Executive Licensing Panel - minutes

Centre 0148 (Shropshire and Mid-Wales Fertility Centre)

Interim Inspection Report

Tuesday, 20 August 2019

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Helen Crutcher Dina Halai	Director of Strategy and Corporate Affairs Risk and Business Planning Manager Scientific Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Victoria Brown	Licensing Manager Inspector (Scientific) - Induction

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 Shropshire and Mid-Wales Fertility Centre, is based in Shrewsbury and has been licensed by the HFEA since 1994. The centre provides a full range of fertility services to patients.

1.2. The panel noted that, in the 12 months to 31 March 2019, the centre had provided 584 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre.

1.3. The panel noted that, for IVF and ICSI, HFEA register data, for the year ending March 2019, show the centre's success rates are in line with the national averages, with the following exception:

- The clinical pregnancy rate following FET in women aged under 38 years is lower than average at a statistically significant level.

1.4. The panel noted that, in 2018, the centre reported two cycles of partner insemination, with no pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.5. The panel noted that HFEA register data for the year ending March 2019 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 11.7%. This represents performance that is not likely to be statistically different to the 10% multiple live birth rate target for this period.

1.6. The panel noted that an unannounced inspection took place on 6 June 2019.

1.7. The panel noted that at the time of inspection there was one major area of non-compliance concerning infection control. There were also two 'other' areas of non-compliance regarding the Quality Management System (QMS) and premises and equipment. Since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendation concerning the QMS, 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 surrounding infection control and premise and equipment.

1.8. The panel noted that the inspectorate recommended the continuation of the centre's treatment and storage licence.

2. Decision

2.1. The panel recommended that the centre should encourage patients to provide feedback via the 'Choose a Fertility Clinic' facility on the HFEA website, noting that only 4 patients had used this facility in the last 12 months.

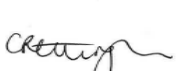
2.2. The panel also noted that, since the last renewal inspection in June 2017, the centre has received two risk tool alerts related to performance in frozen embryo transfer treatment cycles, for patients under 40, to which the PR has responded during discussions at the time of this inspection.

2.3. The panel was satisfied the centre was fit to have its treatment and storage licence continued, subject to the recommendations made in the report being implemented within the prescribed timescales.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

23 August 2019

Interim Licensing Report

Centre name: Shropshire and Mid-Wales Fertility Centre
Centre number: 0148
Date licence issued: 1 December 2017
Licence expiry date: 30 November 2021
Additional conditions applied to this licence: None
Date of inspection: 6 June 2019
Inspectors: Mhairi West, Sandrine Oakes and Victoria Brown (observing)
Date of Executive Licensing Panel: 20 August 2019

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. The current foci for an interim inspection are:

- **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.

Summary for the Executive Licensing Panel

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence.

The ELP is asked to note that this report makes recommendations for improvement in relation to one major and two 'other' areas of non compliance or poor practice.

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:

'Other' areas of practice that require improvement:

- The PR should ensure that the process used to monitor consent to storage expiry dates is robust and accurate.

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

Major areas of non compliance:

- The PR should ensure compliance with infection control regulations and the safe management of healthcare waste guidance.

'Other' areas of practice that require improvement:

- The PR should ensure that the backup power supplies in place at the centre for critical equipment operation are validated and tested on a regular schedule.

Information about the centre

The Shropshire and Mid-Wales Fertility Centre, is based in Shrewsbury and has been licensed by the HFEA since 1994. The centre provides a full range of fertility services to patients.

The centre was last inspected in July 2018, in response to an application to vary the centre's licence (change premises). The centre is now located in a 'health park' some miles from its previous location.

The centre provided 584 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2019. In relation to activity levels this is a medium centre.

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]

HFEA held register data for the year ending March 2019 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exceptions;

- The clinical pregnancy rate following FET in women aged under 38 years is lower than average at a statistically significant level.

In 2018, the centre reported two cycles of partner insemination with no pregnancies.

Multiple births[2]

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

HFEA held register data for the year ending March 2019 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 11.7%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: preparation and procedure for embryo transfer. All of the procedures observed were witnessed using a manual system in accordance 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

[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%.

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, the 'bring-forward' system was discussed with staff and storage records were reviewed. These activities 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 appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

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; traceability.

The centre's procedures for auditing and acting on the findings of audits are broadly compliant with requirements because the electronic records which are used to manage the bring forward process are not audited against the paper records of storage consent, to ensure their accuracy. The inspection team acknowledge that there have not been any reported incidents involving an inaccurate consent period being recorded in the electronic database. However, as the electronic database is compiled using manual data input, and no further checks on the accuracy of this manual process are done until a few months before the consented storage period is due to expire, an error may not be discovered for a significant length of time and could result in gametes or embryos being held in storage without effective legal consent.

See recommendation 2.

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

- patient support
- information provision
- counselling
- extension of storage consent
- consent
- imports of gametes and embryos from outside the EU/EEA
- the use of CE marked medical devices
- 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.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be 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.

During the inspection, we reviewed infection control practices and found them to be partially compliant with guidance for the following reasons;

- A number of bags containing dirty linen and instruments awaiting sterilisation were on the floor of the office area corridor awaiting collection.
- Several closed sharp bins were observed being stored in a carboard box under a desk on the floor of the office area, awaiting collection for disposal. Staff were unsure about the collection schedule or how long the sharp bins had been stored under the desk.
- Several boxes of consumables were stored on the floor of the store room. This was an area of practice requiring action that was identified in the centre's own recent infection control audit. Corrective actions had been documented and implemented by 31 October 2018, but the practice has reoccurred.

The inspection team acknowledge that, by mid-day of the inspection, it was observed that all items located on the corridor floor, including the used sharp bins, had been cleared and either collected or stored in an appropriate location.

See recommendation 1.

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'.

The CE mark status of the following medical devices was reviewed in the course of the inspection; various items of laboratory plasticware, consumables and media. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

The centre has an Uninterrupted Power Supply (UPS) system and an external power generator, both of which would be used to provide power to the critical equipment within the centre, in the event of an electrical power failure. However, the PR informed the inspector that the generator had not yet been tested as the exhaust is right beside the air conditioning system to the laboratory. The UPS system has been tested once. The inspection acknowledges that the PR is aware of the need for testing of back up equipment, and this has been discussed within the centre team.

See recommendation 3.

Patient experience

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 four patients have provided feedback in the last 12 months, giving an average five star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.'

The centre's own most recent patient survey responses were therefore reviewed. The inspection team were impressed with the detail employed in the feedback questionnaire, and the analysis performed, and actions taken by the centre. Feedback was comparable to that provided to the HFEA. The feedback was generally very good, with the exception of several negative comments regarding counselling at the centre. These were discussed with the PR. He advised the inspectors that actions have already been taken to address this matter. The inspection team recommends the centre continue to monitor patient feedback to ensure the actions taken are effective.

The website also gives the ability for patients to comment on the cost of treatment. All patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting staff at the clinic.

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.

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, the pre-inspection assessment and observations during the visit to the centre, 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 2017, recommendations for improvement were made in relation to three major areas of non compliance.

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

Following the 'change of premises' inspection in July 2018, recommendations were made to address three major and one 'other' area of non compliance.

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

On-going monitoring of centre success rates

Since the last renewal inspection in June 2017 the centre has received two risk tool alerts related to performance, to which the PR has responded and, during discussions at the time of this inspection, provided a commitment to keep success rates in this group of patients under review.

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 clinic is compliant with requirements to submit information to the HFEA. There are currently no significant data submission issues at this clinic. This conclusion is based on a review of the clinic's register submissions conducted on 24 May 2019.

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 June 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.

Areas of practice that require the attention of the Person Responsible

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, 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	Inspection team's response to the PR's statement
None found			

‘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 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 partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Infection Control There were a number of non-compliant infection control issues noted on inspection please see main body of report for detail. The inspection team acknowledge that, by mid-day of the inspection, it was observed that all items located on the corridor floor, including the used sharp bins, had been cleared. SLC T2.	The PR should ensure that equipment, laundry refuse etc are suitably stored whilst awaiting collection/disposal. The PR should ensure there is a regular schedule for collection of waste products and materials and provide evidence of this to the centre’s inspector by 6 September 2019. The PR should inform the centre’s inspector of the actions taken to address the	We acknowledge that on the day of inspection, clear laundry bags containing scrubs for laundering, which were tied and sealed at the top, were placed in the administration area corridor (which is not accessible to patients). There were also empty blue boxes, which are used for the transport of instruments for sterilisation. We have investigated this issue and the team is now clear that these items will be	The Executive acknowledge the PR’s commitment to addressing this non-compliance and the actions taken. No further action required, further than the submission of evidence of a schedule for regular collection of waste materials, by 6 September 2019.

Department of Health: Health Building Note 00-09: Infection control in the built environment (2013) (section 3.105). Environment and sustainability Health Technical Memorandum 07-01: Safe management of healthcare waste (2013) (section 3.27).	non-compliances in this report and provide information of how he will ensure that this non-compliance will not reoccur, by 6 September 2019.	stored in the locked 'bin store' adjacent to the recovery area and sluice. Additionally, sharps bins (which are locked by patients prior to being returned to the department) are stored in the sluice area before being transferred to the external bin store for collection.	

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area 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	Inspection team’s response to the PR’s statement
2. QMS The records of storage consent have not been audited against the electronic records which are used to manage the bring forward process, to ensure their accuracy. SLC T36.	The PR should ensure that the process used to monitor consent to storage expiry dates is robust and accurate. The PR should review the process for populating the electronic records used to manage the bring forward process, considering measures to ensure their accuracy, and should submit this review to the centre’s inspector by 12 September 2019. Three months after any changes have been implemented, the database should be audited for effectiveness. A summary of this audit should be provided to	A new system of checking will be introduced, so that the point at which key data is entered onto the database is witnessed/checked by a second individual against the original notes. We will also undertake a sample historical audit of entries to determine if there are any discrepancies. It should be noted that no discrepancies were highlighted by the inspection team.	The Executive acknowledge the PR’s commitment to addressing this non-compliance and the actions taken. No further action required, other than submission of the historical audit by 12 September 2019.

	the centre's inspector by 12 December 2019.		
3. Premises & Equipment The centre has an Uninterrupted Power Supply (UPS) system and an external power generator, both of which would be used to provide power to the critical equipment within the centre, in the event of an electrical power failure. The generator has not yet been tested as the exhaust is right beside the air conditioning system to the laboratory. The UPS system has been tested once. Neither backup systems have a testing schedule. The inspector acknowledges that the PR is aware of the need for testing of back up equipment, and this has been discussed within the centre team. SLC T24.	The PR should ensure that the backup power supplies in place at the centre for critical equipment operation are validated and tested on a regular schedule. The PR should review the process for providing power to critical equipment in the event of an electrical supply fail, to ensure it includes a testing schedule for the equipment which will supply the power in this event. This reviewed process should be submitted to the centre's inspector by 6 September 2019.	The generator and the UPS were both tested when the building was commissioned. Since then they have both been tested once. The UPS acts to smooth the flow of electricity whilst the generator turns on and off. On this occasion it was noted that a diesel smell percolated to the laboratory, presumably from the diesel generator. This has been reported to the engineers/designers of the facility and they are working to fix the problem. In the meantime, to reduce risk, the testing schedule (which was to be monthly) has been put on hold. We hope to have this issue addressed as soon as possible. In addition we are organising a generator test for the next period of time that the laboratory will contain no Embryos (21st & 22nd September). The alterations to the air flow systems are scheduled for the 21st and 22nd	The Executive acknowledge the PR's commitment to addressing this non-compliance. The submission date for the process review is extended to 6 October 2019. The PR should keep the centre's inspector updated if he doesn't expect to meet this deadline. Further action required.

		of September and, therefore, unfortunately we will not be able to meet the suggested schedule of the 6th September and would request and extension to October for this issue please.	

Additional information from the Person Responsible