Executive Licensing Panel Minutes

Centre 0276 (Reproductive Medicine Clinic, Bristol)

Interim Inspection Report

Date:	23 March 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Kathleen Sarsfield-Watson Anna Coundley	Director of Strategy and Corporate Affairs Communications Manager Policy Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood India Hickey	Licensing Manager Research Officer (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 Reproductive Medicine Clinic, Bristol is located within St. Michael's Hospital, which is part of University Hospital Bristol NHS Foundation Trust. The centre has held a treatment (insemination using partner sperm) licence with the HFEA since 2007.

1.2. The panel noted that the centre provides partner intrauterine insemination treatment to NHS patients. The centre does not have facilities on site for the analysis or preparation of semen for use in treatment, so this service is provided by the Bristol Centre for Reproductive Medicine (HFEA licensed centre 0295) nearby. The male partner attends centre 0295 to produce a semen sample which is prepared for insemination. The sample is transported back to the Reproductive Medicine Clinic by the patient(s) where the insemination is performed.

1.3. The panel noted that, in the 2020, the centre had provided 4 partner intrauterine insemination cycles. In relation to activity levels this is a very small sized centre.

1.4. The panel noted that 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.

1.5. The panel noted that the centre provides insemination treatments only and is therefore not subject to the requirements of General Direction 0003 regarding multiple births. However, insemination treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. No multiple pregnancies have been reported by the centre in the last two years.

1.6. The panel noted that the centre was last inspected in January 2019 and an interim inspection should have been conducted by January 2021. However, due to the Covid-19 pandemic, a Desk Based Assessment and Risk Based Approach (DBA/RBA), was performed. It was concluded that any items of concern identified were of relatively low risk and could be reviewed effectively using virtual technology. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

1.7. The panel noted that the virtual inspection was conducted on 27 January 2021 and included videoconferencing with key members of centre staff. This process also took into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection and the on-going monitoring of the centre's performance.

1.8. The panel noted that at the time of the inspection, there were two 'other' areas of non-compliance concerning patient support and the safety and suitability of premises and facilities. Since the inspection, the Person Responsible (PR) has fully implemented the recommendation concerning the safety and suitability of premises and facilities. The PR has given a commitment to fully implement the non-compliance related to patient support.

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

1.10. The panel noted that the inspection team recommends the continuation of the centre's treatment (insemination using partner sperm) licence, particularly noting the many positive comments, made by patients, in relation to their experiences, gained through the centre's own feedback mechanism.

2. Decision

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

3. Chairs signature

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

Signature

Clare Ettinghausen

Name

Date

29 March 2021

Interim Licensing Report

Centre name: Reproductive Medicine Clinic, Bristol
Centre number: 0276
Date licence issued: 1 July 2019
Licence expiry date: 30 June 2023
Additional conditions applied to this licence: None
Date of inspection: 27 January 2021
Inspectors: Julie Katsaros (lead), Sara Parlett and Karen Campbell (HFEA observer)
Date of Executive Licensing Panel: 23 March 2021

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, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law). 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 (SLCs).

This is a report of an interim inspection, at the mid-point of the licence period.

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non-compliances, identified during DBA, if not adequately investigated.

HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

This centre was last inspected in January 2019, therefore an on-site inspection should usually be conducted by January 2021. However, following the DBA/RBA for this clinic, it was concluded that any items of concern identified during the DBA were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site

inspection. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

This inspection was therefore carried out by DBA followed by a virtual inspection, which included videoconferencing with key members of centre staff.

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. In particular we note the many positive comments made by patients in relation to their experiences in the centre's own feedback.

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

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

Since the inspection visit the following recommendation has been fully implemented.
'Other' area of practice that require improvement:

- The Person Responsible (PR) should ensure that maintenance checks of equipment kept on the emergency resuscitation trolley are carried out within the specified timeframe directed by the Trust.

The PR has given a commitment to fully implement the following recommendation.
'Other' area of practice that require improvement:

- The PR should ensure that the centre complies with the requirement to have a documented patient support policy in place, which outlines how the centre ensures that patients and their partners receive appropriate psychosocial support from all staff they encounter before, during and after treatment.

Information about the centre

The Reproductive Medicine Clinic, Bristol is located within St. Michael's Hospital, which is part of University Hospital Bristol NHS Foundation Trust. The centre has held a 'Treatment (insemination using partner sperm)' licence with the HFEA since 2007.

The centre provides partner intrauterine insemination treatment only to NHS patients. The centre does not have facilities on site for the analysis or preparation of semen for use in treatment, this service is provided by the Bristol Centre for Reproductive Medicine (HFEA licensed centre 0295) nearby. The male partner attends centre 0295 to produce a semen sample which is prepared for insemination. The sample is transported back to the Reproductive Medicine Clinic by the patient(s) where the insemination is performed.

The centre provided four partner intrauterine insemination cycles in 2020. In relation to activity levels this is a very small centre.

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

In 2020, the centre reported four cycles of partner insemination with no pregnancies, which is in line with the national average.

Multiple births

The centre provides insemination treatments only and is therefore not subject to the requirements of General Direction 0003 regarding multiple births. However, insemination treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. No multiple pregnancies have been reported by the centre in the last two years.

Witnessing

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

The inspection team discussed witnessing processes with staff and reviewed the results of recent audits. These activities indicate that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The centre does not store cryopreserved material, 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.

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: infection control; witnessing and traceability.

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
- patient support
- HFEA Clinic Focus articles regarding zika assessment
- reopening of the clinic during the Covid-19 pandemic.

The centre is effective in implementing learning from their audits and guidance from the HFEA, with the exception noted in this report (see recommendation 1).

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 are approved for the provision of fertility treatment, to ensure the safety of gametes and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of all medical devices was reviewed in the course of the inspection. 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.

Although it is not a requirement for patients undergoing treatment at this centre to be offered counselling, counselling services are available to all patients accessing treatment and a comprehensive counselling specific policy is in place. This, along with discussions had with centre staff during the inspection, indicate that patients are offered a good level of support during treatment, however, the centre's patient support procedures are broadly compliant with HFEA guidance because the centre does not have a documented patient support policy in place. See recommendation 1.

Patient feedback

The centre is currently collating the data for 2020, so the inspection team reviewed patient feedback provided in 2019. Twelve patients provided feedback directly to the clinic. Feedback was positive with many individuals providing written feedback giving compliments about the care received.

On the basis of this feedback and discussions with staff during 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;
- 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 DBA and discussions with staff during the virtual inspection, indicate that the centre is non-compliant with the following HFEA requirement:

- The date by which the suction apparatus on the emergency trolley should have been serviced has been surpassed. See recommendation 2.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2019, recommendations for improvement were made in relation to two 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

As this centre only provides IUI partner treatment, their success rates are not subject to ongoing monitoring through the HFEA risk tool.

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 provided its annual IUI treatment return for 2020 within the required timescale.

Legal parenthood

The centre undertakes partner intrauterine insemination only, therefore this area of practice is not applicable to this centre.

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

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			

‘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 partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
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
1. **Patient support** The centre does not have a documented patient support policy in place. SLC T2 HFEA CoP (9th edition) guidance note 3, section 3.14. Clinic focus October 2019.	The PR should ensure that the centre complies with the requirement to have a documented patient support policy in place, which outlines how the centre ensures that patients and their partners receive appropriate psychosocial support from all staff they encounter before, during and after treatment. It is expected that a patient support policy will be in place by 27 April 2021 and a copy of the policy should be provided to the centre’s inspector.	I recognise the need for a patient support policy as per HFEA CoP guidance note 3. This will be put in place within the next month.	The executive acknowledges the PR’s response and her commitment to fully implementing this recommendation. A copy of the centre’s patient support policy should be provided by 27 April 2021. Further action is required.
Safety and suitability of	The PR should ensure that	Maintenance checks of the	The executive acknowledges

premises and facilities The date by which the suction apparatus on the emergency trolley should have been serviced has been surpassed. SLC T23.	maintenance checks of equipment kept on the emergency resuscitation trolley are carried out within the specified timeframe directed by the Trust. The inspection team acknowledges that the PR acted promptly on the findings and shortly after the inspection confirmed the equipment had been serviced, therefore no further action is required.	equipment falls under the responsibility of the medical engineering department who have been very stretched due to the covid pandemic. We have now incorporated dates for maintenance checks into our monthly departmental nursing checks of the resuscitation equipment - allowing us to alert the medical engineering department if equipment becomes overdue a service.	the PR's immediate actions to fully address this inspection finding. No further action required.

Additional information from the Person Responsible