Executive Licensing Panel - minutes

Centre 0278 (Wrightington Wigan & Leigh Hewitt Fertility Partnership)

Interim Inspection Report

Friday, 16 March 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Caylin Joski-Jethi (Chair) Anna Coundley Niamh Marren	Head of Intelligence Information Access & Policy Manager Regulatory Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel noted that Wrightington Wigan & Leigh Hewitt Fertility Partnership has held a treatment (Insemination using partner sperm) licence with the HFEA since 2007 and provides basic fertility services to NHS and self-funding patients.

1.2. The panel noted that the centre also provides satellite in vitro fertilisation (IVF) services to The Hewitt Fertility Centre (centre 0007) in Liverpool, Hewitt Fertility Centre, Knutsford (centre 0344), Manchester Fertility (centre 0033) and CARE Manchester (centre 0185). Patients who require IVF are treated at the centre up to the point of egg collection, then referred to the primary centres for completion of their treatment. The Person Responsible (PR) estimated that they provide satellite services for approximately 550 cycles per year.

1.3. The panel also noted that, in 2017, the centre reported 70 cycles of partner insemination with nine clinical pregnancies. This represents a clinical pregnancy rate of 13%, which is comparable to the national average.

1.4. The panel noted that the inspection took place on 16 January 2018.

1.5. The panel noted that at the time of the inspection on 16 January 2018, three 'other' areas of non-compliance or poor practice was identified concerning the Quality Management System (QMS), screening of patients and patient feedback. The panel noted that since the inspection, the PR has fully implemented the recommendation concerning patient feedback and has provided a commitment to implementing the recommendations regarding the QMS and screening of patients.

1.6. The panel noted that the inspectorate recommends the continuation of the centre's treatment (Insemination using partner sperm) licence.

2. Decision

2.1. The panel welcomed the engagement of the PR and was pleased to see the low number of non-compliances identified at this interim inspection, encouraging this good practice to continue through to the centre's renewal.

2.2. The panel was satisfied the centre was fit to have its treatment (insemination using partner sperm) licence continued.

3. Chair's signature

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

Signature

Name

Caylin Joski-Jethi (Chair)

Date

22 March 2018

Interim Licensing Report

Centre name: Wrightington Wigan & Leigh Hewitt Fertility Partnership
Centre number: 0278
Date licence issued: 01 July 2016
Licence expiry date: 30 June 2020
Additional conditions applied to this licence: None
Date of inspection: 16 January 2018
Inspectors: Karen Conyers, Janet Kirkland
Date of Executive Licensing Panel: 16 March 2018

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 a short notice 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. For 2015-2018 the foci of 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

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 three 'other' areas of non-compliance or poor practice.

Since the inspection visit the Person Responsible (PR) has confirmed that the following recommendation has been fully implemented:

'Other' area of practice that require improvement:

- The PR should ensure that there are processes in place to enable the collection and review of feedback from all users of the service.

Since the inspection visit the PR has given a commitment to implementing the following recommendations in the prescribed timescales:

'Other' areas of non-compliance:

- The PR should ensure that the quality management system (QMS) includes a regular review of incidents.
- The PR should ensure that patient's travel or medical history is considered, to determine if any additional testing may be required prior to treatment.

There is also one major area of non-compliance detailed in the report that relates to the satellite services provided by this centre. This non-compliance is not considered by the licensing committee when making a decision regarding the continuation of the HFEA licence held by the satellite centre. It is recommended that the PR should liaise with the PRs of the primary centres to ensure that this recommendation is effectively implemented in the prescribed timescales. The PRs for the primary centres have provided a commitment to fully implementing these recommendations.

Information about the centre

The Wrightington Wigan & Leigh Hewitt Fertility Partnership has held a Treatment (Insemination using partner sperm) licence with the HFEA since 2007 and provides basic fertility services to NHS and self-funding patients.

The centre also provides satellite in vitro fertilisation (IVF) services to The Hewitt Fertility Centre (centre 0007) in Liverpool, Hewitt Fertility Centre, Knutsford (centre 0344), Manchester Fertility (centre 0033) and CARE Manchester (centre 0185). Patients who require IVF are treated at the centre up to the point of egg collection, and are then referred to the primary centres for completion of their treatment. The Person Responsible (PR) estimated that they provide satellite services for approximately 550 cycles per year.

The current licence was varied in January 2018 to reflect a change in Licence Holder.

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

For the year 2017 the centre reported 70 cycles of partner insemination with nine clinical pregnancies. This represents a clinical pregnancy rate of 13%, which is comparable to the national average.

Multiple births

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

In 2017, all the clinical pregnancies following partner insemination were singletons.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes 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 procedures with staff and to review witnessing documentation in patient records. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The centre does not store gametes and embryos therefore this area of practice is not applicable to this inspection.

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 would be 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: witnessing, consent, traceability and infection control.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements. However, the centre's QMS was considered to be broadly compliant with requirements for the following reason (recommendation 1):

- The centre does not manage its own incidents, these are reported internally through the Trust's DATIX system. Once incidents are reported on DATIX, centre staff are not able to access any reports, review investigations or consider lessons learned, and are reliant on the Trust to provide feedback to them, but this is only if the Trust considers it necessary. The inspection team was concerned that this may limit centre staff being able to effectively develop or implement learning from any incidents identified. The inspection team notes that the centre has not had any HFEA reportable incidents since 2009, and that at the time of the renewal inspection in 2016, the centre's procedures for reporting adverse incidents were found to compliant with HFEA 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:

- the use of CE marked medical devices
- the use of the most recently issued HFEA consent form versions
- HFEA Clinic Focus articles regarding: screening requirements

The centre is broadly effective in ensuring compliance with guidance issued by the HFEA because it does not fully consider the patient's travel or medical history with regard to the risks of infections (such as Ebola), or whether any additional testing may be required prior to treatment (recommendation 2). The inspection team noted that the centre assesses all patient's travel history in relation to risks of Zika virus exposure or infection.

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 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'.

The CE mark status of the following medical devices was reviewed in the course of the inspection: culture medium and plastic ware. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Satellite activities
The centre provides satellite in vitro fertilisation (IVF) services to four primary centres: Hewitt Fertility Centre (centre 0007) in Liverpool, Hewitt Fertility Centre, Knutsford (centre 0344), Manchester Fertility (centre 0033) and CARE Manchester (centre 0185).

The inspection team noted that the audit of the satellite service carried out by primary centres 0007 and 0344 did not include an audit of practices in relation to 'Procuring, processing and transporting gametes and embryos' (Guidance note 15) such as whether all required screening tests had been carried out, whether timeframes for screening had been met, and whether screening was carried out in a suitably accredited laboratory (recommendation A).

It is noted that centre 0033 has only recently established the satellite agreement and an audit of the satellite service is planned for June 2018. The PR of centre 0185 confirmed that the only activity undertaken by the satellite centre is the preparation of patients for frozen embryo replacement, and that all consents and previously provided blood screening test results are audited by the primary centre prior to treatment.

Patient experience
During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. The centre has sought user satisfaction feedback on the Andrology service but has not sought any formal feedback from patients undergoing IUI treatments (recommendation 3). Feedback from users of the Andrology service (eight responses) was positive, and the only negative comment provided had been acted upon. The inspection team noted that centre had received a number of 'thank you' cards but there is no formal process of reviewing or recording this patient feedback.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients sufficient, accessible and up-to-date information to enable them to make informed decisions;

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 compliant with the HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in January 2016, recommendations for improvement were made in relation to six major and one 'other' area of non-compliances or poor practice. The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales, with the exception of the satellite agreements due to delays in obtaining these from the PRs of the primary centres.

On-going monitoring of centre success rates

As this centre only provides partner IUI treatment, their success rates are not subject to on-going monitoring through the HFEA risk tool and the centre has not therefore been issued with any performance alerts.

Provision of information to the HFEA

The centre provided an annual return for treatments undertaken in 2016 and 2017 within the required timeframe.

Legal parenthood

The centre does not provide treatments where consent to legal parenthood would be required, therefore this area of practice is not applicable to this inspection.

The PR informed the inspection team that treatment where consent to legal parenthood would be required are only carried out at centre 0033, therefore this area of practice would form part of the auditing of the satellite service carried out by that primary centre. The PR of centre 0033 has confirmed that: 'Our procedure for releasing donor sperm for treatment is the same for satellite patients as our own and this does not happen until 2 authorised people verify the legal parenthood consent is in place. This is also audited.'.

Annex 1

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	Executive review
None identified on this inspection			

‘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	Executive review
None identified on this inspection			

‘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	Executive review
QMS 1. The centre does not have a process for monitoring and reviewing incidents that are reported internally through the Trust’s DATIX system. SLC T32.	The PR should ensure that the QMS includes a regular review of incidents. The PR should review the centre’s processes for monitoring and reviewing incidents. A summary report of this review, including details of corrective actions taken, should be provided to the centre’s inspector by 16 April 2018.	Process has been reviewed. We are now able to report anonymously (previously required patient details - confidentiality issue) We will formalise a process to collate all incidents wihtin the department's QMS.	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The PR has provided a brief summary of the review of processes for the monitoring and reviewing of incidents. The PR should provide further details on the actions taken in relation to the processes for the management of internal incidents, including how they can ensure learning from any incidents, by 16 April 2018. **Further action is required**.

Screening of patients 2. The centre does not fully consider the patient's travel or medical history with regard to the risks of infections (such as Ebola), or whether any additional testing may be required prior to treatment. SLC T50d. Clinic Focus March 2016. The inspection team accepts that the frequency of Ebola infection is low, hence have graded this as an 'other' non-compliance.	The PR should ensure that patient's travel or medical history is considered to determine if any additional testing may be required prior to treatment. The PR should review the centre's processes for considering and assessing the patient's travel or medical history. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 16 April 2018. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 16 July 2018. This area of practice is also the responsibility of the PRs at the primary centres. The PR at centre 0278 should work with	We are looking at what other primary centres do to mitigate this risk and wonder whenter the HFEA have examples of best practice that can be shared.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Guidance in relation to Ebola virus has been provided in several Clinic Focus articles published by the HFEA since 2016, and by professional bodies. A summary of the review due by 16 April 2018, and audit due by 16 July 2018 are awaited. **Further action is required**

	the primary centre PRs to ensure compliance.		
Patient feedback 3. The centre has sought user satisfaction feedback on the Andrology service but has not sought any formal feedback from patients undergoing IUI treatments. CoP 23.17.	The PR should ensure that there are processes in place to enable the collection and review of feedback from all users of the service. The PR should review the centre's processes for seeking user feedback and a summary report of this review, including details of corrective actions taken, should be provided to the centre's inspector by 16 April 2018.	We will arrange to carry out a formal patient satisfaction survey	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that a patient satisfaction survey will be undertaken. **No further action is required**

Non-compliance in the transport/satellite activities

These areas of practice that require improvement are within the centre's transport and/or satellite services. Such services are undertaken under the authority of a primary centre's licences. Therefore, the primary centre licence is responsible for non-compliances in the transport and/or satellite service.
The non-compliances and recommendations below will therefore be notified to PRs of primary centres, so they can work with the PR of the transport and/or satellite centre to implement them. These non-compliances are not considered by the licensing committee when making a decision regarding the continuation of the HFEA licence held by the satellite centre.

Area of practice and reference	Action required and timescale for action	PR's Response	Executive Review
Satellite services A. The audit of the satellite service carried out by primary centre 0007 and 0344 did not include an audit of practices in relation to 'Procuring, processing and transporting gametes and embryos' (Guidance note 15). SLC T32 and SLC T36.	The PR should ensure that the auditing of the satellite activities is carried out by the primary centres, and that those audits assess all relevant activities. The PR should work with the PRs of the primary centres to provide an action plan of how to address the issue identified in relation to the audit of satellite activities. A summary of the action plan should be provided to the centre's inspector by 16 April 2018, with a view to ensuring that the actions are fully implemented by 16 July 2018.	meetings taking place with the primary centres to arrange the required audits. The PRs of primary centres 0007 and 0344 provided the following response on 27 February 2018: 'Centre 0278 was audited by centre 0344/0007 on 15.06.17. The audit did not cover Guidance Note 15: procuring, processing, transporting gametes and embryos. The audit tool has now been amended (see attached in email). The amended audit tool will be used to perform the 2018	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The executive also acknowledges the responses and commitment of the PRs of centres 0007 and 0344 to fully implementing this recommendation. A summary of the action plan has been provided. Confirmation that the action has been fully implemented by 16 July 2018 is awaited. **Further action is required**.

		audit of satellite centre 0278. The audit for 2018 will be brought forward to ensure it is performed by 31.03.18 (suitable date to be confirmed) and action plan will be submitted before 05.04.18.'	

Additional information from the Person Responsible