Executive Licensing Panel - minutes

Centre 0026 (BMI The Priory Hospital)

Interim Inspection Report

Tuesday, 26 February 2019

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Niamh Marren Howard Ryan	Director of Strategy and Corporate Affairs Regulatory Policy Manager Report Developer
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Joanne Anton Danielle Vincent Richard Sydee Moya Berry	Senior Governance Manager Policy Manager Communications Manager Director of Finance and Resources Committee Officer

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 BMI The Priory Hospital has been licensed by the HFEA since 1992. The centre is privately owned and offers licensed treatment to both self-funding and NHS funded patients.

1.2. The panel noted that, in the 12 months to 30 September 2018, the centre had provided 438 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a small sized centre.

1.3. The panel noted that HFEA register data, for the year ending 30 June 2018, show the centre's success rates, in terms of clinical pregnancy rates, are in line with the national averages.

1.4. The panel noted that, in 2017, the centre reported two cycles of partner insemination with one pregnancy. 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 30 June 2018, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

1.6. The panel noted that the unannounced inspection took place on 13 November 2018.

1.7. The panel noted that at the time of inspection there was one 'other' area of non-compliance regarding infection control. Since the inspection, the Person Responsible (PR) has given a commitment to fully implementing the recommendation made in the report concerning infection control.

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

2. Decision

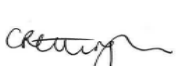
2.1. The panel congratulated the centre on the level of compliance identified at the unannounced interim inspection.

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

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

4 March 2019

Interim Licensing Report

Centre name: BMI The Priory Hospital
Centre number: 0026
Date licence issued: 1 July 2017
Licence expiry date: 30 June 2021
Date of inspection: 13 November 2018
Inspectors: Louise Winstone and Julie Katsaros
Date of Executive Licensing Panel: 26 February 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 focus of an interim inspection is:

- **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 'other' area of non-compliance or poor practice as follows:

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

'Other' area of practice that requires improvement:

- The PR should ensure adherence to infection control best practice guidance and requirements.

Information about the centre

BMI The Priory Hospital has been licensed by the HFEA since 1992. The centre is privately owned and offers licensed treatment to both self-funding and NHS funded patients.

The centre provided 438 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2018. In relation to activity levels this is a small 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 30 June 2018 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

In 2017, the centre reported two cycles of partner insemination with one pregnancy. This represents a clinical pregnancy rate which is comparable to the national average.

Multiple births[2]

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

HFEA held register data for the year ending 30 June 2018 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. 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. During the inspection, the movement of embryos between culture dishes was observed. This procedure was witnessed using a manual witnessing system in accordance with HFEA requirements. The centre's witnessing procedures and audits were also discussed with staff. 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.

---

[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%.

On inspection, reports of audits of all stored gametes and embryos and the 'bring-forward' system were discussed with staff. 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: witnessing, consent and legal parenthood, infection control and medicines management.

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:

- the use of CE marked medical devices
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding: EU TE coding and screening requirements
- awareness of recent HFEA Clinic Alert regarding gas cylinders

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. It was noted however that in the injection teaching room and scan room there were boxes of medication. The inspector was informed that these drugs had been returned by patients and were being used for demonstration purposes. Following

discussion with centre staff all the drugs were immediately discarded and therefore no further recommendation has been made at this time.

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 broadly compliant with guidance because:

- Labels on the sharps bins in the scan room and the injection teach room were not completed and the temporary closure on one sharps bin was not in use.
- A used disposable patient sheet had been left on the handrail in the ensuite toilet of the scan room. Following the inspection, the PR explained that the scan rooms are always cleaned between patients, however, this was not explained at the time of the inspection.

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 all medical devices used in the laboratory 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

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. This feedback gives a star rating to the clinic. The website also allows patients to comment on the cost of treatment. Since this facility was launched, no patients have provided feedback to the HFEA regarding their experiences at this clinic. This was discussed at length with the clinic staff during the inspection. The inspectors were informed that all patients are provided with a leaflet at their first appointment and this information is also provided verbally throughout treatment. All staff acknowledged the importance of collecting patient feedback via this facility. Staff also commented that they have difficulty in collecting information for their own patient satisfaction survey. Whilst it is acknowledged that the clinic is continuously looking for ways to encourage patients to provide feedback, it is important that this is addressed. The clinic is urged to continue to consider ways to improve patient feedback via the HFEA website.

The inspection team reviewed the centre's own most recent patient survey responses that were collected between May and July 2018. Nineteen patients had provided feedback

during this time period and most had provided positive comments complimenting the care received.

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;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- has staff that 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 in 2016, recommendations for improvement were made in relation to one critical, six major and five 'other' areas 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 November 2016, the centre has received one risk tool alert related to performance, to which the PR has responded and, during discussions on the inspection, provided a commitment to keep success rates 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.

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 November 2016, the inspection team reviewed three sets of records of patients who had had successful treatment with donor sperm (in November 2014, April 2015 and October 2015) in circumstances where consent to legal parenthood was required. In one case (treated in April 2015) the patient had put their year of birth in the date of consent form completion section. In the other two records there were alterations in the consent forms that the inspection team was concerned may impact the effectiveness of the consents. During this inspection, the inspection team asked for an update on the couples affected by consent anomalies. Staff confirmed that one couple had received a declaration of parenthood through the family courts and that the other two couples were fully informed but did not wish to take any further action.

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. Four 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.

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

‘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 partially 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			

‘Other’ areas of practice that require improvement

‘Other’ 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
1. Infection control On inspection the following issues were noted: • Labels on sharps bins in the scan room and the injection teach room were not completed and the temporary closure on one sharps bin was not in use. SLC T2. Department of Health: Health Building Note 00-09: Infection control in the built environment (2013) section 3.105. Healthcare-associated infections: prevention and control in primary and community care 2017, section 1.1.4.4.	The PR should ensure adherence to infection control best practice guidance and requirements. The PR should review infection control practices and procedures and address the issues identified in this report. A summary report of this review, with timescales for implementation should be provided to the centre’s inspector by 13 February 2019. Three months after implementing corrective actions, the PR should audit infection control practice to ensure that corrective actions	The centre accepts the finding by the inspector that there were some sharps bins with incomplete labelling and the temporary closure unused. This area of concern has been discussed and minuted at the departmental meeting that was pre-scheduled for the day of the inspection. Other areas which were inspected were found to have correctly labelled and sealed sharps bins. All clinical staff have been informed about the importance of using correct labelling and closure techniques. The results of the audits on 13th February and 13th May	The executive acknowledges the PR’s response and commitment to implementing this recommendation. The audits are to be submitted by 13 February and 13 May 2019. Further action is required. **Update 11 February 2019:** The PR has provided the audit due by 13 February and has committed to provide the follow up audit by 13 May 2019. Further action is required.

	have been effective in achieving compliance. A summary of this audit should be provided to the centre's inspector by 13 May 2019.	will be sent to the Lead Inspector.	

Additional information from the Person Responsible
The PR would like the following factual inaccuracies removed from the report :- 1. Page 5 " During the inspection, no patients were available to provide feedback on their experiences". At no point did the Inspection Team request to see a patient, patients were available for interview on that day despite it being a quieter day. Executive response: the report reflects the comments made by the PR. It is standard practice to ask if any patients would be willing to speak to an inspector. The inspectors apologise if this was not made clear during the inspection. We did however review the centre's own patient feedback which included responses from 19 patients.