teams due to other commitments for both regulators.

The Executive cannot reconcile the PR's claim of a 'flawless' report from HIW which, whilst citing no non-compliances, as in this report, made the following comments for the PRs consideration:

- *'The majority of information provided in leaflet form and on the website, was provided in English only. Given that the clinic operates in Wales, further efforts should be made to routinely provide information in both Welsh and English'. Efforts should also be made to provide information in other languages and formats, taking into consideration the communication needs and wishes of patients using the service'.*
- *'We discussed the need for the registered person to ensure that they fully discharge their obligations under Regulation 28 of the Independent Health Care (Wales) Regulations 2011, in respect of visits to the clinic and the production and sharing of reports following such visits'.*

Paragraph two:
Following the Licence Committee consideration of the two reports in July 2018 the Executive visited the centre on four occasions in the following five months. The report has been amended accordingly.
The Executive cannot reconcile the PR's claim that we wrongly insinuate that the centre needed a frequent level of monitoring to assess their compliance. The minutes of the LC (12 July 2018) clearly state; *'The committee decided to accept the Executive's recommendation that the licence should continue with no additional conditions at this stage* ***on the basis that the Executive will conduct the closest possible monitoring of the centre's performance over the next six months.*** *The committee considered that this will provide*

an opportunity to assess whether corrective actions can be embedded in practice and whether recent improvements in quality can be sustained'.
This statement would suggest that the committee felt that the centre did, indeed, require a frequent and close level of monitoring.

Paragraph three:
The Code of Practice 9th edition provides information to centres regarding surrogacy and legal parenthood stating that:
'If the surrogate is married or in a civil partnership at the time of insemination/transfer, ***her husband, wife or civil partner*** *will be the legal father or parent of any child born as a result of her treatment (and will have parental responsibility) unless:*
a) there is a judicial separation or a separation order in force or
b) it is shown that her husband, wife or civil partner did not consent to the placing of the sperm and eggs, or embryos, in her, or to her insemination.

this section of the code goes on to explaining how a centre might establish a lack of consent 'as a question of fact'.

Since providing his response to this report, the PR has informed the Executive that he has sought further independent legal advice (rather than third party information) and on the basis of that advice has confirmed that the centre **will not** now be completing the SWC (withdrawal of consent to be legal parent in surrogacy) in cases where the surrogate is married.

Paragraph four:
The report clearly states, as the PR has re-iterated in his response, that he confirmed he did not receive the risk tool alert for January 2019. The PR is mistaken in his assumption that it would not be included in this report had he received and responded to it. Success rate alerts are noted in all inspection reports where they have been issued. The Executive acknowledges that there have been identified issues with the PR not receiving email alerts to the risk tool, but the information has always been readily available on the clinic's portal page.