# Human Fertilisation and Embryology Authority

## Minutes of the Executive Licensing Panel

**Meeting held at**
**Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF**
**on**
**30 January 2015**

**Minutes – item no. 2**

**Centre 0026 (BMI the Priory Hospital) Interim Inspection Report**

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| **Members of the Panel:** | Juliet Tizzard<br>**Director of Strategy & Corporate Affairs (Chair)**<br>Nick Jones<br>**Director of Compliance & Information**<br>Hannah Verdin<br>**Head of Regulatory Policy** |
| **Observing:** | |
| **Committee Secretary:** | Dee Knoyle |

**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:**

- HFEA protocol for the conduct of meetings of the Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- guidance for members of the Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- guidance on periods for which new or renewed licences should be granted
- standing orders and instrument of delegation
- indicative sanctions guidance
- HFEA Direction 0008 (where relevant) and any other relevant directions issued by the Authority
- guide to Licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers

## Consideration of Application

1. The Panel noted that BMI the Priory Hospital has held a licence with the HFEA since 1992. The centre provides a full range of fertility services.

2. The Panel noted that the centre's licence is due to expire on 30 April 2017.

3. The Panel noted that the inspection took place on 4 November 2014.

4. The Panel noted that in the 12 months to 30 September 2014, the centre provided 538 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

5. The Panel noted that for IVF and ICSI, HFEA-held register data for the period 1 October 2013 to 30 September 2014 showed the centre's success rates were in line with national averages with the following exception:

    - clinical pregnancy rates following ICSI in patients aged less than 38 were lower than average at a statistically significant level.

6. The Panel noted that for the year 2013 the centre reported 30 cycles of partner insemination with five pregnancies which was consistent with the national average.

7. Between 1 July 2013 and 30 June 2014 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 22%. This represented performance that was likely to be greater than the 10% maximum multiple live birth rate target for this period.

8. The Panel noted that at the time of the interim inspection on 4 November 2014, two major and two other areas of non-compliance were identified. The Panel noted in particular the non-compliance relating to multiple birth rates and acknowledged that the Person Responsible (PR) had engaged with the Inspectorate.

9. The Panel noted the positive comments received from patients in relation to their experience at the centre.

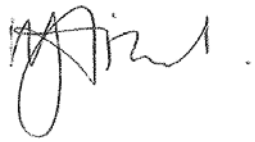
10. The Panel noted that the Inspectorate recommended the continuation of the centre's licence.

## Decision

11. The Panel was concerned about the major non-compliance relating to multiple births. A multiple pregnancy is the single biggest risk of fertility treatment. The Panel agreed that the major non-compliance relating to multiple births requires action from the PR to mitigate future potential risks. The Panel endorsed the Inspectorate's recommendation that the PR should ensure that the centre can meet the current multiple birth rate target.

12. The Panel agreed that, if the Inspectorate is not satisfied with the centre's progress in addressing this non-compliance and has further concerns, it should return to the ELP or take any necessary regulatory action, in line with the Compliance and Enforcement Policy.

13. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment and storage licence continued.



Signed: Date: 12 February 2015
Juliet Tizzard (Chair)

# Interim Licensing Report

**Centre name:** BMI The Priory Hospital
**Centre number:** 0026
**Date licence issued:** 15 May 2013
**Licence expiry date:** 30 April 2017
**Date of inspection:** 4 November 2014
**Inspectors:** Karen Conyers (Lead), Gill Walsh, Louise Winstone (HFEA observer)
**Date of Executive Licensing Panel:** 16 January 2015

## 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 focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

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 with information on which to make a decision about the continuation of the licence.

## Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence. In particular we note the positive response from patients providing feedback about the care that they received.

The Executive Licensing Panel is asked to note that there were recommendations for improvement in relation to two 'major' areas and two 'other' area of non-compliance.

The PR has provided evidence that the following recommendation has already been fully implemented:

'Major' area of non compliance:

- The PR should ensure that the laboratory which undertakes diagnostic semen analysis is accredited by Clinical Pathology Accreditation UK (CPA) or equivalent, or provide evidence to support a status equivalent to accreditation.

The PR has also provided information and evidence that actions have been, and will continue to be taken to implement the following recommendations:

'Major' area of non compliance:

- The Person Responsible (PR) should ensure that the centre can meet the current multiple birth rate target.

'Other' areas of practice that require improvement:

- The PR should ensure that the information (i.e. sex of donor conceived children) required under the Human Fertilisation & Embryology (HF&E) Act 1990 (as amended) 31ZD(3) is recorded.
- The PR should ensure that the time that the witnessing check takes place is recorded.

## 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 was last inspected for renewal of their treatment and storage licence in November 2012 following which, a four year licence was granted.

This licence has been varied to reflect the following changes: April 2013 change of name to BMI The Priory Hospital and in May 2013 change of PR to Mrs Jane Cuthbert and Licence Holder (LH) to Mrs Carol Gulliver.

There have been no significant changes to the centre since the time of the last inspection however the centre is at the planning stages of a programme to expand the footprint to

provide additional laboratory and scanning facilities. An application to vary the centre's licence to reflect this will be submitted in due course.

The centre provides a full range of fertility services excluding embryo testing.

The centre provided 538 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2014. In relation to activity levels this is a medium sized centre.

## Details of Inspection findings

## Quality of Service

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

### Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 October 2013 and 30 September 2014 show the centre's success rates are in line with national averages with the following exception:

- clinical pregnancy rates following ICSI in patients aged less than 38 are lower than average at a statistically significant level (see review below).

For the year 2013 the centre reported 30 cycles of partner insemination with five pregnancies which is consistent with the national average.

### Multiple births[2]

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

Between 1 July 2013 and 30 June 2014 the centre's clinical multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 22%: this represents performance that is likely to be greater than the 10% multiple live birth rate target for this period[1] (see recommendation 1).

### Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos, and that identification errors do not occur. The inspection team were unable to observe witnessing procedures as there were no laboratory activities at the time of inspection. The inspection team were able to discuss the process with staff and review five sets of patient records and concluded that records of manual witnessing are maintained, with one exception: the time at which a witnessing step was undertaken was not recorded in one record seen (see recommendation 4).

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[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%.

### Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is documented in their records, and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent. The records of consent to disclosure to researchers given by five patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately.

### Consent: To the storage of cryopreserved material

A review of the centre's laboratory logs, records and database indicated that gametes and embryos currently in store are being stored within their consented storage period. The storage periods for nine sets of sperm and embryo(s) were cross checked against the consent given by the gamete providers. In all records checked, the embryos/gametes were being stored in accordance with those consenting decisions.

### Staffing

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

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the limited activities being carried out on the day of inspection. Patients were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory appeared to be able to carry out their activities without distraction.

## Patient experience

During the inspection visit we spoke to two patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further 31 patients also provided feedback directly to the HFEA in the time since the last inspection. The feedback was very positive overall and 16 out of 17 individuals who had provided additional written feedback to the HFEA had compliments about the care that they received.

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;
- gives prospective and current patients and donors 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

From the information submitted by the centre in their self assessment questionnaire (SAQ) and from observations during the visit to the centre, the inspection team identified the following non-compliance:

- In the centre's most recent SAQ the centre reported that they may not have full records on the sex of all children born following use of donor sperm which was supplied to other centres many years ago. The centre has some concerns that if requested they may not be able to provide information about the sex of the children born following their donations HF&E Act 1990 (as amended) (see recommendation 3).

## Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in November 2012 recommendations for improvement were made in relation to one area of critical non-compliance, three areas of major non-compliance and nine 'other' areas of non-compliance.

The PR provided information and evidence that some of the recommendations were fully implemented within the prescribed timescales.

The following recommendations have not been implemented:

- The PR should ensure that the centre can meet the current multiple birth rate target (see recommendation 1).
- The PR should ensure that the laboratory which undertakes diagnostic semen analysis is accredited by CPA UK or equivalent, or provide evidence to support a status equivalent to accreditation (see recommendation 2).

In responding to the report immediately after the licence renewal inspection in 2012, the PR had agreed to implement an action plan to seek CPA accreditation. During the inspection the PR described the centre's plans to modify the andrology laboratories to form part of an application for CPA accreditation and that because of this the application for accreditation had not been progressed. Prior to and during the inspection the requirements to demonstrate equivalence to that of CPA accreditation were discussed with the PR. Soon after the inspection the centre provided several documents relating to the diagnostic andrology service. Evidence that the centre has status equivalent to that conferred by CPA was reviewed and was considered broadly satisfactory with one exception: that the standard operating procedure (SOP) for diagnostic semen analysis does not reflect professional (World Health Organisation (WHO)) guidelines (see recommendation 2).

## On-going monitoring of centre success rates

In 2014, the centre received two risk based assessment tool (RBAT) alerts regarding the provision of ICSI in patients <38 years. Following each alert the centre undertook detailed root cause analyses investigating the possible causes of the reduction in success rates. These identified three issues which were immediately rectified and a positive impact on

outcomes was demonstrated. The PR should continue to monitor outcomes and success rates in this group of patients.

## 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. The HFEA information team consider that the centre is compliant with requirements relating to register submissions.

## Legal parenthood audit

The partners of women treated with donated gametes or embryos, where the couple are neither married nor in a civil partnership, must give their consent in order to become the legal parent of any child born. If this consent is not properly taken, it can have serious consequences, such as the partner having to adopt any child born to become the legal parent. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to them. On this inspection we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA and the PR had taken action in response to the audits findings.

# 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 carried out.

### ‘Critical’ area 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’ area of non-compliance requires immediate action to be taken by the Person Responsible.

| Area of practice and reference | Action required and timescale for action | PR Response | Inspection team’s response to the PR’s statement |
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| None identified at 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
- 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.

| Area of practice and reference | Action required and timescale for action | PR Response | Inspection team’s response to the PR’s statement |
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| 1. The centre is unlikely to meet the current multiple birth rate target<br><br>General Direction 0003 | The PR should continue to audit the effectiveness of the centre’s multiple births minimisation strategy and determine whether there are barriers to the effective implementation of the strategy for all patients provided with licensed treatment at the centre.<br><br>A summary report of the audit findings including corrective actions and the timescale for their implementation should be submitted to the centre’s inspector by 4 February 2015. | The centre accepts that it is above the target set by the HFEA which would enable it to meet the 10% multiple birth level prescribed within the Multiple Birth Minimisation Strategy. The centre will audit its data and provide and audit summary and revised strategy within the required time frame.<br><br>The centre would like it noted that for the data submitted during 2014 the centre performed 33.7% eSET on patients aged 37 and under. The centre would also like it acknowledged that 9.1% of multiple pregnancies reported from January 2014- October 2014 resulted from an elective | The Executive acknowledges the PR’s response and commitment to implement this recommendation.<br><br>The Executive has sought opinion on the likely impact of twin pregnancies following eSET and while the impact is acknowledged, it is not considered likely to have a significant impact on the overall multiple pregnancy rate. It is also noted that this is a confounding factor that can be expected to affect all clinics equally.<br><br>The planned audit is awaited.<br><br>Further action required. |

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| | | single embryo transfer. This is a significant contribution to the centre's multiple pregnancy rate. The HFEA data does not recognise the significant impact identical twins have upon the centre's data. | |
| 2. The centre undertakes diagnostic semen analyses however the laboratory is not accredited by CPA or equivalent. Evidence for equivalence was reviewed and considered satisfactory with the exception of the SOP for diagnostic semen analysis which requires review against professional (WHO) guidelines.<br><br>SLC T21<br><br>This has been an ongoing issue since the last inspection. | The PR should ensure that the laboratory which undertakes diagnostic semen analysis is accredited by CPA or equivalent, or provide evidence to support a status equivalent to accreditation.<br><br>Evidence of CPA accreditation, or equivalent should be forwarded to the centre's inspector by 4 February 2015. | Following discussions with the inspector it was agreed that the centre had provided appropriate evidence of equivalence apart from the methodology for assessing sperm count.<br><br>Following discussions the scientific team at the centre decided that the centre would change to using the WHO recognised haemocystometer for counting sperm during diagnostic andrology procedures. This has now been implemented and the protocol will be submitted to the inspector with this response. The centre is therefore confident that it now meets CPA equivalence in its Diagnostic Andrology Services. | The Executive acknowledges receipt of the new SOP and confirms that in the Executive's opinion, the centre has status equivalent to that conferred by CPA. However, the PR is reminded that the centre's inspector should be informed immediately if there are any significant changes to the quality of the evidence which has been reviewed (e.g. poor NEQAS performance) as these may potentially invalidate the status of equivalence.<br><br>No further action is required. |

## ‘Other’ areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a ‘critical’ or ‘major’ area of non compliance, but which indicates a departure from statutory requirements or good practice.

| Area of practice and reference | Action required and timescale for action | PR Response | Inspection team’s response to the PR’s statement |
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| 3. The centre may not have full records on the sex of all children born following use of donor sperm which had been supplied to other centres many years ago.<br><br>HF&E Act 1990 (as amended) 31ZD(3) | The PR should liaise with the HFEA information team to identify and assess the risks of these historic deficiencies and establish suitable corrective actions (if appropriate) to mitigate those risks. The centre’s inspector should be updated on progress in addressing risks on a quarterly basis.<br><br>The PR should review the process for recording the outcome of donation against the requirements for information required to be held in accordance with HF&E Act 1990 (as amended) 31ZD(3).<br><br>The PR should conduct a sample audit of historic sperm donor records to identify the extent to which the information regarding the sex of the | The centre answers this question honestly relating to gender data for live births from donor cycles which were submitted to the HFEA as far back as the early 1990s.<br><br>The centre is confident that it can provide accurate outcome data including gender for all cycles involving the use of donor gametes or embryos performed both at the centre or other HFEA licensed centres that the centre supplied with donor gametes or embryos from the mid 1990s onwards.<br><br>The centre is also confident that it could with time and a great deal of expense retrieving records provide accurate gender data for all donor conceived cycles performed at the centre from the early 1990s.<br><br>The centre is confident that it is aware of all live births resulting from | The Executive acknowledges the PR’s response and the assurance that this information is available for treatments performed since the mid 1990s and that current processes for gathering the necessary information are robust.<br><br>However, the Executive reminds the centre of the recommendation to liaise with the information team to identify and assess the risks of these historic deficiencies and establish suitable corrective actions (if appropriate). Findings of this review will determine the scope of any further work required to ensure that the information regarding the sex of the children born is available.<br><br>Further action is required. |

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| | children born is available.<br><br>A summary of the findings including any actions taken to rectify the missing information should be forwarded to the centre's inspector by 4 April 2015.<br><br>Subject to the findings of that audit the centre may be required to conduct a more extensive audit of donor treatment outcome records. | donor gametes or embryos supplied by The Priory to other HFEA licenced centres.The centre is less sure that other centres which used gametes provided by The Priory would be able to provide the required gender data either to the centre or to the HFEA.<br><br>The centre acknowledges that it cannot provide gender specific data for all live birth cycles which were performed at other HFEA licensed centres. However, the centre believes that the HFEA should already hold this data as a result of data submissions from the other licensed centres. The centre believes that its current processes are robust for recording this data but acknowledges that its processes to data from the early 1990s may not have been as robust as we would wish. The centre is uncertain whether auditing this early data would be of benefit as it believes the HFEA already holds this early data and is indeed already requesting futher information from treatment centres where gaps in their data exist. | |

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| 4. In one of five records reviewed the time of the witnessing check was not recorded. SLC T71 | The PR should ensure that the time that witnessing checks are completed is recorded. The PR should review relevant documentation of procedures and make necessary changes that ensure the time of witnessing is recorded.<br><br>A summary of the review and copy/copies of any amended documentation should be forwarded to the centre's inspector by 4 February 2015.<br><br>Within three months of the implementation of any changes to the witnessing procedures, the centre should conduct an audit of witnessing and a summary report of the findings of the audit should be provided to the HFEA by 4 May 2015. | The centre believes that its witnessing protocol is robust and meets the HFEA requirements. It acknowledges that on this occasion there was a failure of one of the two people witnessing a procedure to time their signature. All witnessing is done contemporaneously and the procedure concerned was performed in front of the patient and other staff so the centre is confident that the procedure was performed contemporaneously.<br><br>The centre acknowledges that the time of the procedure should have been recorded. All staff and consultants have been informed of the requirement to state the time a procedure took place and not to rely upon the second witnesser to complete this section. The centre does not feel that it needs to amend its protocol rather to ensure that all staff are reminded of the obligations they have during witnessing. The centre audits its witnessing protocol on a six monthly basis and is happy to submit its next witnessing audit to the inspector. Previous audits have not revealed an issue of this nature. | The Executive acknowledges the PR's response, findings of their review and the actions taken to remind staff of the importance of complying with the centre's own witnessing procedures.<br><br>A copy of the audit of witnessing practice due by 4 May 2015 is awaited.<br><br>Further action is required. |

| Additional information from the Person Responsible |
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| The centre would like to acknowledge and thank the inspector for delaying the submission of this response until after Christmas. Staff at the centre had a challenging period just before Christmas following the death of Mr Sawers who founded the unit. He was a dear colleague to all at the unit and no doubt to several at the HFEA for whom he acted as an inspector for many years. The delay in this report has been much appreciated and has allowed the staff time to deal with such sad news. The centre is grateful for the HFEAs understanding. |