Executive Licensing Panel Minutes

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

Interim Inspection Report

Date:	9 March 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Laura Riley Dina Halai	Director of Strategy and Corporate Affairs Head of Regulatory Policy Senior Scientific Policy Manager
Executive:	Bernice Ash	Secretary

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 noted that the Centre for Reproduction & Gynaecology Wales (CRGW) is located in Rhodfa Marics and has held a licence with the HFEA since July 2010. The centre provides a full range of fertility services. The centre has satellite arrangements with CRGW Bristol and CRGW Swansea.

1.2. The panel noted that, in the 12 months to 31 October 2020, the centre had provided 414 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a small sized centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom has impacted on treatment numbers.

1.3. The panel noted that, HFEA register data, for the period October 2019 to September 2020, show the centre's success rates for IVF and ICSI are in line with the national averages.

1.4. The panel noted that, in 2019, the centre reported 125 cycles of partner insemination, with eighteen pregnancies. This represents a clinical pregnancy rate of 14% which is comparable to the national average.

1.5. The panel noted that, HFEA register data, between October 2019 and September 2020, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This represents performance that is not likely to be significantly different from the 10% multiple live birth rate target for this period.

1.6. The panel noted that, due to the Covid-19 pandemic, a Desk Based Assessment and Risk Based Approach (DBA/RBA) was taken for the centre's interim inspection; this occurred on 19 January 2021 and was combined with the use of virtual technology. The Person Responsible (PR) had submitted photographic evidence and documents in support of the interim inspection. Video conference calls, with key staff, had also occurred through Microsoft Teams.

1.7. The panel noted that at the time of the inspection, there were no areas of non-compliance identified for improvement.

1.8. The panel noted the centre is well led and provides a good level of patient support.

1.9. The panel noted that the inspection team recommends the continuation of the centre's treatment and storage licence. The inspectorate particularly noted the centre's good patient feedback, attained through its own patient survey and the sustained improvement in the level of compliance.

2. Decision

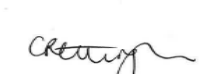
2.1. The panel noted that, in the last 12 months, only twelve patients had provided feedback on their experience of the centre through the 'Choose a Fertility Clinic' facility available on the HFEA website; the panel suggested that the centre should actively encourage patients to use this mechanism to provide feedback.

2.2. The panel was satisfied the centre was fit to have its treatment and storage licence continued.

3. Chairs signature

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

Signature



Name

Clare Ettinghausen

Date

11 March 2021

Interim Licensing Report

Centre name: Centre for Reproduction and Gynaecology Wales (CRGW)
Centre number: 0316
Date licence issued: 9 July 2019
Licence expiry date: 8 July 2023
Additional conditions applied to this licence: None
Date of inspection: 19 January 2021
Inspectors: Polly Todd (lead), Louise Winstone, Sarah Stedman (observer)
Date of Executive Licensing Panel: 9 March 2021

Purpose of the report

Licensed centres receive a licence from the Human Fertilisation and Embryology Authority (HFEA) to operate for up to four years. By law, they must be inspected every two years.

This is a report of an interim inspection. It is a short, focused, inspection reviewing specific themes, which are areas of practice we consider important to evaluate at the mid-point of a centre's licence. We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's overall performance.

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

In response to the national lockdown in place from 6 January 2021, brought about by the Covid-19 pandemic, our inspection methodology was significantly revised to reduce risks of transmission of the virus through onsite inspections. As a result, interim inspections are being conducted via a Desk Based Assessment using a Risk Based Approach (DBA/RBA) combined with virtual technology, unless there are specific concerns that can only be examined onsite.

This inspection was conducted via a DBA/RBA combined with virtual technology. Photographic evidence and documents have been supplied by the PR in support of this inspection and video conference calls with key staff have been conducted using ‘Microsoft Teams’.

Summary for the Executive Licensing Panel

Summary for licensing decision – pre review of draft by PR

The inspection team recommends the continuation of the centre's licence. In particular we note good patient feedback provided to the centre and sustained improvement in the level of compliance.

The centre is well led and provides a good level of patient support.

The ELP is asked to note that this report makes no recommendations for improvement.

Information about the centre

The Centre for Reproduction and Gynaecology Wales (CRGW) is located in Rhodfa Marics and has held a licence with the HFEA since July 2010.

The centre provides a full range of fertility services. Other licensed activities include the storage of gametes and embryos.

The centre has satellite arrangements with CRGW Bristol and CRGW Swansea.

The centre provided 414 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2020. In relation to activity levels this is a small centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers.

The centre followed professional body guidance to suspend all non-essential treatments in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period October 2019 to September 2020 show the centre's success rates are in line with national averages.

In 2019, the centre reported 125 cycles of partner insemination with 18 pregnancies. This represents a clinical pregnancy rate of 14%, which is in line with the national average.

Multiple births[2]

[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] Multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

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

Between October 2019 and September 2020, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur.

The inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and to review the results of recent audits. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed and the 'bring-forward' system was discussed. Documentation provided as part of the DBA and discussions with staff during the virtual inspection indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

The inspection team considered that staffing levels in the clinic were suitable for the activities being carried out, following assessment of information provided as part of the DBA and discussions with the PR during the virtual inspection. The PR regularly reviews staffing requirements in light of changes in working practices due to the Covid-19 pandemic.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: medicines management; infection control; legal parenthood; witnessing; consent to storage.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- leadership
- extension of storage consent
- consent
- ovarian hyperstimulation syndrome reporting
- data submission to the HFEA
- the use of CE marked medical devices
- the content of the centre's website
- the centre's audit of legal parenthood

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

Documentation provided as part of the DBA indicates that the clinic's processes for medicines management and the safe storage, disposal and administration of medicines are compliant with guidance.

Prescription of intralipid 'off label'

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

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

Documentation provided as part of the DBA and discussions during the virtual inspection indicate that the clinic's infection control practices are compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support

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

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

Patient feedback

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 12 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 well, it's important that every patient knows about the rating system. Discussions with the PR at this and previous inspections indicate that the centre is doing as much as possible to encourage patients to use the HFEA website facility for providing feedback. Links to the website are provided on all outgoing emails and information is provided to patients. The PR has considered the use of iPads for patient use but provides a valid rationale for not implementing this method.

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. Some patients provided individual comments to the HFEA complimenting the staff at the clinic.

The centre's own most recent patient survey responses were reviewed. The centre is currently collating the data for 2020, so the inspection team reviewed patient feedback provided in 2019. Out of 368 responses received, 364 patients indicated they would recommend the clinic.

On the basis of this feedback 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.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self assessment questionnaire and pre-inspection assessment indicate that the centre is fully compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2019, there were no recommendations for improvement made.

On-going monitoring of centre success rates

Since the last renewal inspection in February 2019 the centre has not received any performance related risk tool alerts.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The centre has had significant EDI submission issues since at least July 2020 which have been reported on a number of occasions to the HFEA. Through no fault of the PR, he was unable to submit a large amount of data. This matter was escalated within the HFEA and resolved in November 2020. Since then, the PR has submitted data within the required timeframes.

The clinic is compliant with requirements to submit information to the HFEA.

Legal parenthood

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 the inspection in February 2019, 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 using screenshare technology. 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.

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

Annex 1

Areas of practice that require the attention of the Person Responsible

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, 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 made.

Critical areas of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical 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			

‘Major’ areas of non compliance

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

- which poses an indirect risk to the safety of a patient, donor, embryo or 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;
- which can comprise 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
2. None			

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require improvement are any areas of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate 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			

Additional information from the Person Responsible